[de: 4120-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 412

[CMS-1748-P]

RIN 0938-AU38

Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2022 and Updates to the IRF Quality Reporting Program

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would update the prospective payment rates for inpatient rehabilitation facilities (IRFs) for Federal fiscal year (FY) 2022. As required by statute, this proposed 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 2022. In addition, this proposed rule includes proposals for the IRF Quality Reporting Program (QRP).

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on June 7, 2021

ADDRESSES: In commenting, please refer to file code CMS-1748-P.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. <u>Electronically</u>. You may submit electronic comments on this regulation to http://www.regulations.gov. Follow the "Submit a comment" instructions.

2. <u>By regular mail</u>. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-1748-P,

P.O. Box 8016,

Baltimore, MD 21244-8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-1748-P,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

FOR FURTHER INFORMATION CONTACT:

Gwendolyn Johnson, (410) 786-6954, for general information.

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

Kadie Derby, (410) 786-0468, for information about the IRF coverage policies.

Ariel Adams, (410) 786-8571, for information about the IRF quality reporting program.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential

business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: http://www.regulations.gov. Follow the search instructions on that Web site to view public comments. CMS will not post on Regulations.gov public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

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 proposed 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 proposed rule would update the prospective payment rates for IRFs for FY 2022 (that is, for discharges occurring on or after October 1, 2021, and on or before September 30, 2022) 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 proposed 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 2022. This

proposed rule proposes to add one new measure to the IRF QRP and modify the denominator for another measure currently under the IRF QRP beginning with the FY 2023 IRF QRP. In addition, this proposed rule proposes to modify the number of quarters used for publicly reporting certain IRF QRP measures due to the public health emergency (PHE). Finally, we are seeking comment on the use of Health Level Seven International (HL7®) Fast Healthcare Interoperability Resources® (FHIR)-based standards in post-acute care, specifically the IRF QRP, and on our continued efforts to close the health equity gap.

B. Summary of Major Provisions

In this proposed rule, we use the methods described in the FY 2021 IRF PPS final rule (85 FR 48424) to update the prospective payment rates for FY 2022 using updated FY 2020 IRF claims and the most recent available IRF cost report data, which is FY 2019 IRF cost report data. This proposed rule proposes to update certain requirements for the IRF QRP, and also makes requests for information.

C. Summary of Impact

TABLE 1: Cost and Benefit

Provision Description	Transfers/Costs
FY 2022 IRF PPS payment rate update	The overall economic impact of this proposed rule is an estimated $160 million in increased payments from the Federal Government to IRFs during FY 2022.
FY 2022 IRF QRP changes	The overall economic impact of this proposed rule is an estimated increase in cost to IRFs of $487,338.96 beginning with 2022.

II. Background

A. Statutory Basis and Scope

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).

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 index 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 index 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 proposed 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, 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 PHE for COVID–19, and devoting significant resources to that end, we published two interim final rules with comment period affecting IRF 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 42 CFR 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) that are 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 waivers[1] and other flexibilities,[2] some of which are applicable to the IRF PPS.

B. Provisions of the PPACA and the Medicare Access and CHIP Reauthorization Act of 2015

(MACRA) Affecting the IRF PPS in FY 2012 and Beyond

The Patient Protection and Affordable Care Act (PPACA) (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 PPACA, was enacted on

March 30, 2010. In this proposed rule, we refer to the two statutes collectively as the "Patient

Protection and Affordable Care Act" or "PPACA".

The PPACA 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 PPACA 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 2022 is discussed in section V.B.

of this proposed 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.

Sections 3004(b) of the PPACA 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 PPACA 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

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[1] 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).
[2] 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).

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 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 an informational-only bill (type of bill (TOB) 111), which includes Condition Code 04 to their MAC. 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 health information.

To further interoperability in post-acute care settings, CMS and Office of the National Coordinator for Health Information Technology (ONC) participate in the Post-Acute Care Interoperability Workgroup (PACIO) (https://pacioproject.org/) to facilitate collaboration with industry stakeholders to develop FHIR standards. These standards could support the exchange

and reuse of patient assessment data derived from the minimum data set (MDS), inpatient rehabilitation facility patient assessment instrument (IRF-PAI), long term care hospital continuity assessment record and evaluation (LCDS), outcome and assessment information set (OASIS), and other sources. The PACIO Project has focused on FHIR implementation guides for functional status, cognitive status and new use cases on advance directives and speech, and language pathology. We encourage post-acute care (PAC) provider and health IT vendor participation as these efforts advance.

The CMS Data Element Library (DEL) continues to be updated and serves as the authoritative 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). The DEL furthers CMS' goal of data standardization and interoperability. When combined with digital information systems that capture and maintain these coded elements, their standardized clinical content can reduce provider burden by supporting exchange of standardized healthcare data; supporting provider exchange of electronic health information for care coordination, person-centered care; and supporting real-time, data driven, clinical decision making. Standards in the Data Element Library (https://del.cms.gov/DELWeb/pubHome) can be referenced on the CMS Website and in the ONC Interoperability Standards Advisory (ISA). The 2021 ISA is available at https://www.healthit.gov/isa.

The 21st Century Cures Act (Cures Act) (Pub. L. 114-255, enacted on December 13, 2016) requires HHS to take new steps to enable the electronic sharing of health information ensuring interoperability for providers and settings across the care continuum. The Cures Act includes a trusted exchange framework and common agreement (TEFCA) provision[3] that will enable the nationwide exchange of electronic health information across health

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[3] ONC, *Draft 2 Trusted Exchange Framework and Common Agreement,* https://www.healthit.gov/sites/default/files/page/2019-04/FINALTEFCAQTF41719508version.pdf.

information networks and provide an important way to enable bi-directional health information exchange in the future. For more information on current developments related to TEFCA, we refer readers to https://www.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement and https://rce.sequoiaproject.org/.

The ONC final rule entitled, "21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program" final rule (85 FR 25642) published in the May 1, 2020 **Federal Register** (hereinafter "ONC Cures Act Final Rule") implemented policies related to information blocking required under section 4003 of the 21st Century Cures Act. Information blocking is generally defined as a practice by a health IT developer of certified health IT, health information network, health information exchange, or health care provider that, except as required by law or specified by the Secretary of Health and Human Services (HHS) as a reasonable and necessary activity, is likely to interfere with access, exchange, or use of electronic health information. The definition of information blocking includes a knowledge standard, which is different for health care providers than for health IT developers of certified health IT and health information networks or health information exchanges. A healthcare provider must know that the practice is unreasonable as well as likely to interfere with access, exchange, or use of electronic health information. To deter information blocking, health IT developers of certified health IT, health information networks and health information exchanges whom the HHS Inspector General determines, following an investigation, have committed information blocking, are subject to civil monetary penalties of up to $1 million per violation. Appropriate disincentives for health care providers need to be established by the Secretary through rulemaking. Stakeholders can learn more about information blocking at https://www.healthit.gov/curesrule/final-rule-policy/information-blocking. ONC has posted information resources including fact sheets (https://www.healthit.gov/curesrule/resources/fact-sheets) , frequently asked questions (https://www.healthit.gov/curesrule/resources/information-blocking-faqs), and recorded webinars (https://www.healthit.gov/curesrule/resources/webinars).

We invite 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 this proposed rule, we are proposing to update the IRF PPS for FYs 2022 and 2023.

The proposed policy changes and updates to the IRF prospective payment rates for FY 2022 are as follows:

● Update the CMG relative weights and average length of stay values for FY 2022, in a budget neutral manner, as discussed in section IV. of this proposed rule.

● Update the IRF PPS payment rates for FY 2022 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 this proposed rule.

● Update the FY 2022 IRF PPS payment rates by the FY 2022 wage index and the labor-related share in a budget-neutral manner, as discussed in section V. of this proposed rule.

● Describe the calculation of the IRF standard payment conversion factor for FY 2022, as discussed in section V. of this proposed rule.

● Update the outlier threshold amount for FY 2022, as discussed in section VI. of this proposed rule.

● Update the cost-to-charge ratio (CCR) ceiling and urban/rural average CCRs for FY 2022, as discussed in section VI. of this proposed rule.

The proposed policy changes and updates to the IRF QRP for FYs 2022 and 2023 are as follows:

● Propose revisions and updates to quality measures and reporting requirements under the IRF QRP, as well as make requests for information as discussed in section VII. of this proposed rule.

IV. Proposed Update to the Case-Mix Group (CMG) Relative Weights and Average Length of Stay Values for FY 2022

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 this proposed rule, we propose to update the CMG relative weights and average length of stay values for FY 2022. Typically, we use the most recent available data to update the CMG relative weights and average lengths of stay. As such, section 1886(j) of the Act confers broad statutory authority upon the Secretary to propose refinements to the IRF PPS. For FY 2022, we are proposing to use the FY 2020 IRF claims and FY 2019 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 2020 IRF cost report data are available for analysis, but the majority of the FY 2020 IRF claims data are available for analysis. We are proposing 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 2022 CMG relative weights and average length of stay values in the final rule.

We are proposing to apply these data using the same methodologies that we have used to update the CMG relative weights and average length of stay 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 proposed 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 2022 CMG relative weights to the same average CMG relative weight from the CMG relative weights implemented in the FY 2021 IRF PPS final rule (85 FR 48424).

Consistent with the methodology that we have used to update the IRF classification system in each instance in the past, we propose to update the CMG relative weights for FY 2022 in such a way that total estimated aggregate payments to IRFs for FY 2022 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. To calculate the appropriate budget neutrality factor for use in updating the FY 2022 CMG relative weights, we use the following steps:

Step 1. Calculate the estimated total amount of IRF PPS payments for FY 2022 (with no changes to the CMG relative weights).

Step 2. Calculate the estimated total amount of IRF PPS payments for FY 2022 by applying the proposed changes to the CMG relative weights (as discussed in this proposed rule).

Step 3. Divide the amount calculated in step 1 by the amount calculated in step 2 to determine the budget neutrality factor of 1.0000 that would maintain the same total estimated aggregate payments in FY 2022 with and without the proposed changes to the CMG relative weights.

Step 4. Apply the budget neutrality factor from step 3 to the FY 2022 IRF PPS standard

payment amount after the application of the budget-neutral wage adjustment factor.

In section V.E. of this proposed rule, we discuss the proposed use of the existing methodology to calculate the proposed standard payment conversion factor for FY 2022.

In Table 2, "Proposed Relative Weights and Average Length of Stay Values for Case-Mix Groups," we present the proposed CMGs, the comorbidity tiers, the corresponding relative weights, and the average length of stay values for each CMG and tier for FY 2022. The average length of stay 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: Proposed 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	0.9729	0.8639	0.7853	0.7486	9	10	9	9
0102	Stroke M >=63.50 and M <72.50	1.2647	1.1230	1.0209	0.9731	12	12	11	11
0103	Stroke M >=50.50 and M <63.50	1.6180	1.4366	1.3061	1.2449	14	15	14	14
0104	Stroke M >=41.50 and M <50.50	2.0786	1.8457	1.6779	1.5994	18	19	18	18
0105	Stroke M <41.50 and A >=84.50	2.4406	2.1671	1.9701	1.8779	22	23	21	20
0106	Stroke M <41.50 and A <84.50	2.8592	2.5388	2.3080	2.2000	26	26	23	23
0201	Traumatic brain injury M >=73.50	1.0694	0.8797	0.7999	0.7521	11	11	9	9
0202	Traumatic brain injury M >=61.50 and M <73.50	1.3934	1.1462	1.0422	0.9800	13	13	12	11
0203	Traumatic brain injury M >=49.50 and M <61.50	1.7063	1.4036	1.2763	1.2000	14	15	14	13
0204	Traumatic brain injury M >=35.50 and M <49.50	2.0449	1.6822	1.5296	1.4382	18	18	16	16
0205	Traumatic brain injury M <35.50	2.6478	2.1781	1.9805	1.8622	27	23	20	19
0301	Non-traumatic brain injury M >=65.50	1.2338	0.9706	0.8983	0.8467	11	10	10	10
0302	Non-traumatic brain injury M >=52.50 and M <65.50	1.5850	1.2469	1.1540	1.0878	13	13	12	12
0303	Non-traumatic brain injury M >=42.50 and M <52.50	1.8997	1.4945	1.3831	1.3037	16	15	14	14
0304	Non-traumatic brain injury M <42.50 and A >=78.50	2.1769	1.7125	1.5849	1.4939	19	18	16	16
0305	Non-traumatic brain injury M <42.50 and A <78.50	2.4005	1.8884	1.7478	1.6474	21	20	17	17
0401	Traumatic spinal cord injury M >=56.50	1.3850	1.1092	1.0637	0.9614	13	12	12	11
0402	Traumatic spinal cord injury M >=47.50 and M <56.50	1.8554	1.4859	1.4251	1.2880	18	16	14	15
0403	Traumatic spinal cord injury M >=41.50 and M <47.50	2.1403	1.7141	1.6439	1.4858	19	18	17	17
0404	Traumatic spinal cord injury M <31.50 and A <61.50	3.3192	2.6583	2.5494	2.3041	34	30	25	22
0405	Traumatic spinal cord injury M >=31.50 and M <41.50	2.7059	2.1670	2.0783	1.8784	25	22	22	20
0406	Traumatic spinal cord injury M >=24.50 and M <31.50 and A >=61.50	3.6190	2.8983	2.7796	2.5122	34	30	30	26
0407	Traumatic spinal cord injury M <24.50 and A >=61.50	4.6385	3.7148	3.5627	3.2200	49	37	34	36
0501	Non-traumatic spinal cord injury M >=60.50	1.3162	0.9883	0.9260	0.8455	11	11	10	10
0502	Non-traumatic spinal cord injury M >=53.50 and M <60.50	1.6620	1.2480	1.1693	1.0677	15	13	13	12
0503	Non-traumatic spinal cord injury M >=48.50 and M <53.50	1.9053	1.4306	1.3405	1.2239	16	15	14	14
0504	Non-traumatic spinal cord injury M >=39.50 and M <48.50	2.2500	1.6895	1.5830	1.4453	20	17	17	16
0505	Non-traumatic spinal cord injury M <39.50	3.1486	2.3642	2.2152	2.0226	28	24	23	21
0601	Neurological M >=64.50	1.3629	1.0324	0.9664	0.8634	11	11	10	10
0602	Neurological M >=52.50 and M <64.50	1.6674	1.2631	1.1823	1.0563	13	13	12	12
0603	Neurological M >=43.50 and M <52.50	1.9848	1.5036	1.4074	1.2573	16	15	14	14
0604	Neurological M <43.50	2.4144	1.8290	1.7120	1.5295	20	18	17	16
0701	Fracture of lower extremity M >=61.50	1.1986	0.9563	0.9156	0.8348	11	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	1.5247	1.2165	1.1648	1.0620	13	13	13	12
0703	Fracture of lower extremity M >=41.50 and M <52.50	1.8632	1.4865	1.4233	1.2977	16	16	15	14
0704	Fracture of lower extremity M <41.50	2.2489	1.7943	1.7180	1.5664	18	18	18	17
0801	Replacement of lower-extremity joint M >=63.50	1.1386	0.8833	0.8184	0.7626	11	10	9	9
0802	Replacement of lower-extremity joint M >=57.50 and M <63.50	1.3289	1.0310	0.9551	0.8901	11	11	10	10
0803	Replacement of lower-extremity joint M >=51.50 and M <57.50	1.4961	1.1606	1.0752	1.0020	13	13	12	11
0804	Replacement of lower-extremity joint M >=42.50 and M <51.50	1.6875	1.3092	1.2129	1.1303	15	14	13	12
0805	Replacement of lower-extremity joint M <42.50	2.0883	1.6201	1.5009	1.3987	17	16	16	15
0901	Other orthopedic M >=63.50	1.2475	0.9593	0.8989	0.8157	11	11	10	9
0902	Other orthopedic M >=51.50 and M <63.50	1.5716	1.2086	1.1325	1.0276	13	13	12	12
0903	Other orthopedic M >=44.50 and M <51.50	1.8481	1.4212	1.3317	1.2084	15	15	14	13
0904	Other orthopedic M <44.5	2.1660	1.6656	1.5607	1.4162	18	17	16	15
1001	Amputation lower extremity M >=64.50	1.2472	1.0560	0.9389	0.8675	12	12	10	10
1002	Amputation lower extremity M >=55.50 and M <64.50	1.5259	1.2919	1.1487	1.0613	14	14	13	12
1003	Amputation lower extremity M >=47.50 and M <55.50	1.8229	1.5434	1.3723	1.2679	15	17	15	14
1004	Amputation lower extremity M <47.50	2.2744	1.9257	1.7122	1.5820	19	19	18	17
1101	Amputation non-lower extremity M >=58.50	1.3540	1.1270	1.0487	0.8804	13	12	11	10
1102	Amputation non-lower extremity M >=52.50 and M <58.50	1.6828	1.4006	1.3034	1.0941	14	13	14	10
1103	Amputation non-lower extremity M <52.50	1.9108	1.5905	1.4800	1.2424	16	16	15	14
1201	Osteoarthritis M >=61.50	1.4794	0.9137	0.9137	0.8190	12	10	10	10
1202	Osteoarthritis M >=49.50 and M <61.50	1.9225	1.1874	1.1874	1.0643	15	12	13	12
1203	Osteoarthritis M <49.50 and A >=74.50	2.3207	1.4333	1.4333	1.2848	17	16	16	14
1204	Osteoarthritis M <49.50 and A <74.50	2.3997	1.4821	1.4821	1.3285	16	14	16	14
1301	Rheumatoid other arthritis M >=62.50	1.2121	1.0358	0.8850	0.8198	10	12	9	10
1302	Rheumatoid other arthritis M >=51.50 and M <62.50	1.5199	1.2989	1.1098	1.0280	12	12	12	11
1303	Rheumatoid other arthritis M >=44.50 and M <51.50 and A >=64.50	1.8332	1.5666	1.3385	1.2399	14	15	14	13
1304	Rheumatoid other arthritis M <44.50 and A >=64.50	2.1843	1.8667	1.5949	1.4774	16	24	16	16
1305	Rheumatoid other arthritis M <51.50 and A <64.50	2.2272	1.9033	1.6262	1.5064	15	17	17	15
1401	Cardiac M >=68.50	1.1149	0.8984	0.8349	0.7612	10	10	9	9
1402	Cardiac M >=55.50 and M <68.50	1.4213	1.1454	1.0644	0.9704	12	12	11	11
1403	Cardiac M >=45.50 and M <55.50	1.7207	1.3866	1.2885	1.1748	15	14	13	13
1404	Cardiac M <45.50	2.1001	1.6924	1.5727	1.4339	18	17	16	15
1501	Pulmonary M >=68.50	1.2741	1.0574	0.9784	0.9197	12	11	10	9
1502	Pulmonary M >=56.50 and M <68.50	1.5564	1.2917	1.1951	1.1235	13	12	12	11
1503	Pulmonary M >=45.50 and M <56.50	1.8125	1.5043	1.3918	1.3084	15	15	14	13
1504	Pulmonary M <45.50	2.1270	1.7653	1.6333	1.5354	19	17	15	15

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
1601	Pain syndrome M >=65.50	1.1283	0.8615	0.8604	0.7719	10	10	9	9
1602	Pain syndrome M >=58.50 and M <65.50	1.3396	1.0229	1.0216	0.9166	11	11	11	10
1603	Pain syndrome M >=43.50 and M <58.50	1.6496	1.2596	1.2580	1.1286	14	13	14	13
1604	Pain syndrome M <43.50	1.9420	1.4828	1.4809	1.3287	15	14	16	14
1701	Major multiple trauma without brain or spinal cord injury M >=57.50	1.3943	1.0494	0.9731	0.8991	11	12	11	11
1702	Major multiple trauma without brain or spinal cord injury M >=50.50 and M <57.50	1.7121	1.2886	1.1949	1.1040	16	13	13	12
1703	Major multiple trauma without brain or spinal cord injury M >=41.50 and M <50.50	2.0059	1.5098	1.4000	1.2935	18	16	15	14
1704	Major multiple trauma without brain or spinal cord injury M >=36.50 and M <41.50	2.3279	1.7522	1.6248	1.5011	19	19	17	16
1705	Major multiple trauma without brain or spinal cord injury M <36.50	2.5833	1.9443	1.8030	1.6658	21	20	19	18
1801	Major multiple trauma with brain or spinal cord injury M >=67.50	1.2504	0.9567	0.8874	0.8130	13	11	11	10
1802	Major multiple trauma with brain or spinal cord injury M >=55.50 and M <67.50	1.5317	1.1719	1.0870	0.9959	16	13	12	11
1803	Major multiple trauma with brain or spinal cord injury M >=45.50 and M <55.50	1.8860	1.4430	1.3384	1.2262	17	17	14	14
1804	Major multiple trauma with brain or spinal cord injury M >=40.50 and M <45.50	2.2274	1.7042	1.5807	1.4482	25	18	17	15
1805	Major multiple trauma with brain or spinal cord injury M >=30.50 and M <40.50	2.6837	2.0533	1.9046	1.7449	26	21	20	19
1806	Major multiple trauma with brain or spinal cord injury M <30.50	3.7070	2.8362	2.6308	2.4102	38	29	24	28
1901	Guillain-Barré M >=66.50	1.0976	0.9081	0.8405	0.8366	11	11	10	10
1902	Guillain-Barré M >=51.50 and M <66.50	1.6045	1.3274	1.2287	1.2229	15	14	14	14
1903	Guillain-Barré M >=38.50 and M <51.50	2.3095	1.9107	1.7686	1.7603	20	21	19	19
1904	Guillain-Barré M <38.50	3.6029	2.9807	2.7590	2.7461	39	29	29	29
2001	Miscellaneous M >=66.50	1.2041	0.9660	0.8936	0.8160	11	10	10	9
2002	Miscellaneous M >=55.50 and M <66.50	1.4854	1.1916	1.1024	1.0066	13	12	12	11
2003	Miscellaneous M >=46.50 and M <55.50	1.7534	1.4067	1.3013	1.1883	15	15	14	13
2004	Miscellaneous M <46.50 and A >=77.50	2.0603	1.6529	1.5291	1.3963	18	17	16	15
2005	Miscellaneous M <46.50 and A <77.50	2.2181	1.7794	1.6462	1.5032	19	18	16	16
2101	Burns M >=52.50	1.9171	1.3320	1.1494	1.1100	19	14	13	12
2102	Burns M <52.50	2.7811	1.9324	1.6675	1.6103	24	21	16	17
5001	Short-stay cases, length of stay is 3 days or fewer				0.1659				3
5101	Expired, orthopedic, length of stay is 13 days or fewer				0.6894				7
5102	Expired, orthopedic, length of stay is 14 days or more				2.0452				19

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
5103	Expired, not orthopedic, length of stay is 15 days or fewer				0.9082				9
5104	Expired, not orthopedic, length of stay is 16 days or more				2.2323				21

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 proposed revisions for FY 2022 would affect particular CMG relative weight values, which would affect the overall distribution of payments within CMGs and tiers. We note that, because we propose to implement the CMG relative weight revisions in a budget-neutral manner (as previously described), total estimated aggregate payments to IRFs for FY 2022 would not be affected as a result of the proposed CMG relative weight revisions. However, the proposed revisions would 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	28	0.0%
Increased by between 5% and 15%	3,148	0.8%
Changed by less than 5%	365,764	97.3%
Decreased by between 5% and 15%	6,850	1.8%
Decreased by 15% or more	39	0.0%

As shown in Table 3, 97.3 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 proposed revisions for FY 2022. The proposed changes in the average length of stay values for FY 2022, compared with the FY 2021 average length of stay values, are small and do not show any particular trends in IRF length of stay patterns.

We invite public comment on our proposed updates to the CMG relative weights and average length of stay values for FY 2022.

V. Proposed FY 2022 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 the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Thus, in this proposed rule, we are proposing to update the IRF PPS payments for FY 2022 by a market basket increase factor 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 (MCR) data for both freestanding and hospital-based IRFs (80 FR 47049 through 47068). Beginning with 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.

B. Proposed FY 2022 Market Basket Update and Productivity Adjustment

For FY 2022 (that is, beginning October 1, 2021 and ending September 30, 2022), we are proposing to update the IRF PPS payments by a market basket increase factor as required by section 1886(j)(3)(C) of the Act, with a productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act. For FY 2022, we are proposing to use the same methodology described in the FY 2021 IRF PPS final rule (85 FR 48432 through 48433), with one proposed modification to the 2016-based IRF market basket.

For the price proxy for the For-profit Interest cost category of the 2016-based IRF market basket, we are proposing to use the iBoxx AAA Corporate Bond Yield index instead of the Moody's AAA Corporate Bond Yield index. Effective for December 2020, the Moody's AAA Corporate Bond series is no longer available for use under license to IHS Global Inc. (IGI), the nationally-recognized economic and financial forecasting firm with which we contract to forecast the components of the market baskets and multi-factor productivity (MFP). Since IGI is no longer licensed to use and publish the Moody's series, IGI was required to discontinue the publication of the associated historical data and forecasts of this series. Therefore, IGI constructed a bond yield index (iBoxx) that closely replicates the Moody's corporate bond yield indices currently used in the market baskets.

We compared the iBoxx AAA Corporate Bond Yield index with the Moody's AAA Corporate Bond Yield index and found that the average growth rates in the history of the two series are very similar. Over the historical time period of FY 2001 to FY 2020, the 4-quarter percent change moving average growth in the iBoxx series was approximately 0.1 percentage point higher, on average, than the Moody's series. However, given the relatively small weight for this cost category, replacing the Moody's series with the iBoxx series does not impact the historical top-line market basket increases when rounded to the nearest tenth of a percentage point over the past ten fiscal years (FY 2011 to FY 2020). Therefore, because the iBoxx AAA Corporate Bond Yield index captures the same technical concept as the current corporate bond proxy and tracks similarly to the current measure that is no longer available, we believe that using the iBoxx AAA Corporate Bond Yield index is technically appropriate to use in the 2016-based IRF market basket.

Consistent with historical practice, we are proposing to estimate the market basket update for the IRF PPS for FY 2022 based on IGI's forecast using the most recent available data. Based on IGI's fourth quarter 2020 forecast with historical data through the third quarter of 2020, the proposed 2016-based IRF market basket increase factor for FY 2022 is projected to be

2.4 percent. We are also proposing that if more recent data become 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 update), we would use such data, if appropriate, to determine the FY 2022 market basket update in the final rule.

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 MFP (as projected by the Secretary for the 10-year period ending with the applicable FY, year, cost reporting period, or other annual period) (the "MFP adjustment"). The U.S. Department of Labor's Bureau of Labor Statistics (BLS) publishes the official measure of private nonfarm business MFP. Please see http://www.bls.gov/mfp for the BLS historical published MFP data. A complete description of the MFP projection methodology is available on the CMS website at https://www.cms.gov/Research-Statistics-Dataand-Systems/Statistics-Trends-andReports/MedicareProgramRatesStats/MarketBasketResearch.html.

Using IGI's fourth quarter 2020 forecast, the 10-year moving average growth of MFP for FY 2022 is projected to be 0.2 percent. Thus, in accordance with section 1886(j)(3)(C) of the Act, we are proposing to base the FY 2022 market basket update, which is used to determine the applicable percentage increase for the IRF payments, on IGI's fourth quarter 2020 forecast of the 2016-based IRF market basket. We are proposing to then reduce this percentage increase by the estimated MFP adjustment for FY 2022 of 0.2 percentage point (the 10-year moving average growth of MFP for the period ending FY 2022 based on IGI's fourth quarter 2020 forecast).

Therefore, the proposed FY 2022 IRF update is equal to 2.2 percent (2.4 percent market basket update less 0.2 percentage point MFP adjustment). Furthermore, if more recent data become 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 MFP), we would use such data, if appropriate, to determine the FY 2022 market basket update and MFP adjustment in the final rule.

For FY 2022, the Medicare Payment Advisory Commission (MedPAC) recommends that we reduce IRF PPS payment rates by 5 percent. As discussed, and in accordance with sections 1886(j)(3)(C) and 1886(j)(3)(D) of the Act, the Secretary is proposing to update the IRF PPS payment rates for FY 2022 by an adjusted market basket increase factor which, based on the most recently available data, is 2.2 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 2022.

We invite public comment on our proposals.

C. Proposed Labor-Related Share for FY 2022

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 which 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 are proposing to continue to classify a cost category as labor-related if the costs are labor-intensive and vary with the local labor market.

Based on our definition of the labor-related share and the cost categories in the 2016-based IRF market basket, we calculate the proposed labor-related share for FY 2022 as the

sum of the FY 2022 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 relative importance from the 2016-based IRF market basket. For more details regarding the methodology for determining specific cost categories for inclusion in the 2016-based IRF labor-related share, see the FY 2020 IRF PPS final rule (84 FR 39087 through 39089).

The relative importance reflects the different rates of price change for these cost categories between the base year (2016) and FY 2022. Based on IGI's fourth quarter 2020 forecast of the 2016-based IRF market basket, the sum of the FY 2022 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 69.0 percent. We are proposing that the portion of Capital-Related costs that are influenced by the local labor market is 46 percent. Since the relative importance for Capital-Related costs is 8.4 percent of the 2016-based IRF market basket for FY 2022, we are proposing to take 46 percent of 8.4 percent to determine the labor-related share of Capital-Related costs for FY 2022 of 3.9 percent. Therefore, we are proposing a total labor-related share for FY 2022 of 72.9 percent (the sum of 69.0 percent for the labor-related share of operating costs and 3.9 percent for the labor-related share of Capital-Related costs). We are proposing that if more recent data become available after publication of this proposed rule and before the publication of the final rule (for example, a more recent estimate of the labor-related share), we will use such data, if appropriate, to determine the FY 2022 IRF labor-related share in the final rule.

Table 4 shows the current estimate of the proposed FY 2022 labor-related share and the FY 2021 final labor-related share using the 2016-based IRF market basket relative importance.

TABLE 4: Proposed FY 2022 IRF Labor-Related Share and FY 2021 IRF Labor-Related Share

	Proposed FY 2022 Labor-Related Share [1]	FY 2021 Final Labor Related Share [2]
Wages and Salaries	48.4	48.6
Employee Benefits	11.5	11.4
Professional Fees: Labor-Related [3]	4.9	5.0
Administrative and Facilities Support Services	0.8	0.7
Installation, Maintenance, and Repair Services	1.6	1.6
All Other: Labor-Related Services	1.8	1.8
Subtotal	**69.0**	**69.1**
Labor-related portion of Capital-Related (46%)	3.9	3.9
Total Labor-Related Share	**72.9**	**73.0**

[1] Based on the 2016-based IRF market basket relative importance, IGI 4th quarter 2020 forecast.
[2] Based on the 2016-based IRF market basket relative importance as published in the **Federal Register** (85 FR 48434).
[3] Includes all contract advertising and marketing costs and a portion of accounting, architectural, engineering, legal, management consulting, and home office contract labor costs.

D. Proposed Wage Adjustment for FY 2022

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.

For FY 2022, we propose to maintain the policies and methodologies described in the FY 2021 IRF PPS final rule (85 FR 48435) related to the labor market area definitions and the wage index methodology for areas with wage data. Thus, we propose to use the core based statistical areas (CBSAs) labor market area definitions and the FY 2022 pre-reclassification and pre-floor hospital wage index data. In accordance with section 1886(d)(3)(E) of the Act, the FY 2022 pre-reclassification and pre-floor hospital wage index is based on data submitted for hospital cost reporting periods beginning on or after October 1, 2017, and before October 1, 2018

(that is, FY 2018 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 propose 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 2022 IRF PPS wage index.

We invite public comment on our proposals.

2. Core-Based Statistical Areas (CBSAs) for the FY 2022 IRF Wage Index

a. Background

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 a hospital'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 have 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 is not proposing to adopt the revised OMB delineations identified in OMB Bulletin No. 20-01 for FY 2022.

4. Proposed Wage Adjustment

To calculate the wage-adjusted facility payment for the proposed payment rates set forth in this proposed rule, we would multiply the proposed unadjusted Federal payment rate for IRFs by the FY 2022 labor-related share based on the 2016-based IRF market basket relative importance (72.9 percent) to determine the labor-related portion of the standard payment amount. A full discussion of the calculation of the labor-related share is located in section V.C. of this proposed 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 propose to calculate a budget-neutral wage

adjustment factor as established in the FY 2004 IRF PPS final rule (68 FR 45689), codified at

§ 412.624(e)(1), as described in the steps below. We propose to use the listed steps to ensure

that the FY 2022 IRF standard payment conversion factor reflects the proposed update to the

wage indexes (based on the FY 2018 hospital cost report data) and the proposed 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 2021 (as published in the FY 2021 IRF PPS

final rule (85 FR 48424)).

Step 2. Calculate the total amount of estimated IRF PPS payments using the proposed

FY 2022 wage index values (based on updated hospital wage data) and the proposed FY 2022

labor-related share of 72.9 percent.

Step 3. Divide the amount calculated in step 1 by the amount calculated in step 2. The

resulting quotient is the proposed FY 2022 budget-neutral wage adjustment factor of 1.0027.

Step 4. Apply the budget neutrality factor from step 3 to the FY 2022 IRF PPS standard

payment amount after the application of the increase factor to determine the proposed FY 2022

standard payment conversion factor.

We discuss the calculation of the proposed standard payment conversion factor for

FY 2022 in section V.E. of this proposed rule.

We invite public comment on the proposed IRF wage adjustment for FY 2022.

E. Description of the Proposed IRF Standard Payment Conversion Factor and Payment Rates for

FY 2022

To calculate the proposed standard payment conversion factor for FY 2022, as illustrated in Table 5, we begin by applying the proposed increase factor for FY 2022, as adjusted in accordance with sections 1886(j)(3)(C) of the Act, to the standard payment conversion factor for FY 2021 ($16,856). Applying the proposed 2.2 percent increase factor for FY 2022 to the standard payment conversion factor for FY 2021 of $16,856 yields a standard payment amount of $17,227. Then, we apply the proposed budget neutrality factor for the FY 2022 wage index, and labor-related share of 1.0027, which results in a standard payment amount of $17,273. We next apply the proposed budget neutrality factor for the CMG relative weights of 1.0000, which results in the standard payment conversion factor of $17,273 for FY 2022.

We invite public comment on the proposed FY 2022 standard payment conversion factor.

TABLE 5: Calculations to Determine the Proposed FY 2022 Standard Payment Conversion Factor

Explanation for Adjustment		Calculations
Standard Payment Conversion Factor for FY 2021		$16,856
Proposed Market Basket Increase Factor for FY 2022 (2.4 %), reduced by 0.2 percentage point for the productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act	x	1.022
Budget Neutrality Factor for the Updates to the Wage Index and Labor-Related Share	x	1.0027
Budget Neutrality Factor for the Revisions to the CMG Relative Weights	x	1.0000
Proposed FY 2022 Standard Payment Conversion Factor	=	$17,273

After the application of the proposed CMG relative weights described in section IV. of this proposed rule to the proposed FY 2022 standard payment conversion factor ($17,273), the resulting unadjusted IRF prospective payment rates for FY 2022 are shown in Table 6.

TABLE 6: FY 2022 Payment Rates

CMG	Payment Rate Tier 1	Payment Rate Tier 2	Payment Rate Tier 3	Payment Rate No Comorbidity
0101	$16,804.90	$14,922.14	$13,564.49	$12,930.57
0102	$21,845.16	$19,397.58	$17,634.01	$16,808.36
0103	$27,947.71	$24,814.39	$22,560.27	$21,503.16
0104	$35,903.66	$31,880.78	$28,982.37	$27,626.44
0105	$42,156.48	$37,432.32	$34,029.54	$32,436.97
0106	$49,386.96	$43,852.69	$39,866.08	$38,000.60
0201	$18,471.75	$15,195.06	$13,816.67	$12,991.02
0202	$24,068.20	$19,798.31	$18,001.92	$16,927.54
0203	$29,472.92	$24,244.38	$22,045.53	$20,727.60
0204	$35,321.56	$29,056.64	$26,420.78	$24,842.03
0205	$45,735.45	$37,622.32	$34,209.18	$32,165.78
0301	$21,311.43	$16,765.17	$15,516.34	$14,625.05
0302	$27,377.71	$21,537.70	$19,933.04	$18,789.57
0303	$32,813.52	$25,814.50	$23,890.29	$22,518.81
0304	$37,601.59	$29,580.01	$27,375.98	$25,804.13
0305	$41,463.84	$32,618.33	$30,189.75	$28,455.54
0401	$23,923.11	$19,159.21	$18,373.29	$16,606.26
0402	$32,048.32	$25,665.95	$24,615.75	$22,247.62
0403	$36,969.40	$29,607.65	$28,395.08	$25,664.22
0404	$57,332.54	$45,916.82	$44,035.79	$39,798.72
0405	$46,739.01	$37,430.59	$35,898.48	$32,445.60
0406	$62,510.99	$50,062.34	$48,012.03	$43,393.23
0407	$80,120.81	$64,165.74	$61,538.52	$55,619.06
0501	$22,734.72	$17,070.91	$15,994.80	$14,604.32
0502	$28,707.73	$21,556.70	$20,197.32	$18,442.38
0503	$32,910.25	$24,710.75	$23,154.46	$21,140.42
0504	$38,864.25	$29,182.73	$27,343.16	$24,964.67
0505	$54,385.77	$40,836.83	$38,263.15	$34,936.37
0601	$23,541.37	$17,832.65	$16,692.63	$14,913.51
0602	$28,801.00	$21,817.53	$20,421.87	$18,245.47
0603	$34,283.45	$25,971.68	$24,310.02	$21,717.34
0604	$41,703.93	$31,592.32	$29,571.38	$26,419.05
0701	$20,703.42	$16,518.17	$15,815.16	$14,419.50
0702	$26,336.14	$21,012.60	$20,119.59	$18,343.93
0703	$32,183.05	$25,676.31	$24,584.66	$22,415.17
0704	$38,845.25	$30,992.94	$29,675.01	$27,056.43
0801	$19,667.04	$15,257.24	$14,136.22	$13,172.39
0802	$22,954.09	$17,808.46	$16,497.44	$15,374.70
0803	$25,842.14	$20,047.04	$18,571.93	$17,307.55
0804	$29,148.19	$22,613.81	$20,950.42	$19,523.67
0805	$36,071.21	$27,983.99	$25,925.05	$24,159.75
0901	$21,548.07	$16,569.99	$15,526.70	$14,089.59
0902	$27,146.25	$20,876.15	$19,561.67	$17,749.73
0903	$31,922.23	$24,548.39	$23,002.45	$20,872.69
0904	$37,413.32	$28,769.91	$26,957.97	$24,462.02
1001	$21,542.89	$18,240.29	$16,217.62	$14,984.33
1002	$26,356.87	$22,314.99	$19,841.50	$18,331.83
1003	$31,486.95	$26,659.15	$23,703.74	$21,900.44
1004	$39,285.71	$33,262.62	$29,574.83	$27,325.89
1101	$23,387.64	$19,466.67	$18,114.20	$15,207.15
1102	$29,067.00	$24,192.56	$22,513.63	$18,898.39
1103	$33,005.25	$27,472.71	$25,564.04	$21,459.98
1201	$25,553.68	$15,782.34	$15,782.34	$14,146.59
1202	$33,207.34	$20,509.96	$20,509.96	$18,383.65
1203	$40,085.45	$24,757.39	$24,757.39	$22,192.35
1204	$41,450.02	$25,600.31	$25,600.31	$22,947.18
1301	$20,936.60	$17,891.37	$15,286.61	$14,160.41

CMG	Payment Rate Tier 1	Payment Rate Tier 2	Payment Rate Tier 3	Payment Rate No Comorbidity
1302	$26,253.23	$22,435.90	$19,169.58	$17,756.64
1303	$31,664.86	$27,059.88	$23,119.91	$21,416.79
1304	$37,729.41	$32,243.51	$27,548.71	$25,519.13
1305	$38,470.43	$32,875.70	$28,089.35	$26,020.05
1401	$19,257.67	$15,518.06	$14,421.23	$13,148.21
1402	$24,550.11	$19,784.49	$18,385.38	$16,761.72
1403	$29,721.65	$23,950.74	$22,256.26	$20,292.32
1404	$36,275.03	$29,232.83	$27,165.25	$24,767.75
1501	$22,007.53	$18,264.47	$16,899.90	$15,885.98
1502	$26,883.70	$22,311.53	$20,642.96	$19,406.22
1503	$31,307.31	$25,983.77	$24,040.56	$22,599.99
1504	$36,739.67	$30,492.03	$28,211.99	$26,520.96
1601	$19,489.13	$14,880.69	$14,861.69	$13,333.03
1602	$23,138.91	$17,668.55	$17,646.10	$15,832.43
1603	$28,493.54	$21,757.07	$21,729.43	$19,494.31
1604	$33,544.17	$25,612.40	$25,579.59	$22,950.64
1701	$24,083.74	$18,126.29	$16,808.36	$15,530.15
1702	$29,573.10	$22,257.99	$20,639.51	$19,069.39
1703	$34,647.91	$26,078.78	$24,182.20	$22,342.63
1704	$40,209.82	$30,265.75	$28,065.17	$25,928.50
1705	$44,621.34	$33,583.89	$31,143.22	$28,773.36
1801	$21,598.16	$16,525.08	$15,328.06	$14,042.95
1802	$26,457.05	$20,242.23	$18,775.75	$17,202.18
1803	$32,576.88	$24,924.94	$23,118.18	$21,180.15
1804	$38,473.88	$29,436.65	$27,303.43	$25,014.76
1805	$46,355.55	$35,466.65	$32,898.16	$30,139.66
1806	$64,031.01	$48,989.68	$45,441.81	$41,631.38
1901	$18,958.84	$15,685.61	$14,517.96	$14,450.59
1902	$27,714.53	$22,928.18	$21,223.34	$21,123.15
1903	$39,891.99	$33,003.52	$30,549.03	$30,405.66
1904	$62,232.89	$51,485.63	$47,656.21	$47,433.39
2001	$20,798.42	$16,685.72	$15,435.15	$14,094.77
2002	$25,657.31	$20,582.51	$19,041.76	$17,387.00
2003	$30,286.48	$24,297.93	$22,477.35	$20,525.51
2004	$35,587.56	$28,550.54	$26,412.14	$24,118.29
2005	$38,313.24	$30,735.58	$28,434.81	$25,964.77
2101	$33,114.07	$23,007.64	$19,853.59	$19,173.03
2102	$48,037.94	$33,378.35	$28,802.73	$27,814.71
5001	$-	$-	$-	$2,865.59
5101	$-	$-	$-	$11,908.01
5102	$-	$-	$-	$35,326.74
5103	$-	$-	$-	$15,687.34
5104	$-	$-	$-	$38,558.52

F. Example of the Methodology for Adjusting the Proposed Prospective Payment Rates

Table 7 illustrates the methodology for adjusting the proposed prospective payments (as described in section V. of this proposed rule). The following examples are based on two hypothetical Medicare beneficiaries, both classified into CMG 0104 (without comorbidities). The proposed unadjusted prospective payment rate for CMG 0104 (without comorbidities) appears in Table 7.

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 0.8606, 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 0.8686, and a teaching status adjustment of 0.0784.

To calculate each IRF's labor and non-labor portion of the proposed prospective payment, we begin by taking the unadjusted prospective payment rate for CMG 0104 (without comorbidities) from Table 7. Then, we multiply the proposed labor-related share for FY 2022 (72.9 percent) described in section V.C. of this proposed rule by the proposed unadjusted prospective payment rate. To determine the non-labor portion of the proposed prospective payment rate, we subtract the labor portion of the Federal payment from the proposed unadjusted prospective payment.

To compute the proposed wage-adjusted prospective payment, we multiply the labor portion of the proposed 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 proposed wage-adjusted Federal payment by adding the wage-adjusted labor amount to the non-labor portion of the proposed Federal payment.

Adjusting the proposed 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 7 illustrates the components of the adjusted payment calculation.

TABLE 7: Example of Computing the FY 2022 IRF Prospective Payment

Steps		Rural Facility A (Spencer Co., IN)		Urban Facility B (Harrison Co., IN)	
1	Unadjusted Payment		$27,626.44		$27,626.44
2	Labor Share	X	0.729	X	0.729
3	Labor Portion of Payment	=	$20,139.67	=	$20,139.67
4	CBSA-Based Wage Index \	X	0.8606	X	0.8686
5	Wage-Adjusted Amount	=	$17,332.20	=	$17,493.32
6	Non-Labor Amount	+	$7,486.77	+	$7,486.77
7	Wage-Adjusted Payment	=	$24,818.97	=	$24,980.09
8	Rural Adjustment	X	1.149	X	1.000
9	Wage- and Rural-Adjusted Payment	=	$28,517.00	=	$24,980.09
10	LIP Adjustment	X	1.0156	X	1.0454
11	Wage-, Rural- and LIP-Adjusted Payment	=	$28,961.86	=	$26,114.18
12	Wage- and Rural-Adjusted Payment		$28,517.00		$24,980.09
13	Teaching Status Adjustment	X	0	X	0.0784
14	Teaching Status Adjustment Amount	=	$0.00	=	$1,958.44
15	Wage-, Rural-, and LIP-Adjusted Payment	+	$28,961.86	+	$26,114.18
16	Total Adjusted Payment	=	$28,961.86	=	$28,072.62

Thus, the proposed adjusted payment for Facility A would be $28,961.86, and the adjusted payment for Facility B would be $28,072.62.

VI. Proposed Update to Payments for High-Cost Outliers under the IRF PPS for FY 2022

A. Proposed Update to the Outlier Threshold Amount for FY 2022

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 2021 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, and 85 FR 48444, 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 2022, we propose to use FY 2020 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 41316 and 41362 through 41363), which is also the same methodology that we used to update the outlier threshold amounts for FYs 2006 through 2021. 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 2022, we estimate the amount of FY 2022 IRF PPS aggregate and outlier payments using the most recent claims available (FY 2020) and the proposed FY 2022 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 estimate that IRF outlier payments as a percentage of total estimated payments would be approximately 3.3 percent in FY 2021. Therefore, we propose to update the outlier threshold amount from $ 7,906 for FY 2021 to $9,192 for FY 2022 to maintain estimated outlier payments at approximately 3 percent of total estimated aggregate IRF payments for FY 2022.

We invite public comment on the proposed update to the FY 2022 outlier threshold amount to maintain estimated outlier payments at approximately 3 percent of total estimated IRF payments.

B. Proposed Update to the IRF Cost-to-Charge Ratio Ceiling and Urban/Rural Averages for FY 2022

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 FR 45674, 45692 through 45694), we propose to apply a ceiling to IRFs' CCRs. Using the methodology described in that final rule, we propose to update the national urban and rural CCRs for IRFs, as well as the national CCR ceiling for FY 2022, 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 2022 , as discussed below in this section.

- Other IRFs for which accurate data to calculate an overall CCR are not available.

Specifically, for FY 2022, we propose to estimate a national average CCR of 0.478 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 propose to estimate a national average CCR of 0.393 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 proposed rule, we have used the most recent available cost report data (FY 2019). This includes all IRFs whose cost reporting periods begin on or after October 1, 2018, and before October 1, 2019. If, for any IRF, the FY 2019 cost report was missing or had an "as submitted" status, we used data from a previous FY's (that is, FY 2004 through FY 2018) 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 2019 cost report data for this proposed rule, we estimate a national average CCR of 0.478 for rural IRFs, and a national average CCR of 0.393 for urban IRFs.

In accordance with past practice, we propose to set the national CCR ceiling at 3 standard deviations above the mean CCR. Using this method, we propose a national CCR ceiling of 1.34 for FY 2022. This means that, if an individual IRF's CCR were to exceed this ceiling of 1.34 for FY 2022, 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 are also proposing that if more recent data become available after the publication of this proposed rule and before the publication of the final rule, we would use such data to determine the FY 2022 national average rural and urban CCRs and the national CCR ceiling in the final rule.

We invite public comment on the proposed update to the IRF CCR ceiling and the urban/rural averages for FY 2022.

VII. 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. Under the IRF QRP, the Secretary must reduce by 2 percentage points the annual increase factor for discharges occurring during a fiscal year for any IRF that does not submit data in accordance with the IRF QRP requirements established by the Secretary. For more information on the background and statutory authority for the IRF QRP, we refer readers to the FY 2012 IRF PPS final rule (76 FR 47873 through 47874), the CY 2013 Hospital Outpatient Prospective Payment System/Ambulatory Surgical Center (OPPS/ASC) Payment Systems and Quality Reporting Programs final rule (77 FR 68500 through 68503), the FY 2014 IRF PPS final rule (78 FR 47902), the FY 2015 IRF PPS final rule (79 FR 45908), the FY 2016 IRF PPS final rule (80 FR 47080 through 47083), the FY 2017 IRF PPS final rule (81 FR 52080 through 52081), the FY 2018 IRF PPS final rule (82 FR 36269 through 36270), the FY 2019 IRF PPS final rule (83 FR 38555 through 38556), and the FY 2020 IRF PPS final rule (84 FR 39054 through 39165).

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 2022 IRF QRP

The IRF QRP currently has 17 measures for the FY 2022 program year, which are set out in Table 8.

TABLE 8: Quality Measures Currently Adopted for the FY 2022 IRF QRP

Short Name	Measure Name & Data Source
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 (NQF #2631).
Change in Mobility	IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634).
Discharge Mobility Score	IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (NQF #2636).
Change in Self-Care	IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (NQF #2633).
Discharge Self-Care Score	IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (NQF #2635).
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 (NQF #0138).
CDI	National Healthcare Safety Network (NHSN Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717).
HCP Influenza Vaccine	Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431).
Claims-Based	
MSPB IRF	Medicare Spending Per Beneficiary (MSPB)–Post Acute Care (PAC) IRF QRP (NQF #3561).
DTC	Discharge to Community–PAC IRF QRP (NQF #3479).
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.

*In response to the public health emergency (PHE) for the Coronavirus Disease 2019 (COVID-19), CMS released an interim final rule (85 FR 27595 through 27596) which delayed the compliance date for the collection and reporting of the Transfer of Health Information measures for at least 1 full fiscal year after the end of the PHE.

C.   IRF QRP Quality Measure Proposals Beginning with the FY 2023 IRF QRP

Section 1899B(h)(1) of the Act permits the Secretary to remove, suspend, or add quality measures or resource use or other measures described in sections 1899B(c)(1) and section 1899B(d)(1) of the Act respectively, so long as the Secretary publishes in the **Federal Register** (with a notice and comment period) a justification for such removal, suspension, or addition. We propose to adopt one new measure: the COVID-19 Vaccination Coverage among Healthcare Personnel (HCP)[4] measure as an "other" measure under the resource use or other measure

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[4] The measure steward changed the name of the measure from SARS-CoV-2 Vaccination Coverage among Healthcare Personnel to COVID-19 Vaccination Coverage among Healthcare Personnel. There were no changes to the measure itself, other than the name change.

domain under section 1899B(d)(1) of the Act beginning with the FY 2023 IRF QRP. In accordance with section 1899B(a)(1)(B) of the Act, the data used to calculate this measure is standardized and interoperable. The proposed measure supports the Meaningful Measures domain of Promote Effective Prevention and Treatment of Chronic Disease. CMS identified the measure's concept as a priority in response to the current public health crisis. This process measure was developed with the Centers for Disease Control and Prevention (CDC) to track COVID-19 vaccination coverage among HCP in the IRF setting. This measure is described in more detail below.

In addition, we propose to update the denominator for one measure, the Transfer of Health (TOH) Information to the Patient–Post-Acute Care (PAC) measure to exclude patients discharged home under the care of an organized home health service or hospice.

1.   Proposed COVID-19 Vaccination Coverage among Healthcare Personnel (HCP) Measure Beginning with the FY 2023 IRF QRP

a.   Background

On January 31, 2020, the Secretary of the U.S. Department Health and Human Services declared a public health emergency (PHE) for the United States in response to the global outbreak of SARS-CoV-2, a novel (new) coronavirus that causes a disease named "coronavirus disease 2019" (COVID-19).[5] COVID-19 is a contagious respiratory infection[6] that can cause serious illness and death. Older individuals, racial and ethnic minorities, and those with underlying medical conditions are considered to be at higher risk for more serious complications from COVID-19.[7,8] As of March 31, 2021, the U.S. reported over 30 million cases of

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[5] U.S. Dept of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response. (2020). Determination that a Public Health Emergency Exists. Available at https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.
[6] Centers for Disease Control and Prevention. (2020). Your Health: Symptoms of Coronavirus. Available at https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.
[7] Centers for Disease Control and Prevention. (2020). Your Health: Symptoms of Coronavirus. Available at https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.
[8] Centers for Disease Control and Prevention (2021). Health Equity Considerations and Racial and Ethnic Minority Groups. Available at https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html.

COVID-19 and over 548,000 COVID-19 deaths.[9]   Hospitals and health systems saw significant

surges of COVID-19 patients as community infection levels increased.[10]   In December 2020 and

January 2021, media outlets reported that more than 100,000 Americans were in the hospital

with COVID-19.[11]

Evidence indicates that COVID-19 primarily spreads when individuals are in close

contact with one another.[12] The virus is typically transmitted through respiratory droplets or

small particles created when someone who is infected with the virus coughs, sneezes, sings, talks

or breathes.[13] Experts believe that COVID-19 spreads less commonly through contact with a

contaminated surface[14] (although that is not thought to be a common way that COVID-19

spreads), and that in certain circumstances, infection can occur through airborne transmission.[15]

According to the CDC, those at greatest risk of infection are persons who have had prolonged,

unprotected close contact (that is, within 6 feet for 15 minutes or longer) with an individual with

confirmed SARS-CoV-2 infection, regardless of whether the individual has symptoms.[16]

Although personal protective equipment (PPE) and other infection-control precautions can

reduce the likelihood of transmission in health care settings, COVID-19 can spread between

health care personnel (HCP) and patients given the close contact that may occur during the

[9] Centers for Disease Control and Prevention. (2020). CDC COVID Data Tracker. Available at https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days.

[10]Associated Press. Tired to the Bone. Hospitals Overwhelmed with Virus Cases. November 18, 2020. Accessed on December 16, 2020, at https://apnews.com/article/hospitals-overwhelmed-coronavirus-cases-74a1f0dc3634917a5dc13408455cd895. Also see: New York Times. Just how full are U.S. intensive care units? New data paints an alarming picture. November 18, 2020. Accessed on December 16, 2020, at https://www.nytimes.com/2020/12/09/world/just-how-full-are-us-intensive-care-units-new-data-paints-an-alarming-picture.html.

[11] NPR. U.S. Hits 100,000 COVID-19 Hospitalizations, Breaks Daily Death Record. Dec. 2, 2020. Accessed on December 17, 2020 at https://www.npr.org/sections/coronavirus-live-updates/2020/12/02/941902471/u-s-hits-100-000-covid-19-hospitalizations-breaks-daily-death-record; The Wall Street Journal. Coronavirus Live Updates: U.S. Hospitalizations, Newly Reported Cases, Deaths Edge Downward. Accessed on January 11 at https://www.wsj.com/livecoverage/covid-2021-01-11.

[12] Centers for Disease Control and Prevention. (2021). COVID-19. Your Health. Frequently Asked Questions. Accessed on January 11, 2021 at https://www.cdc.gov/coronavirus/2019-ncov/faq.html.

[13] Centers for Disease Control and Prevention (2021). COVID-19. Your Health. Frequently Asked Questions. Accessed on January 11, 2021 at https://www.cdc.gov/coronavirus/2019-ncov/faq.html.

[14] Centers for Disease Control and Prevention (2021). COVID-19. Your Health. Frequently Asked Questions. Accessed on January 11, 2021 at https://www.cdc.gov/coronavirus/2019-ncov/faq.html.

[15] Centers for Disease Control and Prevention. (2020). Centers for Disease Control Scientific Brief: SARS-CoV-2 and Potential Airborne Transmission. Available at https://www.cdc.gov/coronavirus/2019-ncov/more/scientific-brief-sars-cov-2.html.

[16] Centers for Disease Control and Prevention. (2020). Clinical Questions about COVID-19: Questions and Answers. Accessed on December 2, 2020 at https://www.cdc.gov/coronavirus/2019-ncov/hcp/faq.html.

provision of care.[17]   The CDC has emphasized that health care settings, including IRFs, can be

high-risk places for COVID-19 exposure and transmission.[18]   Vaccination is a critical part of the

nation's strategy to effectively counter the spread of COVID-19 and ultimately help restore

societal functioning.[19]

On December 11, 2020, the Food and Drug Administration (FDA) issued the first

Emergency Use Authorization (EUA) for a COVID-19 vaccine in the United States.[20]

Subsequently, the FDA issued EUAs for additional COVID-19 vaccines.   In issuing these EUAs,

the FDA determined that it was reasonable to conclude that the known and potential benefits of

each vaccine, when used as authorized to prevent COVID-19, outweighed its known and

potential risks.[21,22,23]

As part of its national strategy to address COVID-19, the current administration stated

that it would work with states and the private sector to execute an aggressive vaccination strategy

and has outlined a goal of administering 200 million shots in 100 days.[24]   Although the goal of

the U.S. government is to ensure that every American who wants to receive a COVID-19 vaccine

can receive one, federal agencies recommended that early vaccination efforts focus on those

critical to the PHE response, including healthcare personnel (HCP)[25], and individuals at highest

risk for developing severe illness from COVID-19.[26]   For example, the CDC's Advisory

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[17] Centers for Disease Control and Prevention. (2020). Interim U.S. Guidance for Risk Assessment and Work Restrictions for Healthcare Personnel with Potential Exposure to COVID-19. Accessed on December 2 at https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html.

[18] Dooling, K, McClung, M, et al. "The Advisory Committee on Immunization Practices' Interim Recommendations for Allocating Initial Supplies of COVID-19 Vaccine -- United States, 2020." Morb Mortal Wkly Rep. 2020; 69(49): 1857-1859.

[19] Centers for Disease Control and Prevention. (2020). COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations. Accessed on December 18 at https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf.

[20] U.S. Food and Drug Administration. (2020). Pfizer-BioNTech COVID-19 Vaccine EUA Letter of Authorization. Available at https://www.fda.gov/media/144412/download.

[21] Ibid.

[22] U.S. Food and Drug Administration. (2021). ModernaTX, Inc. COVID-19 Vaccine EUA Letter of Authorization. Available at https://www.fda.gov/media/144636/download.

[23] U.S. Food and Drug Administration (2020). Janssen Biotech, Inc. COVID-19 Vaccine EUA Letter of Authorization. Available at https://www.fda.gov/media/146303/download.

[24] The White House. Remarks by President Biden on the COVID-19 Response and the State of Vaccinations. March 29, 2021. Accessed at https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/03/29/remarks-by-president-biden-on-the-covid-19-response-and-the-state-of-vaccinations/

[25] Centers for Disease Control and Prevention. Glossary of Terms. https://cdc.gov/infectioncontrol/guidelines/healthcare-personnel/appendix/terminology.html.

[26] Health and Human Services, Department of Defense. (2020) From the Factory to the Frontlines: The Operation Warp Speed

Committee on Immunization Practices (ACIP) recommended that HCP should be among those individuals prioritized to receive the initial, limited supply of the COVID-19 vaccination, given the potential for transmission in health care settings and the need to preserve health care system capacity. [27] Research suggests most states followed this recommendation,[28] and HCP began receiving the vaccine in mid-December of 2020.[29]

HCP are at risk of carrying COVID-19 infection to patients, experiencing illness or death as a result of COVID-19 themselves, and transmitting it to their families, friends, and the general public. We believe it is important to require that IRFs report COVID-19 HCP vaccination in order to assess whether they are taking steps to limit the spread of COVID-19 among their HCP, reduce the risk of transmission of COVID-19 within their facilities, and to help sustain the ability of IRFs to continue serving their communities throughout the PHE and beyond.

We also believe that publishing facility level COVID-19 HCP vaccination rates on Care Compare would be helpful to many patients, including those who are at high-risk for developing serious complications from COVID-19, as they choose facilities from which to seek treatment. Under CMS' Meaningful Measures framework, the COVID-19 Vaccination Coverage among Healthcare Personnel measure addresses the quality priority of "Promote Effective Prevention & Treatment of Chronic Disease" through the Meaningful Measures Area of "Preventive Care."

Therefore, this rule proposes a new measure, COVID-19 Vaccination Coverage among HCP to assess the proportion of an IRF's healthcare workforce that has been vaccinated against COVID-19.

Strategy for Distributing a COVID-19 Vaccine. Accessed December 18 at https://www.hhs.gov/sites/default/files/strategy-for-distributing-covid-19-vaccine.pdf; Centers for Disease Control (2020). COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations. Accessed December 18 at https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf.

[27] Dooling, K, McClung, M, et al. "The Advisory Committee on Immunization Practices' Interim Recommendations for Allocating Initial Supplies of COVID-19 Vaccine -- United States, 2020." Morb. Mortal Wkly Rep. 2020; 69(49): 1857-1859. ACIP also recommended that long-term care residents be prioritized to receive the vaccine, given their age, high levels of underlying medical conditions, and congregate living situations make them high risk for severe illness from COVID-19.

[28] Kates, J, Michaud, J, Tolbert, J. "How Are States Prioritizing Who Will Get the COVID-19 Vaccine First?" Kaiser Family Foundation. December 14, 2020. Accessed on December 16 at https://www.kff.org/policy-watch/how-are-states-prioritizing-who-will-get-the-covid-19-vaccine-first/.

[29] Associated Press. 'Healing is Coming:' US Health Workers Start Getting Vaccine. December 15, 2020. Accessed on December 16 at https://apnews.com/article/us-health-workers-coronavirus-vaccine-56df745388a9fc12ae93c6f9a0d0e81f.

b.   Stakeholder Input

In the development and specification of the measure, a transparent process was employed to seek input from stakeholders and national experts and engage in a process that allows for pre-rulemaking input on each measure, under section 1890A of the Act.[30] To meet this requirement, the following opportunity was provided for stakeholder input.

The pre-rule making 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, through federal rulemaking process, for use in Medicare program(s). This allows multi-stakeholder groups to provide recommendations to the Secretary on the measures included on the list. The COVID-19 Vaccination Coverage among Healthcare Personnel measure was included on the publicly available "List of Measures under Consideration for December 21, 2020". [31] Five comments were received from industry stakeholders during the pre-rulemaking process on the COVID-19 Vaccination Coverage among HCP measure, and support was mixed. Commenters generally supported the concept of the measure. However, there was concern about the availability of the vaccine and measure definition for HCP, and some commenters encouraged CMS to continue to update the measure as new evidence comes in.

c.   Measure Applications Partnership (MAP) Review

When the Measure Applications Partnership (MAP) Post-Acute Care/Long-Term Care (PAC-LTC) Workgroup convened on January 11, 2021, it reviewed the MUC List and the COVID-19 Vaccination Coverage among HCP measure. The MAP recognized that the proposed measure represents a promising effort to advance measurement for an evolving national pandemic and that it would bring value to the IRF QRP measure set by providing transparency about an important COVID-19 intervention to help limit COVID-19 infections.[32] The MAP also

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[30] Centers for Medicare & Medicaid Services. Pre-rulemaking. Accessed at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Pre-Rulemaking.
[31] National Quality Forum. List of Measures Under Consideration for December 21, 2020. Accessed at https://www.cms.gov/files/document/measures-under-consideration-list-2020-report.pdf on January 12, 2021.
[32] Measure Applications Partnership. MAP Preliminary Recommendations 2020-2021. Accessed on February 3, 2021 at https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94650.

stated that collecting information on COVID-19 vaccination coverage among healthcare personnel and providing feedback to facilities would allow facilities to benchmark coverage rates and improve coverage in their facility, and that reducing rates of COVID-19 in healthcare personnel may reduce transmission among patients and reduce instances of staff shortages due to illness.[33]

In its preliminary recommendations, the MAP PAC-LTC Workgroup did not support this measure for rulemaking, subject to potential for mitigation.[34] To mitigate its concerns, the MAP believed that the measure needed well-documented evidence, finalized specifications, testing, and NQF endorsement prior to implementation.[35] Subsequently, the MAP Coordinating Committee met on January 25, 2021, and reviewed the COVID-19 Vaccination Coverage among Healthcare Personnel measure. In the 2020-2021 MAP Final Recommendations, the MAP offered conditional support for rulemaking contingent on CMS bringing the measures back to the MAP once the specifications are further clarified. The final MAP report is available at http://www.qualityforum.org/Publications/2021/03/MAP_2020-2021_Considerations_for_Implementing_Measures_Final_Report_-_Clinicians,_Hospitals,_and_PAC-LTC.aspx.

In response to the MAP request for CMS to bring the measure back once the specifications were further clarified, CMS met with the MAP Coordinating Committee on March 15, 2021. First, CMS and CDC clarified the alignment of the COVID-19 Vaccination Coverage among HCP with the Influenza Vaccination Coverage among HCP (NQF #0431), an NQF-endorsed measure since 2012. The COVID-19 Vaccination Coverage among HCP measure is calculated using the same approach as the Influenza Vaccination Coverage among HCP measure.[36] The approach to identifying HCPs eligible for the COVID-19 vaccination is

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[33] Ibid.
[34] Ibid.
[35] Ibid.
[36] The Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) measure which is NQF endorsed and was adopted in the IRF QRP in the FY 2014 IRF PPS Final Rule (78 FR 47905 through 47906), and in the LTCH QRP in the FY 2013 IPPS/LTCH PPS Final Rule (77 FR 53630 through 53631).

analogous to those used in the NQF endorsed flu measure which underwent rigorous review from technical experts about the validity of that approach and for which ultimately received NQF endorsement. More recently, prospective cohorts of health care personnel, first responders, and other essential and frontline workers over 13 weeks in eight U.S. locations confirmed that authorized COVID-19 vaccines are highly effective in real-world conditions. Vaccine effectiveness of full immunization with two doses of vaccines was 90 percent.[37]

Additionally, to support the measure's data element validity, CDC conducted testing of the COVID-19 vaccination numerator using data collected through the NHSN and independently reported through the Federal Pharmacy Partnership for Long-term Care Program for delivering vaccines to long-term care facilities. These are two completely independent data collection systems. In initial analyses of the first month of vaccination, the number of HCP vaccinated in approximately 1,200 facilities, which had data from both systems, the number of HCP vaccinated was highly correlated between these two systems with a correlation coefficient of nearly 90 percent in the second 2 weeks of reporting. Of note, assessment of data element reliability may not be required by NQF if data element validity is demonstrated.[38] In addition, for assessing the validity of new performance measure score (in this case, percentage COVID-19 vaccination coverage), NQF allows assessment by face validity (subjective determination by experts that the measure appears to reflect quality of care, done through a systematic and transparent process)[39] and the MAP concurred with face validity of the measure of COVID-19 vaccination coverage. Materials from the March 15, 2021 MAP Coordinating Committee meeting are on the NQF website at https://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367.

This measure is not NQF endorsed, but CMS, in collaboration with the CDC, plans to

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[37] Centers for Disease Control and Preventions. Morbidity and Mortality Weekly Report. March 29, 2021. Available at https://www.cdc.gov/mmwr/volumes/70/wr/mm7013e3.htm?s_cid=mm7013e3_w.
[38] National Quality Form. Key Points for Evaluating Scientific Acceptability. Revised January 3, 2020. https://www.qualityforum.org/Measuring_Performance/Scientific_Methods_Panel/Docs/Evaluation_Guidance.aspx#:~:text=NQF%20is%20not%20prescriptive%20about,reliability%20or%20validity%20testing%20results.&text=Reliability%20and%20validity%20must%20be,source%20and%20level%20of%20analysis).
[39] Ibid.

submit the measure for NQF endorsement in the future.

d.   Competing and Related Measures

Section 1886(j)(7)(D)(i) of the Act requires that, absent an exception under section 1886(j)(7)(D)(ii) of the Act, measures specified by the Secretary under section 1886(j)(7)(D) of the Act be endorsed by the entity with a contract under section 1890(a) of the Act, currently the National Quality Forum (NQF). 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 permits the Secretary to specify a measure that is not so endorsed, as long as due consideration is given to the measures that have been endorsed or adopted by a consensus organization identified by the Secretary. Section 1899B(e)(2)(A) of the Act requires that, subject to section 1899B(e)(2)(B) of the Act, each measure specified by the Secretary under section 1899B of the Act be endorsed by the entity with a contract under section 1890(a) of the Act. However, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

The proposed COVID-19 Vaccination Coverage among HCP measure is not currently NQF endorsed and has not been submitted to the NQF for consideration, so we considered whether there are other available measures that assess COVID-19 vaccinations among HCP. After review of the NQF's consensus-endorsed measures, we were unable to identify any NQF endorsed measures for IRFs focused on capturing COVID-19 vaccination coverage of HCP and we found no other feasible and practical measure on the topic of COVID-19 vaccination coverage among HCP, and we found no other feasible and practical measure on the topic of COVID-19 vaccination coverage among HCP. The only other vaccination coverage of HCP measure found was the Influenza Vaccination Coverage among Healthcare Personnel (NQF

#0431) measure which is NQF endorsed and was adopted in the IRF QRP in the FY 2014 IRF PPS Final Rule (78 FR 47905 through 47906).

Given the novel nature of the SARS-CoV-2 virus, and the significant and immediate risk it poses in IRFs, we believe it is necessary to propose the measure as soon as possible. Therefore, after consideration of other available measures that assess COVID-19 vaccination rates among HCP, we believe the exception under section 1899B(e)(2)(B) of the Act applies. This proposed measure has the potential to generate actionable data on vaccination rates that can be used to target quality improvement among IRF providers.

e.   Quality Measure Calculation

The COVID-19 Vaccination Coverage among Healthcare Personnel (HCP) measure is a process measure developed by the CDC to track COVID-19 vaccination coverage among HCP in facilities such as IRFs. Since this proposed measure is a process measure, rather than an outcome measure, it does not require risk-adjustment.

The denominator would be the number of HCP eligible to work in the IRF for at least one day during the reporting period, excluding persons with contraindications to COVID-19 vaccination, that are described by the CDC.[40]

The numerator would be the cumulative number of HCP eligible to work in the IRF for at least one day during the reporting period and who received a complete vaccination course against SARS-CoV-2. A complete vaccination course may require one or more doses depending on the specific vaccine used. The finalized measure specifications are available on the CDC website at https://www.cdc.gov/nhsn/nqf/index.html.

We propose that IRFs would submit data for the measure through the CDC/NHSN data collection and submission framework.[41] This framework is currently used for reporting the

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[40] Centers for Disease Control and Prevention. Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United Sates, Appendix B. Accessed at https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Appendix-B.
[41] Centers for Disease Control and Prevention. Surveillance for Weekly HCP COVID-19 Vaccination. Accessed at https://www.cdc.gov/nhsn/hps/weekly-covid-vac/index.html on February 10, 2021.

CAUTI (NQF #0138) and Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) measures. IRFs would use the COVID-19 vaccination data reporting module in the NHSN Healthcare Personnel Safety (HPS) Component to report the number of HCP eligible who have worked at the facility that week (denominator) and the number of those HCP who have received a completed COVID-19 vaccination course (numerator). IRFs would submit COVID-19 vaccination data for at least one week each month. If IRFs submit more than one week of data in a month, the most recent week's data would be used for measure calculation purposes. Each quarter, the CDC would calculate a summary measure of COVID-19 vaccination coverage from the three monthly modules reported for the quarter. This quarterly rate would be publicly reported on the Care Compare website. Subsequent to the first refresh, one additional quarter of data would be added to the measure calculation during each advancing refresh, until the point four full quarters of data is reached. Thereafter, the measure would be reported using four rolling quarters of data on Care Compare.

For purposes of submitting data to CMS for the FY 2023 IRF QRP, IRFs would be required to submit data for the period October 1, 2021 through December 31, 2021. Following the data submission quarter for the FY 2023 IRF QRP, subsequent compliance for the IRF QRP would be based on four quarters of such data submission. For more information on the measure's proposed public reporting period, we refer readers to section VII.G.2 of this proposed rule.

We invite public comment on our proposal to add a new measure, COVID-19 Vaccination Coverage among Healthcare Personnel measure, to the IRF QRP beginning with the FY 2023 IRF QRP.

2.   Proposed Update to the Transfer of Health (TOH) Information to the Patient – Post-Acute Care (PAC) Measure Beginning with the FY 2023 IRF QRP

This rule proposes to update the Transfer of Health Information to the Patient – Post-Acute Care (PAC) measure denominator to exclude patients discharged home under the care of

an organized home health service or hospice. This measure assesses for and reports on the timely transfer of health information, specifically transfer of a medication list. We adopted this measure in the FY 2020 IRF PPS final rule (84 FR 39099 through 39107) beginning with the FY 2022 IRF QRP. It is a process-based measure that evaluates for the transfer of information when a patient is discharged from his or her current PAC setting to a private home/apartment, board and care home, assisted living, group home, transitional living, or home under the care of an organized home health service organization or hospice.

This measure, adopted under section 1899B(c)(1)(E) of the Act, was developed to be a standardized measure for the IRF QRP, LTCH QRP, SNF QRP, and Home Health (HH) QRP. The measure is calculated by one standardized data element that asks, "At the time of discharge, did the facility provide the patient's current reconciled medication list to the patient, family, and/or caregiver?" The discharge location is captured by items on the Inpatient Rehabilitation Facility-Patient Assessment Instrument (IRF-PAI).

Specifically, this rule proposes to update the measure denominator. Currently the measure denominators for both the TOH-Patient and the TOH-Provider measure assess the number of patients discharged home under the care of an organized home health service organization or hospice. In order to align the measure with the SNF QRP, LTCH QRP and HH QRP and avoid counting the patient in both TOH measures in the IRF QRP, this rule proposes to remove this location from the definition of the denominator for the TOH-Patient measure. Therefore, we are proposing to update the denominator for the TOH-Patient measure to only discharges to a private home/apartment, board and care home, assisted living, group home, or transitional living. For additional technical information regarding the TOH-Patient measure, we refer readers to the document titled "Final Specifications for IRF QRP Quality Measures and Standardized Patient Assessment Data Elements (SPADEs)" available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/Downloads/Final-Specifications-for-IRF-QRP-Quality-Measures-and-SPADEs.pdf

We are inviting public comment on our proposal to update the denominator of the Transfer of Health (TOH) Information to the Patient – Post-Acute Care (PAC) measure beginning with the FY 2023 IRF QRP.

D.   IRF QRP Quality Measures under Consideration for Future Years: Request for Information

We are seeking input on the importance, relevance, appropriateness, and applicability of each of the measures and concepts under consideration listed in Table 9 for future years in the IRF QRP.

TABLE 9: Future Measures and Measure Concepts Under Consideration for the IRF QRP

Assessment-Based Quality Measures and Measure Concepts
Frailty
Opioid use and frequency
Patient reported outcomes
Shared decision making process
Appropriate pain assessment and pain management processes
Health equity

While we will not be responding to specific comments submitted in response to this Request for Information in the FY 2022 IRF PPS final rule, we intend to use this input to inform our future measure development efforts.

E.   Fast Healthcare Interoperability Resources (FHIR) in support of Digital Quality Measurement in Quality Programs – Request for Information

1. Background

The IRF QRP is authorized by section 1886(j)(7) of the Act and furthers our mission to improve the quality of health care for beneficiaries through measurement, transparency, and public reporting of data. The IRF QRP and CMS's other quality programs are foundational for contributing to improvements in health care, enhancing patient outcomes, and informing consumer choice.

In October 2017, we launched the Meaningful Measures Framework. This framework captures our vision to address health care quality priorities and gaps, including emphasizing

digital quality measurement (dQM), reducing measurement burden, and promoting patient perspectives, while also focusing on modernization and innovation. The scope of the Meaningful Measures Framework has evolved to accommodate the changes in the health care environment, initially focusing on measure and burden reduction to include the promotion of innovation and modernization of all aspects of quality.[42] There is a need to streamline our approach to data collection, calculation, and reporting to fully leverage clinical and patient-centered information for measurement, improvement, and learning.

In alignment with Meaningful Measures 2.0, we are seeking feedback on our future plans to define digital quality measures (dQMs) for the IRF QRP. We also are seeking feedback on the potential use of Fast Healthcare Interoperable Resources (FHIR) for dQMs within the IRF QRP aligning where possible with other quality programs. FHIR is a free and open source standards framework (in both commercial and government settings) created by Health Level Seven International (HL7®) that establishes a common language and process for all health information technology.

2. Definition of Digital Quality Measures

We are considering adopting a standardized definition of Digital Quality Measures (dQMs) in alignment across quality programs, including the IRF QRP. We are considering in the future to propose the adoption within the IRF QRP the following definition: Digital Quality Measures (dQMs) are quality measures that use one or more sources of health information that are captured and can be transmitted electronically via interoperable systems.[43] A dQM includes a calculation that processes digital data to produce a measure score or measure scores. Data sources for dQMs may include administrative systems, electronically submitted clinical assessment data, case management systems, EHRs, instruments (for example, medical devices and wearable devices), patient portals or applications (for example, for collection of patient-

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[42] Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization
[43] Definition taken from the CMS Quality Conference 2021.

generated health data), health information exchanges (HIEs) or registries, and other sources. As an example, the quality measures calculated from patient assessment data submitted electronically to CMS would be considered digital quality measures.

3. Use of FHIR for Future dQMs in the IRF QRP

One of the first areas CMS has identified relative to improving our digital strategy is through the use of Fast Healthcare Interoperability Resources (FHIR)-based standards to exchange clinical information through application programming interfaces (APIs), aligning with other programs where possible, to allow clinicians to digitally submit quality information one time that can then be used in many ways. We believe that in the future proposing such a standard within the IRF QRP could potentially enable collaboration and information sharing, which is essential for delivering high-quality care and better outcomes at a lower cost.

We are currently evaluating the use of FHIR based APIs to access assessment data collected and maintained through the Quality Improvement and Evaluation System (QIES) and Internet QIES (iQIES) health information systems and are working with healthcare standards organizations to assure that their evolving standards fully support our assessment instrument content. Further, as more IRFs are adopting EHRs, we are evaluating using the FHIR interfaces for accessing patient data (including standard assessments) directly from IRF EHRs. Accessing data in this manner could also enable the exchange of data for purposes beyond data reporting to CMS, such as care coordination further increasing the value of EHR investments across the healthcare continuum. Once providers map their EHR data to a FHIR API in standard FHIR formats it could be possible to *send/receive* the data needed for measures and other uses from their EHRs through FHIR APIs.

4. Future Alignment of Measures Across Reporting Programs, Federal and State Agencies, and the Private Sector

We are committed to using policy levers and working with stakeholders to achieve interoperable data exchange and to transition to full digital quality measurement in our quality

programs. We are considering the future potential development and staged implementation of a cohesive portfolio of dQMs across our quality programs (including the IRF QRP), agencies, and private payers. This cohesive portfolio would require, where possible, alignment of: (1) measure concepts and specifications including narrative statements, measure logic, and value sets, and (2) the individual data elements used to build these measure specifications and calculate the measures. Further, the required data elements would be limited to standardized, interoperable elements to the fullest extent possible; hence, part of the alignment strategy will be the consideration and advancement of data standards and implementation guides for key data elements. We would coordinate closely with quality measure developers, federal and state agencies, and private payers to develop and to maintain a cohesive dQM portfolio that meets our programmatic requirements and that fully aligns across federal and state agencies and payers to the extent possible.

We intend this coordination to be ongoing and allow for continuous refinement to ensure quality measures remain aligned with evolving healthcare practices and priorities (for example, patient reported outcomes (PROs), disparities, care coordination), and track with the transformation of data collection. This includes conformance with standards and health IT module updates, future adoption of technologies incorporated within the ONC Health IT Certification Program and may also include standards adopted by ONC (for example, to enable standards-based APIs). The coordination would build on the principles outlined in HHS' National Health Quality Roadmap.[44] It would focus on the quality domains of safety, timeliness, efficiency, effectiveness, equitability, and patient-centeredness. It would leverage several existing federal and public-private efforts including our Meaningful Measures 2.0 Framework; the Federal Electronic Health Record Modernization (DoD/VA); the Core Quality Measure Collaborative, which convenes stakeholders from America's Health Insurance Plans (AHIP),

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[44] Department of Health and Human Services. National Health Quality Roadmap. May 15, 2020. Available at https://www.hhs.gov/sites/default/files/national-health-quality-roadmap.pdf.

CMS, NQF, provider organizations, private payers, and consumers and develops consensus on quality measures for provider specialties; and the NQF-convened Measure Applications Partnership (MAP), which recommends measures for use in public payment and reporting programs. We would coordinate with HL7's ongoing work to advance FHIR resources in critical areas to support patient care and measurement such as social determinants of health. Through this coordination, we would identify which existing measures could be used or evolved to be used as dQMs, in recognition of current healthcare practice and priorities.

This multi-stakeholder, joint federal, state, and industry effort, made possible and enabled by the pending advances towards true interoperability, would yield a significantly improved quality measurement enterprise. The success of the dQM portfolio would be enhanced by the degree to which the measures achieve our programmatic requirements as well as the requirements of other agencies and payers.

5. Solicitation of Comments

We seek input on the following steps that would enable transformation of CMS' quality measurement enterprise to be fully digital:

● What EHR/IT systems do you use and do you participate in a health information exchange (HIE)?

● How do you currently share information with other providers?

● In what ways could we incentivize or reward innovative uses of health information technology (IT) that could reduce burden for post-acute care settings, including but not limited to IRFs?

● What additional resources or tools would post-acute care settings, including but not limited to IRFs, and health IT vendors find helpful to support the testing, implementation, collection, and reporting of all measures using FHIR standards via secure APIs to reinforce the sharing of patient health information between care settings?

● Would vendors, including those that service post-acute care settings, such as IRFs, be

interested in or willing to participate in pilots or models of alternative approaches to quality

measurement that would align standards for quality measure data collection across care settings

to improve care coordination, such as sharing patient data via secure FHIR API as the basis for

calculating and reporting digital measures?

We plan to continue working with other agencies and stakeholders to coordinate and to

inform our transformation to dQMs leveraging health IT standards. While we will not be

responding to specific comments submitted in response to this Request for Information in the FY

2022 IRF PPS final rule, we will actively consider all input as we develop future regulatory

proposals or future subregulatory policy guidance. Any updates to specific program

requirements related to quality measurement and reporting provisions would be addressed

through separate and future notice- and-comment rulemaking, as necessary.

F.   Closing the Health Equity Gap in Post-Acute Care Quality Reporting Programs – Request

for Information

1.   Background

Significant and persistent inequities in health outcomes exist in the United States. In

recognition of persistent health disparities and the importance of closing the health equity gap,

we request information on revising several CMS programs to make reporting of health

disparities based on social risk factors and race and ethnicity more comprehensive and

actionable for providers and patients. Belonging to a racial or ethnic minority group; living

with a disability; being a member of the lesbian, gay, bisexual, transgender, and queer

(LGBTQ+) community; or being near or below the poverty level is often associated with

worse health outcomes. [45,46,47,48] We are committed to achieving health equity by improving

[45]Joynt KE, Orav E, Jha AK. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA. 2011; 305(7):675-681.

[46] Lindenauer PK, Lagu T, Rothberg MB, et al. Income Inequality and 30 Day Outcomes After Acute Myocardial Infarction, Heart Failure, and Pneumonia: Retrospective Cohort Study. British Medical Journal. 2013; 346.

[47] Trivedi AN, Nsa W, Hausmann LRM, et al. Quality and Equity of Care in U.S. Hospitals. New England Journal of Medicine. 2014; 371(24):2298-2308.

[48] Polyakova, M., et al. Racial Disparities In Excess All-Cause Mortality During The Early COVID-19 Pandemic Varied Substantially Across States. Health Affairs. 2021; 40(2): 307-316.

data collection to better measure and analyze disparities across programs and policies.[49,50,51,52,53,54] Such disparities in health outcomes are the result of a number of factors, but importantly for CMS programs, although not the sole determinant, poor access and provision of lower quality health care contribute to health disparities. For instance, numerous studies have shown that among Medicare beneficiaries, racial and ethnic minority individuals often receive lower quality of care, report lower experiences of care, and experience more frequent hospital readmissions and operative complications. [55,56,57,58,59,60] Readmission rates for common conditions in the Hospital Readmissions Reduction Program are higher for black Medicare beneficiaries and higher for Hispanic Medicare beneficiaries with Congestive Heart Failure and Acute Myocardial Infarction.[61,62,63,64,65] Studies have also shown that African Americans are significantly more likely than white Americans to die prematurely from heart

[49] Centers for Medicare & Medicaid Services. CMS Quality Strategy. 2016. Available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.

[50] Report to Congress: Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014 Strategic Plan for Accessing Race and Ethnicity Data. January 5, 2017. Available at https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Research-Reports-2017-Report-to-Congress-IMPACT-ACT-of-2014.pdf.

[51] Rural Health Research Gateway. Rural Communities: Age, Income, and Health Status. Rural Health Research Recap. November 2018.

[52] https://www.minorityhealth.hhs.gov/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf.

[53] www.cdc.gov/mmwr/volumes/70/wr/mm7005a1.htm.

[54] Poteat TC, Reisner SL, Miller M, Wirtz AL. COVID-19 Vulnerability of Transgender Women With and Without HIV Infection in the Eastern and Southern U.S. Preprint. *medRxiv*. 2020;2020.07.21.20159327. Published 2020 Jul 24. doi:10.1101/2020.07.21.20159327.

[55] Martino, SC, Elliott, MN, Dembosky, JW, Hambarsoomian, K, Burkhart, Q, Klein, DJ, Gildner, J, and Haviland, AM. Racial, Ethnic, and Gender Disparities in Health Care in Medicare Advantage. Baltimore, MD: CMS Office of Minority Health. 2020.

[56] Guide to Reducing Disparities in Readmissions. CMS Office of Minority Health. Revised August 2018. Available at https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf.

[57] Singh JA, Lu X, Rosenthal GE, Ibrahim S, Cram P. Racial disparities in knee and hip total joint arthroplasty: an 18-year analysis of national Medicare data. Ann Rheum Dis. 2014 Dec;73(12):2107-15.

[58] Rivera-Hernandez M, Rahman M, Mor V, Trivedi AN. Racial Disparities in Readmission Rates among Patients Discharged to Skilled Nursing Facilities. J Am Geriatr Soc. 2019 Aug;67(8):1672-1679.

[59] Joynt KE, Orav E, Jha AK. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA. 2011;305(7):675-681.

[60] Tsai TC, Orav EJ, Joynt KE. Disparities in surgical 30-day readmission rates for Medicare beneficiaries by race and site of care. Ann Surg. Jun 2014;259(6):1086-1090.

[61] Rodriguez F, Joynt KE, Lopez L, Saldana F, Jha AK. Readmission rates for Hispanic Medicare beneficiaries with heart failure and acute myocardial infarction. Am Heart J. Aug 2011;162(2):254-261 e253.

[62] Centers for Medicare and Medicaid Services. Medicare Hospital Quality Chartbook: Performance Report on Outcome Measures; 2014.

[63] Guide to Reducing Disparities in Readmissions. CMS Office of Minority Health. Revised August 2018. Available at https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf.

[64] Prieto-Centurion V, Gussin HA, Rolle AJ, Krishnan JA. Chronic obstructive pulmonary disease readmissions at minority-serving institutions. Ann Am Thorac Soc. Dec 2013;10(6):680-684.

[65] Joynt KE, Orav E, Jha AK. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA. 2011;305(7):675-681.

disease and stroke.[66] The COVID-19 pandemic has further illustrated many of these longstanding health inequities with higher rates of infection, hospitalization, and mortality among black, Latino, and Indigenous and Native American persons relative to white persons.[67,68] As noted by the Centers for Disease Control "long-standing systemic health and social inequities have put many people from racial and ethnic minority groups at increased risk of getting sick and dying from COVID-19".[69] One important strategy for addressing these important inequities is by improving data collection to allow for better measurement and reporting on equity across post-acute care programs and policies.

We are also committed to achieving equity in health care outcomes for our beneficiaries by supporting providers in quality improvement activities to reduce health inequities, enabling them to make more informed decisions, and promoting provider accountability for health care disparities.[70,71] For the purposes of this rule, we are using a definition of equity established in Executive Order 13985, as "the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality."[72] We note that this definition was recently established by the current administration, and provides a useful,

[66] HHS. Heart disease and African Americans. (March 29, 2021). https://www.minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=19.
[67] https://www.cms.gov/files/document/medicare-covid-19-data-snapshot-fact-sheet.pdf.
[68] Ochieng N, Cubanski J, Neuman T, Artiga S, and Damico A. Racial and Ethnic Health Inequities and Medicare. Kaiser Family Foundation. February 2021. Available at https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/.
[69] https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html.
[70] https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.
[71] Report to Congress: Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014 Strategic Plan for Accessing Race and Ethnicity Data. January 5, 2017. Available at https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Research-Reports-2017-Report-to-Congress-IMPACT-ACT-of-2014.pdf.
[72] https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government.

common definition for equity across different areas of government, although numerous other definitions of equity exist.

Our ongoing commitment to closing the equity gap in CMS quality programs is demonstrated by a portfolio of programs aimed at making information on the quality of health care providers and services, including disparities, more transparent to consumers and providers. The CMS Equity Plan for Improving Quality in Medicare outlines a path to equity which aims to support Quality Improvement Networks and Quality Improvement Organizations (QIN-QIOs); federal, state, local, and tribal organizations; providers; researchers; policymakers; beneficiaries and their families; and other stakeholders in activities to achieve health equity. The CMS Equity Plan includes three core elements: (1) increasing understanding and awareness of disparities; (2) developing and disseminating solutions to achieve health equity; and (3) implementing sustainable actions to achieve health equity. [73] The CMS Quality Strategy and Meaningful Measures Framework[74] include elimination of racial and ethnic disparities as a central principle. Our ongoing commitment to closing the health equity gap in the IRF QRP is demonstrated by the adoption of standardized patient assessment data elements (SPADEs) which include several social determinants of health (SDOH) that were finalized in the FY 2020 IRF PPS final rule for the IRF QRP (84 FR 39149 through 39161).

We continue to work with federal and private partners to better leverage data on social risk to improve our understanding of how these factors can be better measured in order to close the health equity gap. Among other things, we have developed an Inventory of Resources for Standardized Demographic and Language Data Collection[75] and supported collection of

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[73] Centers for Medicare & Medicaid Services Office of Minority Health. The CMS Equity Plan for Improving Quality in Medicare. https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH_Dwnld-CMS_EquityPlanforMedicare_090615.pdf.
[74] https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.
[75] Centers for Medicare and Medicaid Services. Building an Organizational Response to Health Disparities Inventory of Resources for Standardized Demographic and Language Data Collection. 2020. https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Data-Collection-Resources.pdf.

specialized International Classification of Disease, 10th Edition, Clinical Modification (ICD-10-

CM) codes for describing the socioeconomic, cultural, and environmental determinants of health.

We continue to work to improve our understanding of this important issue and to identify policy

solutions that achieve the goals of attaining health equity for all patients.

2.   Solicitation of Public Comment

Under authority of the IMPACT Act and section 1886(j)(7) of the Act, we are seeking

comment on the possibility of revising measure development, and the collection of other

SPADEs that address gaps in health equity in the IRF QRP. Any potential health equity data

collection or measure reporting within a CMS program that might result from public comments

received in response to this solicitation would be addressed through a separate notice-and-

comment rulemaking in the future.

Specifically, we are inviting public comment on the following:

● Recommendations for quality measures or measurement domains that address

health equity, for use in the IRF QRP.

● As finalized in the FY 2020 IRF PPS Final Rule (84 FR 39149 through 39161),

IRFs must report certain standardized patient assessment data (SPADEs) on SDOH, including

race, ethnicity, preferred language, interpreter services, health literacy, transportation and

social isolation.[76] CMS is seeking guidance on any additional items, including SPADEs that

could be used to assess health equity in the care of IRF patients, for use in the IRF QRP.

● Recommendations for how CMS can promote health equity in outcomes among

IRF patients. For example, we are interested in feedback regarding whether including

facility-level quality measure results stratified by social risk factors and social determinants of

health (for example, dual eligibility for Medicare and Medicaid, race) in confidential feedback

reports could allow facilities to identify gaps in the quality of care they provide. (For

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[76] In response to the COVID-19 PHE, CMS released an Interim Final Rule (85 FR 27595 through 27597) which delayed the compliance date for the collection and reporting of the SDOH for at least one full fiscal year after the end of the PHE.

example, methods similar or analogous to the CMS Disparity Methods[77] which provide hospital-level confidential results stratified by dual eligibility for condition-specific readmission measures which are currently included in the Hospital Readmission Reduction Program (see 84 FR 42496 through 42500)).

● Methods that commenters or their organizations use in employing data to reduce disparities and improve patient outcomes, including the source(s) of data used, as appropriate.

● Given the importance of structured data and health IT standards for the capture, use, and exchange of relevant health data for improving health equity, the existing challenges providers encounter for effective capture, use, and exchange of health information, such as data on race, ethnicity, and other social determinants of health, to support care delivery and decision making.

While we will not be responding to specific comments submitted in response to this Request for Information in the FY 2022 IRF PPS final rule, we intend to use this input to inform future policy development. We look forward to receiving feedback on these topics, and note for readers that responses to the RFI should focus on how they could be applied to the quality reporting program requirements. Please note that any responses provided will not impact payment decisions.

G.   Form, Manner, and Timing of Data Submission under the IRF QRP

1.   Background

We refer readers to the regulatory text at 42 CFR 412.634(b) for information regarding the current policies for reporting IRF QRP data.

2.   Proposed Schedule for Data Submission of the COVID-19 Vaccination Coverage among Healthcare Personnel Measure with the FY 2023 IRF QRP

As discussed in section VII.C.1 of this proposed rule, we are proposing to adopt the COVID-19 Vaccination Coverage among HCP measure beginning with the FY 2023 IRF QRP.

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[77] https://qualitynet.cms.gov/inpatient/measures/disparity-methods/methodology.

Given the time-sensitive nature of this measure in light of the PHE, this rule proposes an initial data submission period from October 1, 2021 through December 31, 2021. Starting in CY 2022, IRFs would be required to submit data for the entire calendar year beginning with the FY 2024 IRF QRP.

IRFs would submit data for the measure through the CDC/NHSN web-based surveillance system. IRFs currently utilize the NHSN for purposes of meeting other IRF QRP requirements.[78] IRFs would use the COVID-19 vaccination data reporting module in the NHSN Healthcare Personnel Safety (HPS) Component to report the cumulative number of HCP eligible to work in the healthcare facility for at least 1 day during the reporting period, excluding persons with contraindications to COVID-19 vaccination (denominator) and the cumulative number of HCP eligible to work in the IRF for at least 1 day during the reporting period and who received a complete vaccination course against COVID-19 (numerator). IRFs would submit COVID-19 vaccination data through the NHSN for at least one week each month and the CDC would report to CMS quarterly.

We invite public comment on this proposal.

H.   Proposed 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 the IRF QRP data available to the public after ensuring that IRFs have the opportunity to review their data prior to public display. IRF QRP measure data are currently displayed on the *Inpatient Rehabilitation Facilities* website within Care Compare and the Provider Data Catalog. Both Care Compare and the Provider Data Catalog replaced IRF Compare and Data.Medicare.gov, which were both retired in December 2020. For a more detailed discussion about our policies regarding public display of IRF QRP measure data and procedures for the opportunity to review

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[78] Centers for Disease Control and Prevention. Surveillance for Weekly HCP COVID-19 Vaccination. Accessed at https://www.cdc.gov/nhsn/hps/weekly-covid-vac/index.html on February 10, 2021.

and correct data and information, we refer readers to the FY 2017 IRF PPS final rule (81 FR 52125 through 52131).

2.   Proposal for Public Reporting of the COVID-19 Vaccination Coverage among Healthcare Personnel (HCP) Measure Beginning with the FY 2023 IRF QRP

We propose to publicly report the COVID-19 Vaccination Coverage among Healthcare Personnel (HCP) measure beginning with the September 2022 Care Compare refresh or as soon as technically feasible based on data collected for Q4 2021 (October 1, 2021 through December 31, 2021). If finalized as proposed, an IRF's HCP COVID-19 vaccination coverage rates would be displayed based on one quarter of data updated quarterly. Subsequent to this, one additional quarter of data would be added to the measure calculation during each advancing refresh, until the point four full quarters of data is reached. Thereafter, the measure would be reported using four rolling quarters of data.

We invite public comment on the proposal for the public display of the measure, COVID-19 Vaccination Coverage among HCP.

3.   Proposals for Public Reporting of Quality Measures in the IRF QRP with Fewer Quarters Due to COVID-19 Public Health Emergency (PHE) Exemptions

a.   COVID-19 Public Health Emergency Temporary Exemptions

Under the authority of section 319 of the Public Health Service Act, the Secretary of Health and Human Services declared a public health emergency (PHE) effective as of January 27, 2020. On March 13, 2020, subsequent to a presidential declaration of national emergency under the Stafford Act, the Secretary invoked section 1135(b) of the Act (42 U.S.C. 1320b-5) to waive or modify the requirements of titles XVIII, XIX, and XXI of the Act and regulations related to the PHE for COVID-19, effective as of March 1, 2020.[79] On March 27, 2020, we sent a guidance memorandum under the subject title, "Exceptions and Extensions for Quality Reporting Requirements for Acute Care Hospitals, PPS-Exempt Cancer Hospitals,

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[79] https://www.phe.gov/emergency/news/healthactions/section1135/Pages/covid19-13March20.aspx.

Inpatient Psychiatric Facilities, Skilled Nursing Facilities, Home Health Agencies, Hospices, Inpatient Rehabilitation Facilities, Long-Term Care Hospitals, Ambulatory Surgical Centers, Renal Dialysis Facilities, and MIPS Eligible Clinicians Affected by COVID-19" to the Medicare Learning Network (MLN) Connects Newsletter and Other Program-Specific Listserv Recipients,[80] hereafter referred to as the March 27, 2020 CMS Guidance Memo. In that memo we granted an exception to the IRF QRP reporting requirements from Q4 2019 (October 1, 2019–December 31, 2019), Q1 2020 (January 1, 2020–March 31, 2020), and Q2 2020 (April 1, 2020–June 30, 2020). We also stated that we would not publicly report any IRF QRP data that might be greatly impacted by the exceptions from Q1 and Q2 of 2020. This exception impacted the schedule for public reporting that would have included those two quarters of data.

IRF quality measures are publicly reported on Care Compare. Care Compare uses four quarters of data for IRF-PAI assessment-based measures and eight quarters for claims-based measures. Table 10 displays the original schedule for public reporting of IRF QRP measures.[81]

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[80] https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf.

[81] More information about the IRF QRP Public Reporting schedule can be found on the IRF QRP Public Reporting website at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Public-Reporting.

TABLE 10: IRF Quarters in Care Compare Original Schedule for Refreshes Affected by COVID-19 PHE Exemptions - Assessment and Claims Based Measures

Quarter Refresh	IRF Quarters in Original Schedule for Care Compare
Actual December 2020 (on Care Compare)	IRF-PAI: Q1 2019 – Q4 2019 (4 quarters)* Claims: Q4 2017 – Q3 2019 (8 quarters)
Original December 2020	IRF-PAI: Q2 2019 – Q1 2020 (4 quarters) Claims: Q4 2017 – Q3 2019 (8 quarters)
March 2021	IRF-PAI: Q3 2019 – Q2 2020 (4 quarters) Claims: Q4 2017 – Q3 2019 (8 quarters)
June 2021	IRF-PAI: Q4 2019 – Q3 2020 (4 quarters) Claims: Q4 2017 – Q3 2019 (8 quarters)
September 2021	IRF-PAI: Q1 2020 – Q4 2020 (4 quarters) Claims: Q4 2018 – Q3 2020 (8 quarters)
December 2021	IRF-PAI: Q2 2020 – Q1 2021 (4 quarters) Claims: Q4 2018 – Q3 2020 (8 quarters)
March 2022	IRF-PAI: Q3 2020 – Q2 2021 (4 quarters) Claims: Q4 2018 – Q3 2020 (8 quarters)
June 2022	IRF-PAI: Q4 2020 – Q3 2021 (4 quarters) Claims: Q4 2018 – Q3 2020 (8 quarters)
September 2022	IRF-PAI: Q1 2021 – Q4 2021 (4 quarters) Claims: Q4 2019 – Q3 2021 (8 quarters)
December 2022	IRF-PAI: Q2 2021 – Q1 2022 (4 quarters) Claims: Q4 2019 – Q3 2021 (8 quarters)
March 2023	IRF-PAI: Q3 2021 – Q2 2022 (4 quarters) Claims: Q4 2019 – Q3 2021 (8 quarters)
June 2023	IRF-PAI: Q4 2021 – Q3 2022 (4 quarters) Claims: Q4 2019 – Q3 2021 (8 quarters)

* The September 2020 refresh was postponed to December 2020 for technical reasons. The period of performance listed here reflects the data that was originally scheduled to be used to calculate provider performance for the December 2020 refresh.

During 2020, we conducted testing to inform decisions about publicly reporting data for those refreshes, which include partially and/or fully exempt data (discussed below). The testing helped us develop a plan for posting data that are as up-to-date as possible and that also meet acceptable standards for public reporting. We believe that the plan allows us to provide consumers with helpful information on the quality of IRF care, while also making the necessary adjustments to accommodate the exemption provided IRFs. The following sections provide the results of our testing, and explains how we used the results to develop plans for accommodating exempt and partially-exempt data in public reporting.

b. Exempted Quarters

In the March 27, 2020, Medicare Learning Network (MLN) Newsletter on Exceptions and Extensions for Quality Reporting Program (QRP) Requirements, we stated that we would not report any PAC quality data that might be greatly impacted by the exemptions granted for

Quarter 1 and Quarter 2 of 2020. Given the timing of the PHE onset, we determined that we would not use IRF-PAI assessments or IRF claims from Quarter 1 and Quarter 2 of 2020 for public reporting, but that we would assess the COVID-19 PHE impact on data from Quarter 4 2019. Before proceeding with the December 2020 refresh, we conducted testing to ensure that, despite the voluntary nature of reporting for that quarter, public reporting would still meet our public reporting standards. We found the level of reporting, measured in the number of eligible stays and providers, and the reported outcomes, to be in line with levels and trends observed in FY 2018 and FY 2019. We note that Quarter 4 2019 ended before the onset of the COVID-19 pandemic in the United States. Thus, we proceeded with including these data in IRF QRP measure calculations for the December 2020 refresh.

c.   Update on Data Freeze and Proposal for December 2021 Public Reporting Methodology for IRF Claims-based and IRF-PAI Assessment-based Measures

In addition to the March 2021 refresh, there are several other forthcoming refreshes for which the original public reporting schedules included exempted quarters of IRF QRP data. The impacted refreshes for IRF-PAI assessment and claims based measures are outlined above (Table 10). We determined that freezing the data displayed on the website with the December 2020 refresh values – that is, hold data constant after the December 2020 refresh data on the website without subsequent update – would be the most straightforward, efficient, and equitable approach for IRFs. Thus, we decided that, for as many refreshes as necessary, we would hold data constant on the website with the December 2020 data, and communicate this decision to the public.

Because December 2020 refresh data will become increasingly out-of-date and thus less useful for consumers, we analyzed whether it would be possible to use fewer quarters of data for one or more refreshes and thus reduce the number of refreshes that continue to display December 2020 data. Using fewer quarters of more up-to-date data requires that: (1) a sufficient percentage of IRFs would still likely have enough assessment data to report quality measures (reportability);

and (2) fewer quarters would likely produce similar measure scores for providers, with similar reliability, and thus not unfairly represent the quality of care IRFs provide during the period reported in a given refresh (reliability).

To assess these criteria, we conducted reportability and reliability analysis using 3 quarters of data in a refresh, instead of the standard 4 quarters of data for reporting assessment-based measures and using 6 quarters instead of 8 for claims-based measures. Specifically, we used historical data to calculate IRF-PAI assessment-based and IRF claims-based measures under two scenarios:

(1) Standard Public Reporting (SPR) Base Scenario: We used four quarters of CY 2019 data as a proxy alternative for the exempted quarters in CY 2020 in order to compare results. For assessment-based measures, the quarters used in this scenario are Q1 through Q4 2019. For claims-based measures, the quarters used in this scenario are Q1 2018 through Q4 2019.

(2) COVID-19 Affected Reporting (CAR) Scenario: We calculated IRF QRP measures using 3 quarters (Q2 2019 through Q4 2019) of IRF QRP data for assessment-based measures, and 6 quarters (Q1 2018 through Q4 2018 and Q3 2019 through Q4 2019) for claims-based measures. The CAR scenario uses the most recently available data to simulate the public health emergency reality where quarters 1 and 2 of a calendar year must be excluded from calculation. Quarterly trends in IRF-PAI assessment-based and IRF claims-based measures indicate that these measures do not exhibit substantial seasonal variation.

To assess performance in these scenarios, we calculated the reportability as the percent of IRFs meeting the case minimum for public reporting (the public reporting threshold). To test the reliability of restricting the IRFs included in the SPR Base Scenario to those included in the CAR Scenario, we performed three tests on the set of IRFs included in both scenarios. First, we evaluated measure correlation using the Pearson and Spearman correlation coefficients, which assess the alignment of IRFs' provider scores. Second, for each scenario, we conducted a split-half reliability analysis and estimated intraclass correlation (ICC) scores, where higher scores

imply better internal reliability. Modest differences in ICC scores between both scenarios would suggest that using fewer quarters of data does not impact the internal reliability of the results. Third, we estimated reliability scores where a higher value indicates that measure scores are relatively consistent for patients admitted to the same IRF and variation in the measure reflects true differences across providers. To calculate the reliability results, we restricted the IRFs included in the SPR scenario included in the CAR scenario.

Our testing indicated that the expected impact of using fewer quarters of data on reportability and reliability of IRF-PAI assessment-based measures and IRF claims-based measures is acceptable.

We are proposing to use the CAR scenario as the approach for the following affected refreshes: for IRF-PAI assessment-based measures, the affected refresh is the December 2021 refresh; for claims-based measures, the affected refreshes occur from December 2021 through June 2023. For the earlier three affected refreshes (March, June, and September 2021), we decided to hold constant the Care Compare website with December 2020 data. We communicated this decision in a Public Reporting Tip Sheet, which is located at https://www.cms.gov/files/document/irfqrp-covid19prtipsheet-october-2020.pdf .

Our proposal of the CAR approach for the affected refreshes would allow us to begin displaying more recent data in December 2021, rather than continue displaying December 2020 data (Q1 2019 through Q4 2019 for assessment-based measures, Q4 2017 through Q3 2019 for claims-based measures). We believe that resuming public reporting refreshes starting in December 2021 with fewer quarters of data can assist consumers by providing more recent quality data as well as more actionable data for IRF providers. Our testing results indicate we can achieve these positive impacts with acceptable changes in reportability and reliability. Table 11 summarizes the revised schedule (that is, frozen data) and the proposed schedule (that is, using fewer quarters in the affected refreshes) for assessment-based measures. Table 12 summarizes the revised schedule (that is, frozen data) and the proposed schedule (that is, using fewer quarters

in the affected refreshes) for claims-based measures.

We invite public comments on the proposal to use the CAR scenario to publicly report

IRF measures for the December 2021- June 2023 refreshes.

TABLE 11: Revised and Proposed Schedule for Refreshes Affected by COVID-19 PHE Exemptions for IRF-PAI Assessment--based QMs

Quarter Refresh	IRF-PAI Assessment Quarters in Revised/Proposed Schedule for Care Compare (number of quarters)
December 2020	Q1 2019 – Q4 2019 (4)
March 2021	Q1 2019 – Q4 2019 (4)
June 2021	Q1 2019 – Q4 2019 (4)
September 2021	Q1 2019 – Q4 2019 (4)
December 2021	Q3 2020 – Q1 2021 (3)
March 2022	Q3 2020 – Q2 2021 (4)* *Normal reporting resumes with 4 quarters of data.

Note: The shaded cells represent data held constant due to PHE related to COVID-19.

TABLE 12: Revised and Proposed Schedule for Refreshes Affected by COVID-19 PHE Exemptions for IRF Claims--based QMs

Quarter Refresh	Claims-based Quarters in Revised/Proposed Schedule for Care Compare (number of quarters)
December 2020	Q4 2017 – Q3 2019 (8)
March 2021	Q4 2017 – Q3 2019 (8)
June 2021	Q4 2017 – Q3 2019 (8)
September 2021	Q4 2017 – Q3 2019 (8)
December 2021	Q4 2018 – Q4 2019, Q3 2020 (6)
March 2022	Q4 2018 – Q4 2019, Q3 2020 (6)
June 2022	Q4 2018 – Q4 2019, Q3 2020 (6)
September 2022	Q4 2019, Q3 2020 – Q3 2021 (6)
December 2022	Q4 2019, Q3 2020 – Q3 2021 (6)
March 2023	Q4 2019, Q3 2020 – Q3 2021 (6)
June 2023	Q4 2019, Q3 2020 – Q3 2021 (6)
September 2023	Q4 2020 – Q3 2022 (8)* *Normal reporting resumes with 8 quarters of data.

Note: The shaded cells represent data held constant due to PHE related to COVID-19.

d. Update on Data Freeze and Proposal for December 2021 Public Reporting Methodology for

NHSN-based Measures

CDC recommends using the four most recent non-contiguous non-exempted quarters of

data for NHSN reporting in the IRF QRP. This non-contiguous compilation of quarterly reporting would continue until the time when four contiguous quarters of reporting resumes (based on CDC's review, this would occur in July 2022). Tables 13 and 14 display the original schedules for public reporting of IRF CDI NHSN and CAUTI NHSN measures and the HCP Influenza NHSN measure, respectively. Tables 15 and 16 summarize the revised schedule and the proposed schedules for IRF CDI and CAUTI NHSN measures and the HCP Influenza measure, respectively.

TABLE 13: IRF Quarters in Care Compare Original Schedule for Refreshes Affected by COVID-19 PHE Exemptions – CDI and CAUTI NHSN Measures

Quarter Refresh	CDI and CAUTI Quarters in Original Schedule for Care Compare (number of quarters)
Actual December 2020 (on Care Compare)	Q4 2018 – Q3 2019 (4)*
Original December 2020	Q1 2019 – Q4 2019 (4)
March 2021	Q2 2019 – Q1 2020 (4)
June 2021	Q3 2019 – Q2 2020 (4)
September 2021	Q4 2019 – Q3 2020 (4)
December 2021	Q1 2020 – Q4 2020 (4)
March 2022	Q2 2020 – Q1 2021 (4)
June 2022	Q3 2020 – Q2 2021 (4)

*The September 2020 refresh was postponed to December 2020 for technical reasons.

TABLE 14: IRF Quarters in Care Compare Original Schedule for Refreshes Affected by COVID-19 PHE Exemptions – HCP Influenza Measure

Quarter Refresh	HCP Influenza Quarters in Original Schedule for Care Compare (number of quarters)
Actual December 2020 (on Care Compare)	Q4 2017 – Q1 2018 (2)*
Original December 2020	Q4 2018 – Q1 2019 (2)
March 2021	Q4 2018 – Q1 2019 (2)
June 2021	Q4 2018 – Q1 2019 (2)
September 2021	Q4 2018 – Q1 2019 (2)
December 2021	Q4 2019 – Q1 2020 (2)
March 2022	Q4 2019 – Q1 2020 (2)
June 2022	Q4 2019 – Q1 2020 (2)
September 2022	Q4 2019 – Q1 2020 (2)
December 2022	Q4 2020 – Q1 2021 (2)

*The September 2020 refresh was postponed to December 2020 for technical reasons.

TABLE 15: Revised and Proposed Schedule for Refreshes Affected by COVID-19 PHE Exemptions for the CDI and CAUTI NHSN Measures

Quarter Refresh	CDI and CAUTI Quarters in Revised/Proposed Schedule for Care Compare (number of quarters)
December 2020	Q4 2018 – Q3 2019 (4)
March 2021	Q4 2018 – Q3 2019 (4)
June 2021	Q4 2018 – Q3 2019 (4)
September 2021	Q4 2018 – Q3 2019 (4)
December 2021	Q1 2019 – Q4 2019 (4)
March 2022	Q2 2019 – Q4 2019, Q3 2020 (4)
June 2022*	Q3 2020 – Q2 2021 * Normal reporting resumes with 4 contiguous quarters of data.

Note: The shaded cells represent data held constant due to PHE related to COVID-19.

TABLE 16: Revised and Proposed Schedule for Refreshes Affected by COVID-19 PHE Exemptions for the HCP Influenza NHSN Measure

Quarter Refresh	HCP Influenza Quarters in Revised/Proposed Schedule for Care Compare (number of quarters)
December 2020	Q4 2017 – Q1 2018 (2)
March 2021	Q4 2017 – Q1 2018 (2)
June 2021	Q4 2017 – Q1 2018 (2)
September 2021	Q4 2017 – Q1 2018 (2)
December 2021	Q4 2018 – Q1 2019 (2)
March 2022	Q4 2018 – Q1 2019 (2)
June 2022	Q4 2018 – Q1 2019 (2)
September 2022	Q4 2018 – Q1 2019 (2)
December 2022	Q4 2020 – Q1 2021 (2)* * Normal reporting resumes.

Note: The shaded cells represent data held constant due to PHE related to COVID-19.

VIII. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), 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 OMB for review and approval. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

● The need for the information collection and its usefulness in carrying out the proper functions of our agency;

● The accuracy of our estimate of the information collection burden;

● The quality, utility, and clarity of the information to be collected; and

● Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

This proposed rule does not impose any new information collection requirements as outlined in the regulation. However, this proposed rule does make reference to an associated information collection that is not discussed in the regulation text contained in this document. The following is a discussion of this information collection, which has already received OMB approval.

As stated in section VII.C. of this proposed rule, for purposes of calculating the IRF Annual Increase Factor (AIF), we propose that IRFs submit data on one new quality measure: COVID-19 Vaccination Coverage among Healthcare Personnel (HCP) beginning with the FY 2023 IRF QRP. The aforementioned measure will be collected via the following means.

A. COVID-19 Vaccination Coverage among Healthcare Personnel (HCP) Measure

The data source for this quality measure is the Centers for Disease Control and Prevention (CDC)/National Healthcare Safety Network (NHSN). Data collection by the NHSN occurs via a web-based tool hosted by the CDC. This reporting service is provided free of

charge to healthcare facilities, including IRFs. IRFs currently utilize the NHSN for purposes of

meeting other IRF QRP requirements.

We note that the CDC would account for the burden associated with the COVID-19

Vaccination Coverage among HCP measure collection under OMB control number 0920-1317

(expiration 1/31/2024). Currently, the CDC does not estimate burden for COVID-19 vaccination

reporting under the CDC PRA package currently approved under OMB control number 0920-

1317 because the agency has been granted a waiver under section 321 of the National Childhood

Vaccine Injury Act of 1986 (Pub. L. 99-660, enacted on November 14, 1986 (NCVIA).[82]

However, we refer readers to section X.C.7. of this proposed rule, where CMS has provided an

estimate of the burden and cost to IRFs, and the CDC will include it in a revised information

collection request for 0920-1317.

In section VII.C.2. of this proposed rule, we are proposing to update the Transfer of

Health (TOH) Information to the Patient – Post-Acute Care (PAC) measure to exclude residents

discharged home under the care of an organized home health service or hospice. This measure

was adopted in the FY 2020 IRF PPS final rule (84 FR 39099 through 39107) and burden

accounted for in OMB control number 0938-0842 (expiration December 31, 2022). The

proposed update would not affect the information collection burden already established.

If you comment on these information collection requirements, that is, reporting,

recordkeeping or third-party disclosure requirements, please submit your comments as specified

in the ADDRESSES section of this proposed rule.

Comments must be received on/by June 7, 2021.

IX.   **Response to Comments**

Because of the large number of public comments we normally receive on **Federal**

Register documents, we are not able to acknowledge or respond to them individually. We will

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[82] Section 321 of the NCVIA provides the PRA waiver for activities that come under the NCVIA, including those in the NCVIA at section 2102 of the Public Health Service Act (42 U.S.C. 300aa-2). Section 321 is not codified in the U.S. Code, but can be found in a note at 42 U.S.C. 300aa-1.

consider all comments we receive by the date and time specified in the "DATES" section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

X. Regulatory Impact Analysis

A. Statement of Need

This proposed rule would update the IRF prospective payment rates for FY 2022 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 proposed rule would also implement section 1886(j)(3)(C) of the Act, which requires the Secretary to apply a MFP adjustment to the market basket increase factor for FY 2012 and subsequent years.

Furthermore, this proposed rule would adopt policy changes under the statutory discretion afforded to the Secretary under section 1886(j) of the Act.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action that is likely to result in a rule: (1) having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health

or safety, or state, local or tribal governments or communities (also referred to as "economically significant"); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866.

Section (6)(a) of Executive Order 12866 provides that a regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimate the total impact of the policy updates described in this proposed rule by comparing the estimated payments in FY 2022 with those in FY 2021. This analysis results in an estimated $160 million increase for FY 2022 IRF PPS payments. Additionally, we estimate that costs associated with the proposal to update the reporting requirements under the IRF QRP result in an estimated $487,338.96 addition to costs in FY 2022 for IRFs. We estimate that this rulemaking is "economically significant" as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Also, the rule has been reviewed by OMB. 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%2019%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 1,109 IRFs, of which approximately 54 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 17, we estimate that the net revenue impact of this proposed rule on all IRFs is to increase estimated payments by approximately 1.8 percent. The rates and policies set forth in this proposed rule will not have a significant impact (not greater than 3 percent) on a substantial number of small entities. The estimated impact on small entities is shown in Table 17. 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 603 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 17, we estimate that the net revenue impact of this proposed rule on rural IRFs is to increase estimated payments by approximately 1.9 percent based on the data of the 133 rural units and 12 rural hospitals in our database of 1,109 IRFs for which data were available. We estimate an overall impact for rural IRFs in all areas between 0.4 percent and 3.4 percent. As a result, we anticipate this proposed rule would have a positive impact on a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-04, enacted on 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 2021, that threshold is approximately $158 million. This proposed 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 proposed rule would not have a substantial effect on state and local governments, preempt state law, or otherwise have a federalism implication.

2. Detailed Economic Analysis

This proposed rule would update the IRF PPS rates contained in the FY 2021 IRF PPS final rule (85 FR 48424). Specifically, this proposed rule would update the CMG relative weights and average length of stay values, the wage index, and the outlier threshold for high-cost cases. This proposed rule would apply a MFP adjustment to the FY 2022 IRF market basket increase factor in accordance with section 1886(j)(3)(C)(ii)(I) of the Act.

We estimate that the impact of the changes and updates described in this proposed rule would be a net estimated increase of $160 million in payments to IRF providers. The impact analysis in Table 17 of this proposed rule represents the projected effects of the updates to IRF PPS payments for FY 2022 compared with the estimated IRF PPS payments in FY 2021. 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 2022, we are proposing standard annual revisions described in this proposed rule (for example, the update to the wage index and market basket increase factor used to adjust the Federal rates). We are also implementing a productivity adjustment to the FY 2022 IRF market basket increase factor in accordance with section 1886(j)(3)(C)(ii)(I) of the Act. We estimate the total increase in payments to IRFs in FY 2022, relative to FY 2021, would be approximately $160 million.

This estimate is derived from the application of the FY 2022 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 $190 million. However, there is an estimated $30 million decrease in aggregate payments to IRFs due to the proposed update to the outlier threshold amount. Therefore, we estimate that these updates would result in a net increase in estimated payments of $160 million from FY 2021 to FY 2022.

The effects of the proposed updates that impact IRF PPS payment rates are shown in Table 17. The following proposed updates that affect the IRF PPS payment rates are discussed separately below:

- The effects of the proposed update to the outlier threshold amount, from approximately 3.3 percent to 3.0 percent of total estimated payments for FY 2022, consistent with section 1886(j)(4) of the Act.

- The effects of the proposed annual market basket update (using the 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)(i)(I) of the Act.

● The effects of applying the proposed budget-neutral labor-related share and wage index adjustment, as required under section 1886(j)(6) of the Act.

● The effects of the proposed budget-neutral changes to the CMG relative weights and average LOS values under the authority of section 1886(j)(2)(C)(i) of the Act.

● The total change in estimated payments based on the FY 2022 payment changes relative to the estimated FY 2021 payments.

3. Description of Table 17

Table 17 shows the overall impact on the 1,109 IRFs included in the analysis.

The next 12 rows of Table 17 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 964 IRFs located in urban areas included in our analysis. Among these, there are 662 IRF units of hospitals located in urban areas and 302 freestanding IRF hospitals located in urban areas. There are 145 IRFs located in rural areas included in our analysis. Among these, there are 133 IRF units of hospitals located in rural areas and 12 freestanding IRF hospitals located in rural areas. There are 404 for-profit IRFs. Among these, there are 370 IRFs in urban areas and 34 IRFs in rural areas. There are 597 non-profit IRFs. Among these, there are 507 urban IRFs and 90 rural IRFs. There are 108 government-owned IRFs. Among these, there are 87 urban IRFs and 21 rural IRFs.

The remaining four parts of Table 17 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 17. 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 2022 analysis file.

- Column (3) shows the number of cases in each category in our FY 2022 analysis file.

- Column (4) shows the estimated effect of the proposed adjustment to the outlier

threshold amount.

- Column (5) shows the estimated effect of the proposed update to the IRF labor-related

share and wage index, in a budget-neutral manner.

- Column (6) shows the estimated effect of the proposed update to the CMG relative

weights and average LOS values, in a budget-neutral manner.

- Column (7) compares our estimates of the payments per discharge, incorporating all of

the policies reflected in this proposed rule for FY 2022 to our estimates of payments per

discharge in FY 2021.

The average estimated increase for all IRFs is approximately 1.8 percent. This estimated

net increase includes the effects of the proposed IRF market basket increase factor for FY 2022

of 2.2 percent update based on a IRF-specific market basket estimate of 2.4 percent, less a

0.2 percentage point MFP adjustment, as required by section 1886(j)(3)(C)(ii)(I) of the Act. It

also includes the approximate 0.3 percent overall decrease in estimated IRF outlier payments

from the proposed 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 17: IRF Impact Table for FY 2022 (Columns 4 through 7 in percentage)

Facility Classification	Number of IRFs	Number of Cases	Outlier	FY 22 Wage Index and Labor Share	CMG Weights	Total Percent Change [1]
(1)	(2)	(3)	(4)	(5)	(6)	(7)
Total	1,109	381,299	-0.3	0.0	0.0	1.8
Urban unit	662	149,681	-0.5	0.1	-0.2	1.5
Rural unit	133	19,509	-0.6	0.3	-0.3	1.7
Urban hospital	302	207,250	-0.2	-0.1	0.2	2.1
Rural hospital	12	4,859	-0.1	0.5	0.2	2.7
Urban For-Profit	370	200,085	-0.2	0.0	0.2	2.2
Rural For-Profit	34	7,994	-0.2	0.3	0.0	2.3
Urban Non-Profit	507	137,112	-0.5	-0.1	-0.2	1.4
Rural Non-Profit	90	13,614	-0.6	0.4	-0.3	1.6
Urban Government	87	19,734	-0.6	0.5	-0.3	1.9
Rural Government	21	2,760	-0.3	0.3	-0.3	1.9
Urban	964	356,931	-0.3	0.0	0.0	1.8
Rural	145	24,368	-0.5	0.4	-0.2	1.9
Urban by region						
Urban New England	31	14,505	-0.2	-0.6	-0.2	1.1
Urban Middle Atlantic	124	43,245	-0.4	-0.9	0.0	0.9
Urban South Atlantic	154	74,081	-0.3	0.6	0.0	2.5
Urban East North Central	157	45,869	-0.4	0.1	-0.1	1.8
Urban East South Central	54	25,568	-0.2	-0.1	0.1	2.0
Urban West North Central	74	20,284	-0.4	0.8	-0.2	2.4
Urban West South Central	190	80,343	-0.2	-0.4	0.2	1.7
Urban Mountain	81	28,221	-0.3	-0.1	0.0	1.8
Urban Pacific	99	24,815	-0.7	0.6	-0.2	1.9
Rural by region						
Rural New England	5	1,264	-0.5	-0.2	-0.3	1.1
Rural Middle Atlantic	10	981	-0.8	1.1	-0.4	2.0
Rural South Atlantic	16	3,973	-0.2	1.2	0.2	3.4
Rural East North Central	23	3,902	-0.4	0.6	-0.2	2.2
Rural East South Central	21	3,832	-0.3	0.0	-0.3	1.6
Rural West North Central	20	2,837	-0.6	0.0	-0.4	1.2
Rural West South Central	42	6,740	-0.4	0.0	-0.2	1.6
Rural Mountain	5	481	-1.1	0.5	-0.5	1.1
Rural Pacific	3	358	-1.4	0.3	-0.6	0.4
Teaching status						
Non-teaching	1,004	337,797	-0.3	0.0	0.0	1.9
Resident to ADC less than 10%	57	28,282	-0.3	0.0	0.0	1.9
Resident to ADC 10%-19%	37	13,884	-0.7	-0.2	-0.2	1.1
Resident to ADC greater than 19%	11	1,336	-0.4	0.0	-0.4	1.5
Disproportionate share patient percentage (DSH PP)						
DSH PP = 0%	46	9,327	-0.4	-0.8	0.0	1.0
DSH PP <5%	144	55,019	-0.3	-0.1	0.1	1.9
DSH PP 5%-10%	285	116,111	-0.2	0.1	0.1	2.1
DSH PP 10%-20%	387	137,544	-0.4	-0.2	0.0	1.6
DSH PP greater than 20%	247	63,298	-0.5	0.3	-0.1	1.9

[1]This column includes the impact of the updates in columns (4), (5), and (6) above, and of the IRF market basket update for FY 2022 (2.4 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 Proposed Update to the Outlier Threshold Amount

The estimated effects of the proposed update to the outlier threshold adjustment are presented in column 4 of Table 17.

For this proposed rule, we are using preliminary FY 2020 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 3.3 percent in FY 2022. Thus, we propose to adjust the outlier threshold amount in this proposed rule to maintain total estimated outlier payments equal to 3 percent of total estimated payments in FY 2022. The estimated change in total IRF payments for FY 2022, therefore, includes an approximate 0.3 percentage point decrease in payments because the estimated outlier portion of total payments is estimated to decrease from approximately 3.3 percent to 3 percent.

The impact of this proposed outlier adjustment update (as shown in column 4 of Table 17) is to decrease estimated overall payments to IRFs by a 0.3 percentage point.

5. Impact of the Proposed Wage Index and Labor-Related Share

In column 5 of Table 17, we present the effects of the proposed budget-neutral update of the wage index and labor-related share. The proposed 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 proposed changes in the two have a combined effect on payments to providers. As discussed in section V.C. of this proposed rule, we are proposing to update the labor-related share from 73.0 percent in FY 2021 to 72.9 percent in FY 2022.

6. Impact of the Proposed Update to the CMG Relative Weights and Average LOS Values.

In column 7 of Table 17, we present the effects of the proposed budget-neutral update of the CMG relative weights and average LOS values. In the aggregate, we do not estimate that these proposed updates will affect overall estimated payments of IRFs. However, we do expect these updates to have small distributional effects.

7. Effects of Proposed Requirements for the IRF QRP for FY 2022

In accordance with section1886(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 VII.A of this proposed rule, we discuss the method for applying the 2 percentage point reduction to IRFs that fail to meet the IRF QRP requirements. As discussed in section VII.C. of this proposed rule, we are proposing to add one measure to the IRF QRP beginning with the FY 2023 IRF QRP: COVID-19 Vaccination Coverage among Healthcare Personnel (HCP) measure.

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. The proposed IRF QRP requirements add no additional burden to the active collection under OMB control number 0938-0842 (expiration 12/31/2022). Currently, the CDC does not estimate burden for COVID-19 vaccination reporting under the CDC PRA package currently approved under OMB control number 0920-1317 because the agency has been granted a waiver under section 321 of the NCVIA. However, CMS has provided an estimate of burden and cost for IRFs here, and the CDC will include it in a revised information collection request for 0920-1317. Consistent with the CDC's experience of collecting data using the NHSN, we estimate that it would take each IRF an average of 1 hour per month to collect data for the COVID-19 Vaccination Coverage among HCP measure and enter it into NHSN. We have estimated the time to complete this entire activity, since it could vary based on provider systems and staff availability. We believe it would take an administrative assistant from 45 minutes up to 1 hour and 15 minutes to enter this data into NHSN. For the purposes of calculating the costs associated with the collection of information requirements, we obtained mean hourly wages from the U.S. Bureau of Labor Statistics' May2019 National Occupational Employment and Wage Estimates.[83] To account for overhead and fringe benefits, we have doubled the hourly wage. These amounts are detailed in Table 18.

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[83] https://www.bls.gov/oes/current/oes_nat.htm. Accessed on March 30, 2021.

TABLE 18: U.S. Bureau of Labor and Statistics' May 2019 National Occupational Employment and Wage Estimates

Occupation title	Occupation code	Mean Hourly Wage ($/hr)	Overhead and Fringe Benefit ($/hr)	Adjusted Hourly Wage ($/hr)
Administrative Assistant	43-6013	$18.31	$18.31	$36.62

Based on the time range, it would cost each IRF between $27.47 and $45.78 each month or an average cost of $36.62 each month, and between $329.64 and $549.36 each year. We believe the data submission for the COVID-19 Vaccination Coverage among HCP measure would cause IRFs to incur additional average burden of 12 hours per year for each IRF and a total annual burden of 13,308 hours across all IRFs. The estimated annual cost across all 1,109 IRFs in the U.S. for the submission of the COVID-19 Vaccination Coverage among HCP measure would range from $365,570.76 and $609,240.24 with an average of $487,338.96.

We recognize that many IRFs may also be reporting other COVID-19 data to HHS. However, we believe the benefits of reporting data on the COVID-19 Vaccination Coverage among HCP measure to assess whether IRFs are taking steps to limit the spread of COVID-19 among their HCP, reduce the risk of transmission of COVID-19 within their facilities, and to help sustain the ability of IRFs to continue serving their communities throughout the PHE and beyond outweigh the costs of reporting. We welcome comments on the estimated time to collect data and enter it into NHSN.

D. Alternatives Considered

The following is a discussion of the alternatives considered for the IRF PPS updates contained in this proposed 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.

As noted previously in this proposed rule, 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 2022. Thus, in accordance with section 1886(j)(3)(C) of the Act, we propose to update the

IRF prospective payments in this proposed rule by 2.2 percent (which equals the 2.4 percent

estimated IRF market basket increase factor for FY 2022 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 utilizing FY 2019 claims data to update the prospective payment rates for

FY 2022 due to the potential effects of the PHE on the FY 2020 IRF claims data. However, it has

been our long-standing practice to utilize the most recent full fiscal year of data to update the

prospective payment rates, as this data is generally considered to be the best overall predictor of

experience in the upcoming fiscal year. Additionally, the FY 2019 data does not reflect any of

the changes to the CMG definitions or the data used to classify IRF patients into CMGs that

became effective in FY 2020 and will continue to be used in FY 2022. As such, we believe it

would be appropriate to utilize FY 2020 data to update the prospective payment rates for FY

2022 at this time. While we believe maintaining our existing methodology of utilizing the most

recent available IRF data to update the prospective payment rates for FY 2022 is appropriate, we

are soliciting comment on the use of FY 2019 data to update the prospective payment rates for

FY 2022.

Table 19 shows the estimated effects of the use of FY 2019 data on particular aspects of

the proposed FY 2022 IRF PPS compared to those utilizing FY 2020 data.

TABLE 19: Comparison of Proposed FY 2022 Impacts Using FY 2019 Claims and FY 2020 Claims

	FY 2022 Proposed FY 2019 Claims	FY 2022 Proposed FY 2020 Claims
Standard Payment Conversion Factor	17,273	17,273
Outlier Threshold	7,580	9,192
Wage Index Budget Neutrality Factor	1.0029	1.0027
CMG Relative Weights Budget Neutrality Factor	0.9998	1.0000
Market Basket Update	190 million	190 million
Outlier Threshold Adjustment Update	10 million	-30 million
Total Impacts	200 million	160 million

A comparison of the estimated impacts, using FY 2019 data, as shown in Table 20, or FY

2020 data, as shown in Table 17, indicates that overall IRF PPS payments and payments to all subgroups of IRF providers would increase if either data set is used. However, there will be distributional payment effects across providers due to the difference in estimated outlier payments under both scenarios. For more information on the estimated effects of utilizing FY 2019 to update the prospective payment rates for FY 2022, we refer readers to Table 20.

TABLE 20: Estimated Impacts for FY 2022 Utilizing FY 2019 Claims Data

Facility Classification	Number of IRFs	Number of Cases	Outlier	FY 22 Wage Index and Labor Share	CMG Weights	Total Percent Change[1]
(1)	(2)	(3)	(4)	(5)	(6)	(7)
Total	1,118	411,582	0.2	0.0	0.0	2.4
Urban unit	684	162,105	0.3	0.1	0.0	2.6
Rural unit	132	20,806	0.2	0.4	0.0	2.8
Urban hospital	291	223,606	0.1	-0.2	0.0	2.1
Rural hospital	11	5,065	0.0	0.2	0.0	2.4
Urban For-Profit	358	214,659	0.1	-0.1	0.0	2.2
Rural For-Profit	32	8,373	0.1	0.2	0.0	2.4
Urban Non-Profit	524	149,687	0.2	-0.1	0.0	2.4
Rural Non-Profit	90	14,332	0.3	0.4	0.0	2.9
Urban Government	93	21,365	0.3	0.5	0.0	3.0
Rural Government	21	3,166	0.1	0.3	0.0	2.6
Urban	975	385,711	0.1	0.0	0.0	2.3
Rural	143	25,871	0.2	0.3	0.0	2.7
Urban by region						
Urban New England	29	16,126	0.1	-0.6	0.0	1.7
Urban Middle Atlantic	132	48,915	0.2	-0.9	0.0	1.4
Urban South Atlantic	153	78,549	0.1	0.5	0.0	2.9
Urban East North Central	159	50,291	0.2	0.1	0.0	2.5
Urban East South Central	56	28,452	0.1	-0.1	0.0	2.2
Urban West North Central	73	21,183	0.2	0.9	0.0	3.3
Urban West South Central	188	85,415	0.1	-0.4	0.0	1.9
Urban Mountain	87	30,712	0.1	-0.1	0.0	2.3
Urban Pacific	98	26,068	0.3	0.6	0.0	3.2
Rural by region						
Rural New England	5	1,347	0.2	-0.2	0.0	2.1
Rural Middle Atlantic	11	1,189	0.4	0.9	0.0	3.6
Rural South Atlantic	16	3,799	0.1	0.9	0.0	3.2
Rural East North Central	23	4,077	0.2	0.7	0.0	3.1
Rural East South Central	21	4,466	0.1	0.1	0.0	2.3
Rural West North Central	20	3,053	0.3	0.0	0.0	2.5
Rural West South Central	39	7,013	0.2	0.1	0.0	2.5
Rural Mountain	5	564	0.5	0.5	0.0	3.2
Rural Pacific	3	363	0.7	0.3	0.0	3.1
Teaching status						
Non-teaching	1,010	363,470	0.1	0.0	0.0	2.4
Resident to ADC less than 10%	59	31,882	0.2	0.0	0.0	2.4
Resident to ADC 10%-19%	37	14,796	0.3	-0.3	0.0	2.3
Resident to ADC greater than 19%	12	1,434	0.2	0.1	0.0	2.5
Disproportionate share patient percentage (DSH PP)						
DSH PP = 0%	14	1,931	0.1	0.0	0.0	2.2
DSH PP <5%	147	58,245	0.1	-0.3	0.0	2.0
DSH PP 5%-10%	295	128,479	0.1	0.1	0.0	2.4
DSH PP 10%-20%	405	151,645	0.2	-0.2	0.0	2.2
DSH PP greater than 20%	257	71,282	0.2	0.3	0.0	2.8

[1]This column includes the impact of the updates in columns (4), (5), and (6) above, and of the IRF market basket update for FY 2022 (2.4 percent), reduced by 0.2 percentage point for the productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act.

We welcome comments from stakeholders regarding the use of FY 2019 claims data to update the prospective payment rates for FY 2022.

We considered maintaining the existing CMG relative weights and average length of stay values for FY 2022. 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, at this time we believe that it is appropriate to propose to update the CMG relative weights and average length of stay values using FY 2020 claims data to ensure that IRF PPS payments continue to reflect as accurately as possible the current costs of care in IRFs.

We also considered maintaining the existing outlier threshold amount for FY 2022. As outlier payments are a redistribution of payment, it is important to adjust the outlier threshold amount to maintain the targeted 3 percent outlier pool as closely as possible. Maintaining an outlier threshold that would yield estimated outlier payments greater than 3 percent would leave less payment available to cover the costs of non-outlier cases. Therefore, analysis of updated FY 2020 data indicates that estimated outlier payments would be greater than 3 percent of total estimated payments for FY 2022, by approximately 0.3 percent. Consequently, we propose adjusting the outlier threshold amount in this proposed rule to reflect a 0.3 percent decrease thereby setting the total outlier payments equal to 3 percent, instead of 3.3 percent, of aggregate estimated payments in FY 2022.

E. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed 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 2021 IRF PPS proposed rule will be the number of reviewers of this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this proposed rule. It is possible that not all commenters reviewed the FY 2021 IRF PPS proposed rule in detail, and it is also possible that some reviewers chose not to comment on the FY 2021 proposed rule. For

these reasons, we thought that the number of past commenters would be a fair estimate of the number of reviewers of this proposed rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule, and therefore, for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We sought comments on this assumption.

Using the national mean hourly wage data from the May 2019 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 $110.74 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 2 hours for the staff to review half of this proposed rule. For each IRF that reviews the rule, the estimated cost is $221.48 (2 hours x $110.74). Therefore, we estimate that the total cost of reviewing this regulation is $590,908.64 ($221.48 x 2,668 reviewers).

F. Accounting Statement and Table

As required by OMB Circular A-4 (available at https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf), in Table 21, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this proposed rule. Table 21 provides our best estimate of the increase in Medicare payments under the IRF PPS as a result of the proposed updates presented in this proposed rule based on the data for 1,109 IRFs in our database.

TABLE 21: Accounting Statement: Classification of Estimated Expenditure

	Category	Transfers
Change in Estimated Transfers from FY 2021 IRF PPS to FY 2022 IRF PPS	Annualized Monetized Transfers	$160 million
	From Whom to Whom?	Federal Government to IRF Medicare Providers
Change in Estimated Costs from FY2021 IRF QRP to FY 2022 IRF QRP	Annualized monetized cost in FY 2022 for IRFs due to new quality reporting program requirements	$487,338.96
Estimated Costs Associated with Review Cost for FY 2022 IRF PPS	Cost associated with regulatory review cost	$590,908.64

	Category	Transfers
	Total	$1,078,248

G. Conclusion

Overall, the estimated payments per discharge for IRFs in FY 2022 are projected to increase by 1.8 percent, compared with the estimated payments in FY 2021, as reflected in column 7 of Table 17.

IRF payments per discharge are estimated to increase by 1.8 percent in urban areas and 1.9 percent in rural areas, compared with estimated FY 2021 payments. Payments per discharge to rehabilitation units are estimated to increase 1.5 percent in urban areas and 1.7 percent in rural areas. Payments per discharge to freestanding rehabilitation hospitals are estimated to increase 2.1 percent in urban areas and increase 2.7 percent in rural areas.

Overall, IRFs are estimated to experience a net increase in payments as a result of the proposed policies in this proposed rule. The largest payment increase is estimated to be a 3.4 percent increase for rural IRFs located in the rural South Atlantic 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.

Dated: March 29, 2021.

_____

Elizabeth Richter,

Acting Administrator,
Centers for Medicare & Medicaid Services.

Dated: April 6, 2021.

Xavier Becerra,

<u>Secretary</u>,

<u>Department of Health and Human Services</u>.

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