

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 412

[CMS–1750–P]

RIN 0938–AU40

Medicare Program; FY 2022 Inpatient Psychiatric Facilities Prospective Payment System and Quality Reporting Updates for Fiscal Year Beginning October 1, 2021 (FY 2022)

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would update the prospective payment rates, the outlier threshold, and the wage index for Medicare inpatient hospital services provided by Inpatient Psychiatric Facilities (IPF), which include psychiatric hospitals and excluded psychiatric units of an Inpatient Prospective Payment System (IPPS) hospital or critical access hospital. This rule also proposes to update and clarify the IPF teaching policy with respect to IPF hospital closures and displaced residents and proposes a technical change to the 2016-based IPF market basket price proxies. In addition, this proposed rule would update quality measures and reporting requirements under the Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program. These changes would be effective for IPF discharges occurring during the Fiscal Year (FY) beginning October 1, 2021 through September 30, 2022 (FY 2022).

DATES: To be assured consideration, comments must be received at one of the addresses provided below by June 7, 2021.

ADDRESSES: In commenting, please refer to file code CMS–1750–P.

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

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

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1750–P, P.O. Box 8010, 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–1750–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: The IPF Payment Policy mailbox at IPFPaymentPolicy@cms.hhs.gov for general information.

Mollie Knight (410) 786–7948 or Eric Laib (410) 786–9759, for information regarding the market basket update or the labor related share.

Nick Brock (410) 786–5148 or Theresa Bean (410) 786–2287, for information regarding the regulatory impact analysis.

Lauren Lowenstein, (410) 786–4507, for information regarding the inpatient psychiatric facilities 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 website as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that website to view public comments.

Availability of Certain Tables Exclusively Through the Internet on the CMS Website

Addendum A to this proposed rule summarizes the FY 2022 IPF PPS payment rates, outlier threshold, cost of living adjustment factors (COLA) for Alaska and Hawaii, national and upper limit cost-to-charge ratios, and adjustment factors. In addition, the B Addenda to this proposed rule shows the complete listing of ICD–10 Clinical Modification (CM) and Procedure Coding System codes underlying the Code First table, the FY 2022 IPF PPS comorbidity adjustment, and electroconvulsive therapy (ECT) procedure codes. The A and B Addenda are available online at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html>.

Tables setting forth the FY 2022 Wage Index for Urban Areas Based on Core-Based Statistical Area (CBSA) Labor Market Areas and the FY 2022 Wage Index Based on CBSA Labor Market Areas for Rural Areas are available exclusively through the internet, on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/IPFPPS/WageIndex.html>.

I. Executive Summary

A. Purpose

This proposed rule would update the prospective payment rates, the outlier threshold, and the wage index for Medicare inpatient hospital services provided by Inpatient Psychiatric Facilities (IPFs) for discharges occurring during the FY 2022 beginning October 1, 2021 through September 30, 2022. This rule also proposes to update and clarify the IPF teaching policy with respect to IPF hospital closures and displaced residents and proposes a technical change to the 2016-based IPF market basket price proxies. In addition, the proposed rule would update quality measures and reporting requirements under the Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program.

B. Summary of the Major Provisions

1. Inpatient Psychiatric Facilities Prospective Payment System (IPF PPS)

For the IPF PPS, we are proposing to—

- Update IPF PPS teaching policy with respect to IPF hospital closures and displaced residents.
- Replace one of the price proxies currently used for the For-profit Interest cost category in the 2016-based IPF market basket with a similar price proxy.
- Adjust the 2016-based IPF market basket update (2.3 percent) for economy-wide productivity (0.2 percentage point) as required by section 1886(s)(2)(A)(i) of the Social Security Act (the Act), resulting in a proposed IPF payment rate update of 2.1 percent for FY 2022.

• *Make technical rate setting changes:* The IPF PPS payment rates would be adjusted annually for inflation, as well as statutory and other policy factors. This rule proposes to update:

++ The IPF PPS Federal per diem base rate from \$815.22 to \$833.50.

++ The IPF PPS Federal per diem base rate for providers who failed to report quality data to \$817.18.

++ The Electroconvulsive therapy (ECT) payment per treatment from \$350.97 to \$358.84.

- ++ The ECT payment per treatment for providers who failed to report quality data to \$351.81.
- ++ The labor-related share from 77.3 percent to 77.1 percent.
- ++ The wage index budget-neutrality factor to 1.0014.
- ++ The fixed dollar loss threshold amount from \$14,630 to \$14,030 to maintain estimated outlier payments at 2 percent of total estimated aggregate IPF PPS payments.

2. Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program

In this proposed rule, we are proposing to:

- Adopt voluntary patient-level data reporting for data submitted for FY 2023

- payment determination and mandatory patient-level data reporting for FY 2024 payment determination and subsequent years;
- Adopt the Coronavirus disease 2019 (COVID–19) Healthcare Personnel (HCP) Vaccination measure for the FY 2023 payment determination and subsequent years;
 - Adopt the Follow-up After Psychiatric Hospitalization (FAPH) measure for the FY 2024 payment determination and subsequent years; and
 - Remove the following four measures for FY 2024 payment determination and subsequent years:

- ++ Alcohol Use Brief Intervention Provided or Offered and Alcohol Use Brief Intervention Provided (SUB–2/2a) measure;
- ++ Tobacco Use Brief Intervention Provided or Offered and Tobacco Use Brief Intervention Provided (TOB–2/2a) measure;
- ++ Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) measure; and
- ++ Follow-up After Hospitalization for Mental Illness (FUH) measure.

C. Summary of Impacts

Provision description	Total transfers & cost reductions
FY 2022 IPF PPS payment update	The overall economic impact of this proposed rule is an estimated \$90 million in increased payments to IPFs during FY 2022.
FY2023 IPFQR Program update	The overall economic impact of the IPFQR Program provisions of this proposed rule is an estimated \$20,911,738 reduction in information collection burden.

II. Background

A. Overview of the Legislative Requirements of the IPF PPS

Section 124 of the Medicare, Medicaid, and State Children’s Health Insurance Program Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113) required the establishment and implementation of an IPF PPS. Specifically, section 124 of the BBRA mandated that the Secretary of the Department of Health and Human Services (the Secretary) develop a per diem Prospective Payment System (PPS) for inpatient hospital services furnished in psychiatric hospitals and excluded psychiatric units including an adequate patient classification system that reflects the differences in patient resource use and costs among psychiatric hospitals and excluded psychiatric units. “Excluded psychiatric unit” means a psychiatric unit in an inpatient prospective payment system (IPPS) hospital that is excluded from the IPPS, or a psychiatric unit in a Critical Access Hospital (CAH) that is excluded from the CAH payment system. These excluded psychiatric units would be paid under the IPF PPS.

Section 405(g)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) extended the IPF PPS to psychiatric distinct part units of CAHs.

Sections 3401(f) and 10322 of the Patient Protection and Affordable Care Act (Pub. L. 111–148) as amended by section 10319(e) of that Act and by section 1105(d) of the Health Care and

Education Reconciliation Act of 2010 (Pub. L. 111–152) (hereafter referred to jointly as “the Affordable Care Act”) added subsection (s) to section 1886 of the Act.

Section 1886(s)(1) of the Act titled “Reference to Establishment and Implementation of System,” refers to section 124 of the BBRA, which relates to the establishment of the IPF PPS.

Section 1886(s)(2)(A)(i) of the Act requires the application of the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act to the IPF PPS for the rate year (RY) beginning in 2012 (that is, a RY that coincides with a FY) and each subsequent RY. As noted in our FY 2020 IPF PPS final rule with comment period, published in the **Federal Register** on August 6, 2019 (84 FR 38424 through 38482), for the RY beginning in 2019, the productivity adjustment currently in place was equal to 0.4 percentage point.

Section 1886(s)(2)(A)(ii) of the Act required the application of an “other adjustment” that reduced any update to an IPF PPS base rate by a percentage point amount specified in section 1886(s)(3) of the Act for the RY beginning in 2010 through the RY beginning in 2019. As noted in the FY 2020 IPF PPS final rule, for the RY beginning in 2019, section 1886(s)(3)(E) of the Act required that the other adjustment reduction be equal to 0.75 percentage point; this was the final year the statute required the application of this adjustment. Because FY 2021, was a RY beginning in 2020, FY 2021 was

the first year section 1886(s)(2)(A)(ii) did not apply since its enactment.

Sections 1886(s)(4)(A) through (D) of the Act require that for RY 2014 and each subsequent RY, IPFs that fail to report required quality data with respect to such a RY will have their annual update to a standard Federal rate for discharges reduced by 2.0 percentage points. This may result in an annual update being less than 0.0 for a RY, and may result in payment rates for the upcoming RY being less than such payment rates for the preceding RY. Any reduction for failure to report required quality data will apply only to the RY involved, and the Secretary will not take into account such reduction in computing the payment amount for a subsequent RY. More information about the specifics of the current Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program is available in the FY 2020 IPF PPS and Quality Reporting Updates for Fiscal Year Beginning October 1, 2019 final rule (84 FR 38459 through 38468).

To implement and periodically update these provisions, we have published various proposed and final rules and notices in the **Federal Register**. For more information regarding these documents, see the Center for Medicare & Medicaid (CMS) website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/index.html?redirect=/InpatientPsychFacilPPS/>.

B. Overview of the IPF PPS

The November 2004 IPF PPS final rule (69 FR 66922) established the IPF PPS, as required by section 124 of the BBRA and codified at 42 CFR part 412, subpart N. The November 2004 IPF PPS final rule set forth the Federal per diem base rate for the implementation year (the 18-month period from January 1, 2005 through June 30, 2006), and provided payment for the inpatient operating and capital costs to IPFs for covered psychiatric services they furnish (that is, routine, ancillary, and capital costs, but not costs of approved educational activities, bad debts, and other services or items that are outside the scope of the IPF PPS). Covered psychiatric services include services for which benefits are provided under the fee-for-service Part A (Hospital Insurance Program) of the Medicare program.

The IPF PPS established the Federal per diem base rate for each patient day in an IPF derived from the national average daily routine operating, ancillary, and capital costs in IPFs in FY 2002. The average per diem cost was updated to the midpoint of the first year under the IPF PPS, standardized to account for the overall positive effects of the IPF PPS payment adjustments, and adjusted for budget-neutrality.

The Federal per diem payment under the IPF PPS is comprised of the Federal per diem base rate described previously and certain patient- and facility-level payment adjustments for characteristics that were found in the regression analysis to be associated with statistically significant per diem cost differences with statistical significance defined as p less than 0.05. A complete discussion of the regression analysis that established the IPF PPS adjustment factors can be found in the November 2004 IPF PPS final rule (69 FR 66933 through 66936).

The patient-level adjustments include age, Diagnosis-Related Group (DRG) assignment, and comorbidities; additionally, there are adjustments to reflect higher per diem costs at the beginning of a patient's IPF stay and lower costs for later days of the stay. Facility-level adjustments include adjustments for the IPF's wage index, rural location, teaching status, a cost-of-living adjustment for IPFs located in Alaska and Hawaii, and an adjustment for the presence of a qualifying emergency department (ED).

The IPF PPS provides additional payment policies for outlier cases, interrupted stays, and a per treatment payment for patients who undergo electroconvulsive therapy (ECT). During

the IPF PPS mandatory 3-year transition period, stop-loss payments were also provided; however, since the transition ended as of January 1, 2008, these payments are no longer available.

C. Annual Requirements for Updating the IPF PPS

Section 124 of the BBRA did not specify an annual rate update strategy for the IPF PPS and was broadly written to give the Secretary discretion in establishing an update methodology. Therefore, in the November 2004 IPF PPS final rule, we implemented the IPF PPS using the following update strategy:

- Calculate the final Federal per diem base rate to be budget-neutral for the 18-month period of January 1, 2005 through June 30, 2006.
- Use a July 1 through June 30 annual update cycle.
- Allow the IPF PPS first update to be effective for discharges on or after July 1, 2006 through June 30, 2007.

In November 2004, we implemented the IPF PPS in a final rule that published on November 15, 2004 in the **Federal Register** (69 FR 66922). In developing the IPF PPS, and to ensure that the IPF PPS is able to account adequately for each IPF's case-mix, we performed an extensive regression analysis of the relationship between the per diem costs and certain patient and facility characteristics to determine those characteristics associated with statistically significant cost differences on a per diem basis. That regression analysis is described in detail in our November 28, 2003 IPF proposed rule (68 FR 66923; 66928 through 66933) and our November 15, 2004 IPF final rule (69 FR 66933 through 66960). For characteristics with statistically significant cost differences, we used the regression coefficients of those variables to determine the size of the corresponding payment adjustments.

In the November 15, 2004 final rule, we explained the reasons for delaying an update to the adjustment factors, derived from the regression analysis, including waiting until we have IPF PPS data that yields as much information as possible regarding the patient-level characteristics of the population that each IPF serves. We indicated that we did not intend to update the regression analysis and the patient-level and facility-level adjustments until we complete that analysis. Until that analysis is complete, we stated our intention to publish a notice in the **Federal Register** each spring to update the IPF PPS (69 FR 66966).

On May 6, 2011, we published a final rule in the **Federal Register** titled, "Inpatient Psychiatric Facilities

Prospective Payment System—Update for Rate Year Beginning July 1, 2011 (RY 2012)" (76 FR 26432), which changed the payment rate update period to a RY that coincides with a FY update. Therefore, final rules are now published in the **Federal Register** in the summer to be effective on October 1. When proposing changes in IPF payment policy, a proposed rule would be issued in the spring, and the final rule in the summer to be effective on October 1. For a detailed list of updates to the IPF PPS, we refer readers to our regulations at 42 CFR 412.428.

The most recent IPF PPS annual update was published in a final rule on August 4, 2020 in the **Federal Register** titled, "Medicare Program; FY 2021 Inpatient Psychiatric Facilities Prospective Payment System and Special Requirements for Psychiatric Hospitals for Fiscal Year Beginning October 1, 2020 (FY 2021)" (85 FR 47042), which updated the IPF PPS payment rates for FY 2021. That final rule updated the IPF PPS Federal per diem base rates that were published in the FY 2020 IPF PPS Rate Update final rule (84 FR 38424) in accordance with our established policies.

III. Provisions of the FY 2022 IPF PPS Proposed Rule

A. Proposed Update to the FY 2021 Market Basket for the IPF PPS

1. Background

Originally, the input price index that was used to develop the IPF PPS was the "Excluded Hospital with Capital" market basket. This market basket was based on 1997 Medicare cost reports for Medicare participating inpatient rehabilitation facilities (IRFs), IPFs, long-term care hospitals (LTCHs), cancer hospitals, and children's hospitals. Although "market basket" technically describes the mix of goods and services used in providing health care at a given point in time, this term is also commonly used to denote the input price index (that is, cost category weights and price proxies) derived from that market basket. Accordingly, the term market basket as used in this document, refers to an input price index.

Since the IPF PPS inception, the market basket used to update IPF PPS payments has been rebased and revised to reflect more recent data on IPF cost structures. We last rebased and revised the IPF market basket in the FY 2020 IPF PPS rule, where we adopted a 2016-based IPF market basket, using Medicare cost report data for both Medicare participating freestanding psychiatric hospitals and psychiatric units. We refer

readers to the FY 2020 IPF PPS final rule for a detailed discussion of the 2016-based IPF PPS market basket and its development (84 FR 38426 through 38447). References to the historical market baskets used to update IPF PPS payments are listed in the FY 2016 IPF PPS final rule (80 FR 46656).

2. Proposed FY 2022 IPF Market Basket Update

For FY 2022 (beginning October 1, 2021 and ending September 30, 2022), we are proposing to use an estimate of the 2016-based IPF market basket increase factor to update the IPF PPS base payment rate. Consistent with historical practice, we are proposing to estimate the market basket update for the IPF PPS based on IHS Global Inc.'s (IGI) forecast (see section III.A.3 of this proposed rule for a discussion of a proposed technical update to one price proxy that is part of the 2016-based IPF market basket). IGI is a nationally recognized economic and financial forecasting firm that contracts with the CMS to forecast the components of the market baskets and multifactor productivity (MFP). For the proposed rule, based on IGI's fourth quarter 2020 forecast with historical data through the third quarter of 2020, the 2016-based IPF market basket increase factor for FY 2022 is 2.3 percent. Therefore, we are proposing that the 2016-based IPF market basket update for FY 2022 would be 2.3 percent.

Section 1886(s)(2)(A)(i) of the Act requires the application of the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act to the IPF PPS for the RY beginning in 2012 (a RY that coincides with a FY) and each subsequent RY. For this FY 2022 IPF PPS proposed rule, based on IGI's fourth quarter 2020 forecast, the proposed MFP adjustment for FY 2022 (the 10-year moving average of MFP for the period ending FY 2022) is projected to be 0.2 percent. We are proposing to reduce the proposed 2.3 percent IPF market basket update by this 0.2 percentage point productivity adjustment, as mandated by the Act. This results in a proposed estimated FY 2022 IPF PPS payment rate update of 2.1 percent ($2.3 - 0.2 = 2.1$). We are also proposing that if more recent data become available, we would use such data, if appropriate, to determine the FY 2022 IPF market basket update and MFP adjustment for the final rule. For more information on the productivity adjustment, we refer readers to the discussion in the FY 2016 IPF PPS final rule (80 FR 46675).

3. Proposed Update to IPF Market Basket Price Proxies

As discussed in section III.A.1. of this proposed rule, the IPF market basket is an input price index that consists of cost category weights and price proxies derived from the mix of goods and services used in providing health care. For FY 2022, for the For-profit Interest cost category of the 2016-based IPF 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 IGI, which is the nationally-recognized economic and financial forecasting firm with which we contract to forecast the components of the market baskets and MFP.

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 would not impact the historical top-line market basket increases when rounded to the nearest tenth of a percentage point over the past 10 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 IPF market basket.

4. Proposed FY 2022 IPF Labor-Related Share

Due to variations in geographic wage levels and other labor-related costs, we believe that payment rates under the IPF PPS should continue to be adjusted by a geographic wage index, which would apply to the labor-related portion of the Federal per diem base rate (hereafter referred to as the labor-related share).

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 IPF market basket, we are proposing to continue to include in the labor-related share the sum of the relative importance of Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair; All Other: Labor-related Services; and a portion of the Capital-Related cost weight (46 percent) from the 2016-based IPF market basket. The relative importance reflects the different rates of price change for these cost categories between the base year (FY 2016) and FY 2022. Using IGI's fourth quarter 2020 forecast for the 2016-based IPF market basket, the proposed IPF labor-related share for FY 2022 is the sum of the FY 2022 relative importance of each labor-related cost category. For more information on the labor-related share and its calculation, we refer readers to the FY 2020 IPF PPS final rule (84 FR 38445 through 38447). For FY 2022, the proposed labor-related share based on IGI's fourth quarter 2020 forecast of the 2016-based IPF PPS market basket is 77.1 percent. We are also proposing that if more recent data become available, we would use such data, if appropriate, to determine the FY 2022 labor-related share for the final rule.

B. Proposed Updates to the IPF PPS Rates for FY Beginning October 1, 2021

The IPF PPS is based on a standardized Federal per diem base rate calculated from the IPF average per diem costs and adjusted for budget-neutrality in the implementation year. The Federal per diem base rate is used as the standard payment per day under the IPF PPS and is adjusted by the patient-level and facility-level adjustments that are applicable to the IPF stay. A detailed explanation of how we calculated the average per diem cost appears in the November 2004 IPF PPS final rule (69 FR 66926).

1. Determining the Standardized Budget-Neutral Federal per Diem Base Rate

Section 124(a)(1) of the BBRA required that we implement the IPF PPS in a budget-neutral manner. In other words, the amount of total payments under the IPF PPS, including any payment adjustments, must be projected to be equal to the amount of total payments that would have been made if the IPF PPS were not implemented. Therefore, we calculated the budget-

neutrality factor by setting the total estimated IPF PPS payments to be equal to the total estimated payments that would have been made under the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) (Pub. L. 97–248) methodology had the IPF PPS not been implemented. A step-by-step description of the methodology used to estimate payments under the TEFRA payment system appears in the November 2004 IPF PPS final rule (69 FR 66926).

Under the IPF PPS methodology, we calculated the final Federal per diem base rate to be budget-neutral during the IPF PPS implementation period (that is, the 18-month period from January 1, 2005 through June 30, 2006) using a July 1 update cycle. We updated the average cost per day to the midpoint of the IPF PPS implementation period (October 1, 2005), and this amount was used in the payment model to establish the budget-neutrality adjustment.

Next, we standardized the IPF PPS Federal per diem base rate to account for the overall positive effects of the IPF PPS payment adjustment factors by dividing total estimated payments under the TEFRA payment system by estimated payments under the IPF PPS. In addition, information concerning this standardization can be found in the November 2004 IPF PPS final rule (69 FR 66932) and the RY 2006 IPF PPS final rule (71 FR 27045). We then reduced the standardized Federal per diem base rate to account for the outlier policy, the stop loss provision, and anticipated behavioral changes. A complete discussion of how we calculated each component of the budget-neutrality adjustment appears in the November 2004 IPF PPS final rule (69 FR 66932 through 66933) and in the RY 2007 IPF PPS final rule (71 FR 27044 through 27046). The final standardized budget-neutral Federal per diem base rate established for cost reporting periods beginning on or after January 1, 2005 was calculated to be \$575.95.

The Federal per diem base rate has been updated in accordance with applicable statutory requirements and § 412.428 through publication of annual notices or proposed and final rules. A detailed discussion on the standardized budget-neutral Federal per diem base rate and the electroconvulsive therapy (ECT) payment per treatment appears in the FY 2014 IPF PPS update notice (78 FR 46738 through 46740). These documents are available on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/index.html>.

IPFs must include a valid procedure code for ECT services provided to IPF beneficiaries in order to bill for ECT services, as described in our Medicare Claims Processing Manual, Chapter 3, Section 190.7.3 (available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf>.) There were no changes to the ECT procedure codes used on IPF claims as a result of the proposed update to the ICD–10–PCS code set for FY 2022. Addendum B to this proposed rule shows the ECT procedure codes for FY 2022 and is available on our website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html>.

2. Proposed Update of the Federal per Diem Base Rate and Electroconvulsive Therapy Payment per Treatment

The current (FY 2021) Federal per diem base rate is \$815.22 and the ECT payment per treatment is \$350.97. For the proposed FY 2022 Federal per diem base rate, we applied the payment rate update of 2.1 percent—that is, the 2016-based IPF market basket increase for FY 2022 of 2.3 percent less the productivity adjustment of 0.2 percentage point—and the wage index budget-neutrality factor of 1.0014 (as discussed in section III.D.1 of this proposed rule) to the FY 2021 Federal per diem base rate of \$815.22, yielding a proposed Federal per diem base rate of \$833.50 for FY 2022. Similarly, we applied the 2.1 percent payment rate update and the 1.0014 wage index budget-neutrality factor to the FY 2021 ECT payment per treatment of \$350.97, yielding a proposed ECT payment per treatment of \$358.84 for FY 2022.

Section 1886(s)(4)(A)(i) of the Act requires that for RY 2014 and each subsequent RY, in the case of an IPF that fails to report required quality data with respect to such RY, the Secretary will reduce any annual update to a standard Federal rate for discharges during the RY by 2.0 percentage points. Therefore, we are applying a 2.0 percentage point reduction to the Federal per diem base rate and the ECT payment per treatment as follows:

- For IPFs that fail requirements under the IPFQR Program, we applied a 0.1 percent payment rate update—that is, the IPF market basket increase for FY 2022 of 2.3 percent less the productivity adjustment of 0.2 percentage point for an update of 2.1 percent, and further reduced by 2 percentage points in accordance with section 1886(s)(4)(A)(i) of the Act—and the wage index budget-neutrality factor of 1.0014 to the FY 2021 Federal per diem base rate of

\$815.22, yielding a Federal per diem base rate of \$817.18 for FY 2022.

- For IPFs that fail to meet requirements under the IPFQR Program, we applied the 0.1 percent annual payment rate update and the 1.0014 wage index budget-neutrality factor to the FY 2021 ECT payment per treatment of \$350.97, yielding an ECT payment per treatment of \$351.81 for FY 2022.

C. Proposed Updates to the IPF PPS Patient-Level Adjustment Factors

1. Overview of the IPF PPS Adjustment Factors

The IPF PPS payment adjustments were derived from a regression analysis of 100 percent of the FY 2002 Medicare Provider and Analysis Review (MedPAR) data file, which contained 483,038 cases. For a more detailed description of the data file used for the regression analysis, see the November 2004 IPF PPS final rule (69 FR 66935 through 66936). We continue to use the existing regression-derived adjustment factors established in 2005 for FY 2022. However, we have used more recent claims data to simulate payments to finalize the outlier fixed dollar loss threshold amount and to assess the impact of the IPF PPS updates.

2. IPF PPS Patient-Level Adjustments

The IPF PPS includes payment adjustments for the following patient-level characteristics: Medicare Severity Diagnosis Related Groups (MS–DRGs) assignment of the patient's principal diagnosis, selected comorbidities, patient age, and the variable per diem adjustments.

a. Proposed Update to MS–DRG Assignment

We believe it is important to maintain for IPFs the same diagnostic coding and Diagnosis Related Group (DRG) classification used under the IPPS for providing psychiatric care. For this reason, when the IPF PPS was implemented for cost reporting periods beginning on or after January 1, 2005, we adopted the same diagnostic code set (ICD–9–CM) and DRG patient classification system (MS–DRGs) that were utilized at the time under the IPPS. In the RY 2009 IPF PPS notice (73 FR 25709), we discussed CMS' effort to better recognize resource use and the severity of illness among patients. CMS adopted the new MS–DRGs for the IPPS in the FY 2008 IPPS final rule with comment period (72 FR 47130). In the RY 2009 IPF PPS notice (73 FR 25716), we provided a crosswalk to reflect changes that were made under the IPF PPS to adopt the new MS–DRGs. For a

detailed description of the mapping changes from the original DRG adjustment categories to the current MS-DRG adjustment categories, we refer readers to the RY 2009 IPF PPS notice (73 FR 25714).

The IPF PPS includes payment adjustments for designated psychiatric DRGs assigned to the claim based on the patient's principal diagnosis. The DRG adjustment factors were expressed relative to the most frequently reported psychiatric DRG in FY 2002, that is, DRG 430 (psychoses). The coefficient values and adjustment factors were derived from the regression analysis discussed in detail in the November 28, 2003 IPF proposed rule (68 FR 66923; 66928 through 66933) and the November 15, 2004 IPF final rule (69 FR 66933 through 66960). Mapping the DRGs to the MS-DRGs resulted in the current 17 IPF MS-DRGs, instead of the original 15 DRGs, for which the IPF PPS provides an adjustment. For FY 2022, we are not proposing any changes to the IPF MS-DRG adjustment factors.

In the FY 2015 IPF PPS final rule published August 6, 2014 in the **Federal Register** titled, "Inpatient Psychiatric Facilities Prospective Payment System—Update for FY Beginning October 1, 2014 (FY 2015)" (79 FR 45945 through 45947), we finalized conversions of the ICD-9-CM-based MS-DRGs to ICD-10-CM/PCS-based MS-DRGs, which were implemented on October 1, 2015. Further information on the ICD-10-CM/PCS MS-DRG conversion project can be found on the CMS ICD-10-CM website at <https://www.cms.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html>.

For FY 2022, we are proposing to continue to make the existing payment adjustment for psychiatric diagnoses that group to one of the existing 17 IPF MS-DRGs listed in Addendum A. Addendum A is available on our website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html>. Psychiatric principal diagnoses that do not group to one of the 17 designated MS-DRGs would still receive the Federal per diem base rate and all other applicable adjustments, but the payment would not include an MS-DRG adjustment.

The diagnoses for each IPF MS-DRG would be updated as of October 1, 2021, using the final IPPS FY 2022 ICD-10-CM/PCS code sets. The FY 2022 IPPS proposed rule includes tables of the proposed changes to the ICD-10-CM/PCS code sets, which underlie the FY 2022 IPF MS-DRGs. Both the FY 2022 IPPS proposed rule and the tables of

proposed changes to the ICD-10-CM/PCS code sets, which underlie the FY 2022 MS-DRGs are available on the IPPS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html>.

Code First

As discussed in the ICD-10-CM Official Guidelines for Coding and Reporting, certain conditions have both an underlying etiology and multiple body system manifestations due to the underlying etiology. For such conditions, the ICD-10-CM has a coding convention that requires the underlying condition be sequenced first followed by the manifestation. Wherever such a combination exists, there is a "use additional code" note at the etiology code, and a "code first" note at the manifestation code. These instructional notes indicate the proper sequencing order of the codes (etiology followed by manifestation). In accordance with the ICD-10-CM Official Guidelines for Coding and Reporting, when a primary (psychiatric) diagnosis code has a "code first" note, the provider would follow the instructions in the ICD-10-CM text. The submitted claim goes through the CMS processing system, which will identify the primary diagnosis code as non-psychiatric and search the secondary codes for a psychiatric code to assign a DRG code for adjustment. The system will continue to search the secondary codes for those that are appropriate for comorbidity adjustment.

For more information on the code first policy, we refer our readers to the November 2004 IPF PPS final rule (69 FR 66945) and see sections I.A.13 and I.B.7 of the FY 2020 ICD-10-CM Coding Guidelines, available at https://www.cdc.gov/nchs/data/icd/10cmguidelines-FY2020_final.pdf. In the FY 2015 IPF PPS final rule, we provided a code first table for reference that highlights the same or similar manifestation codes where the code first instructions apply in ICD-10-CM that were present in ICD-9-CM (79 FR 46009). In FY 2018, FY 2019 and FY 2020, there were no changes to the final ICD-10-CM/PCS codes in the IPF Code First table. For FY 2021, there were 18 ICD-10-PCS codes deleted from the final IPF Code First table. For FY 2022 there are 18 codes proposed for deletion from the ICD-10-CM/PCS codes in the IPF Code First table. The proposed FY 2022 Code First table is shown in Addendum B on our website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html>.

b. Proposed Payment for Comorbid Conditions

The intent of the comorbidity adjustments is to recognize the increased costs associated with comorbid conditions by providing additional payments for certain existing medical or psychiatric conditions that are expensive to treat. In our RY 2012 IPF PPS final rule (76 FR 26451 through 26452), we explained that the IPF PPS includes 17 comorbidity categories and identified the new, revised, and deleted ICD-9-CM diagnosis codes that generate a comorbid condition payment adjustment under the IPF PPS for RY 2012 (76 FR 26451).

Comorbidities are specific patient conditions that are secondary to the patient's principal diagnosis and that require treatment during the stay. Diagnoses that relate to an earlier episode of care and have no bearing on the current hospital stay are excluded and must not be reported on IPF claims. Comorbid conditions must exist at the time of admission or develop subsequently, and affect the treatment received, length of stay (LOS), or both treatment and LOS.

For each claim, an IPF may receive only one comorbidity adjustment within a comorbidity category, but it may receive an adjustment for more than one comorbidity category. Current billing instructions for discharge claims, on or after October 1, 2015, require IPFs to enter the complete ICD-10-CM codes for up to 24 additional diagnoses if they co-exist at the time of admission, or develop subsequently and impact the treatment provided.

The comorbidity adjustments were determined based on the regression analysis using the diagnoses reported by IPFs in FY 2002. The principal diagnoses were used to establish the DRG adjustments and were not accounted for in establishing the comorbidity category adjustments, except where ICD-9-CM code first instructions applied. In a code first situation, the submitted claim goes through the CMS processing system, which will identify the principal diagnosis code as non-psychiatric and search the secondary codes for a psychiatric code to assign an MS-DRG code for adjustment. The system will continue to search the secondary codes for those that are appropriate for comorbidity adjustment.

As noted previously, it is our policy to maintain the same diagnostic coding set for IPFs that is used under the IPPS for providing the same psychiatric care. The 17 comorbidity categories formerly defined using ICD-9-CM codes were

converted to ICD-10-CM/PCS in our FY 2015 IPF PPS final rule (79 FR 45947 through 45955). The goal for converting the comorbidity categories is referred to as replication, meaning that the payment adjustment for a given patient encounter is the same after ICD-10-CM implementation as it would be if the same record had been coded in ICD-9-CM and submitted prior to ICD-10-CM/PCS implementation on October 1, 2015. All conversion efforts were made with the intent of achieving this goal. For FY 2022, we are proposing to continue to use the same comorbidity adjustment factors in effect in FY 2021, which are found in Addendum A, available on our website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html>.

We have updated the ICD-10-CM/PCS codes, which are associated with the existing IPF PPS comorbidity categories, based upon the proposed FY 2022 update to the ICD-10-CM/PCS code set. The proposed FY 2022 ICD-10-CM/PCS updates include: 8 ICD-10-CM diagnosis codes added to the Poisoning comorbidity category, 4 codes deleted, and 4 changes to Poisoning comorbidity long descriptions; 2 ICD-10-CM diagnosis codes added to the Developmental Disabilities comorbidity category and 1 code deleted; and 3 ICD-10-PCS codes added to the Oncology Procedures comorbidity category. In addition, we are proposing to delete 18 ICD-10-PCS codes from the Code First Table. These updates are detailed in Addenda B of this proposed rule, which are available on our website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html>.

In accordance with the policy established in the FY 2015 IPF PPS final rule (79 FR 45949 through 45952), we reviewed all new FY 2022 ICD-10-CM codes to remove codes that were site “unspecified” in terms of laterality from the FY 2022 ICD-10-CM/PCS codes in instances where more specific codes are available. As we stated in the FY 2015 IPF PPS final rule, we believe that specific diagnosis codes that narrowly identify anatomical sites where disease, injury, or a condition exists should be used when coding patients’ diagnoses whenever these codes are available. We finalized in the FY 2015 IPF PPS rule, that we would remove site “unspecified” codes from the IPF PPS ICD-10-CM/PCS codes in instances when laterality codes (site specified codes) are available, as the clinician should be able to identify a more specific diagnosis based on clinical assessment at the medical encounter.

None of the proposed additions to the FY 2022 ICD-10-CM/PCS codes were site “unspecified” by laterality, therefore, we are not removing any of the new codes.

c. Proposed Patient Age Adjustments

As explained in the November 2004 IPF PPS final rule (69 FR 66922), we analyzed the impact of age on per diem cost by examining the age variable (range of ages) for payment adjustments. In general, we found that the cost per day increases with age. The older age groups are costlier than the under 45 age group, the differences in per diem cost increase for each successive age group, and the differences are statistically significant. For FY 2022, we are proposing to continue to use the patient age adjustments currently in effect in FY 2021, as shown in Addendum A of this rule (see <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html>).

d. Proposed Variable per Diem Adjustments

We explained in the November 2004 IPF PPS final rule (69 FR 66946) that the regression analysis indicated that per diem cost declines as the LOS increases. The variable per diem adjustments to the Federal per diem base rate account for ancillary and administrative costs that occur disproportionately in the first days after admission to an IPF. As discussed in the November 2004 IPF PPS final rule, we used a regression analysis to estimate the average differences in per diem cost among stays of different lengths (69 FR 66947 through 66950). As a result of this analysis, we established variable per diem adjustments that begin on day 1 and decline gradually until day 21 of a patient’s stay. For day 22 and thereafter, the variable per diem adjustment remains the same each day for the remainder of the stay. However, the adjustment applied to day 1 depends upon whether the IPF has a qualifying ED. If an IPF has a qualifying ED, it receives a 1.31 adjustment factor for day 1 of each stay. If an IPF does not have a qualifying ED, it receives a 1.19 adjustment factor for day 1 of the stay. The ED adjustment is explained in more detail in section III.D.4 of this rule.

For FY 2022, we are proposing to continue to use the variable per diem adjustment factors currently in effect, as shown in Addendum A of this rule (available at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html>). A complete discussion of the variable per diem adjustments

appears in the November 2004 IPF PPS final rule (69 FR 66946).

D. Proposed Updates to the IPF PPS Facility-Level Adjustments

The IPF PPS includes facility-level adjustments for the wage index, IPFs located in rural areas, teaching IPFs, cost of living adjustments for IPFs located in Alaska and Hawaii, and IPFs with a qualifying ED.

1. Wage Index Adjustment

a. Background

As discussed in the RY 2007 IPF PPS final rule (71 FR 27061), RY 2009 IPF PPS (73 FR 25719) and the RY 2010 IPF PPS notices (74 FR 20373), in order to provide an adjustment for geographic wage levels, the labor-related portion of an IPF’s payment is adjusted using an appropriate wage index. Currently, an IPF’s geographic wage index value is determined based on the actual location of the IPF in an urban or rural area, as defined in § 412.64(b)(1)(ii)(A) and (C).

Due to the variation in costs and because of the differences in geographic wage levels, in the November 15, 2004 IPF PPS final rule, we required that payment rates under the IPF PPS be adjusted by a geographic wage index. We proposed and finalized a policy to use the unadjusted, pre-floor, pre-reclassified IPPS hospital wage index to account for geographic differences in IPF labor costs. We implemented use of the pre-floor, pre-reclassified IPPS hospital wage data to compute the IPF wage index since there was not an IPF-specific wage index available. We believe that IPFs generally compete in the same labor market as IPPS hospitals so the pre-floor, pre-reclassified IPPS hospital wage data should be reflective of labor costs of IPFs. We believe this pre-floor, pre-reclassified IPPS hospital wage index to be the best available data to use as proxy for an IPF specific wage index. As discussed in the RY 2007 IPF PPS final rule (71 FR 27061 through 27067), under the IPF PPS, the wage index is calculated using the IPPS wage index for the labor market area in which the IPF is located, without taking into account geographic reclassifications, floors, and other adjustments made to the wage index under the IPPS. For a complete description of these IPPS wage index adjustments, we refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41362 through 41390). Our wage index policy at § 412.424(a)(2), requires us to use the best Medicare data available to estimate costs per day, including an appropriate wage index to adjust for wage differences.

When the IPF PPS was implemented in the November 15, 2004 IPF PPS final rule, with an effective date of January 1, 2005, the pre-floor, pre-reclassified IPPS hospital wage index that was available at the time was the FY 2005 pre-floor, pre-reclassified IPPS hospital wage index. Historically, the IPF wage index for a given RY has used the pre-floor, pre-reclassified IPPS hospital wage index from the prior FY as its basis. This has been due in part to the pre-floor, pre-reclassified IPPS hospital wage index data that were available during the IPF rulemaking cycle, where an annual IPF notice or IPF final rule was usually published in early May. This publication timeframe was relatively early compared to other Medicare payment rules because the IPF PPS follows a RY, which was defined in the implementation of the IPF PPS as the 12-month period from July 1 to June 30 (69 FR 66927). Therefore, the best available data at the time the IPF PPS was implemented was the pre-floor, pre-reclassified IPPS hospital wage index from the prior FY (for example, the RY 2006 IPF wage index was based on the FY 2005 pre-floor, pre-reclassified IPPS hospital wage index).

In the RY 2012 IPF PPS final rule, we changed the reporting year timeframe for IPFs from a RY to the FY, which begins October 1 and ends September 30 (76 FR 26434 through 26435). In that FY 2012 IPF PPS final rule, we continued our established policy of using the pre-floor, pre-reclassified IPPS hospital wage index from the prior year (that is, from FY 2011) as the basis for the FY 2012 IPF wage index. This policy of basing a wage index on the prior year's pre-floor, pre-reclassified IPPS hospital wage index has been followed by other Medicare payment systems, such as hospice and inpatient rehabilitation facilities. By continuing with our established policy, we remained consistent with other Medicare payment systems.

In FY 2020 we finalized the IPF wage index methodology to align the IPF PPS wage index with the same wage data timeframe used by the IPPS for FY 2020 and subsequent years. Specifically, we finalized to use the pre-floor, pre-reclassified IPPS hospital wage index from the FY concurrent with the IPF FY as the basis for the IPF wage index. For example, the FY 2020 IPF wage index would be based on the FY 2020 pre-floor, pre-reclassified IPPS hospital wage index rather than on the FY 2019 pre-floor, pre-reclassified IPPS hospital wage index.

We explained in the FY 2020 proposed rule (84 FR 16973), that using the concurrent pre-floor, pre-reclassified

IPPS hospital wage index would result in the most up-to-date wage data being the basis for the IPF wage index. It would also result in more consistency and parity in the wage index methodology used by other Medicare payment systems. The Medicare SNF PPS already used the concurrent IPPS hospital wage index data as the basis for the SNF PPS wage index. Thus, the wage adjusted Medicare payments of various provider types would be based upon wage index data from the same timeframe. CMS proposed similar policies to use the concurrent pre-floor, pre-reclassified IPPS hospital wage index data in other Medicare payment systems, such as hospice and inpatient rehabilitation facilities. For FY 2022, we are proposing to continue to use the concurrent pre-floor, pre-reclassified IPPS hospital wage index as the basis for the IPF wage index.

We would apply the IPF wage index adjustment to the labor-related share of the national base rate and ECT payment per treatment. The labor-related share of the national rate and ECT payment per treatment would change from 77.3 percent in FY 2021 to 77.1 percent in FY 2022. This percentage reflects the labor-related share of the 2016-based IPF market basket for FY 2022 (see section III.A.4 of this rule).

b. Office of Management and Budget (OMB) Bulletins

i. Background

The wage index used for the IPF PPS is calculated using the unadjusted, pre-reclassified and pre-floor IPPS wage index data and is assigned to the IPF on the basis of the labor market area in which the IPF is geographically located. IPF labor market areas are delineated based on the Core-Based Statistical Area (CBSAs) established by the OMB.

Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. However, OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses through OMB Bulletins. These bulletins contain information regarding CBSA changes, including changes to CBSA numbers and titles. OMB bulletins may be accessed online at <https://www.whitehouse.gov/omb/information-for-agencies/bulletins/>. In accordance with our established methodology, the IPF PPS has historically adopted any CBSA changes that are published in the OMB bulletin that corresponds with the IPPS hospital wage index used to determine the IPF wage index.

In the RY 2007 IPF PPS final rule (71 FR 27061 through 27067), we adopted the changes discussed in the OMB Bulletin No. 03-04 (June 6, 2003), which announced revised definitions for MSAs, and the creation of Micropolitan Statistical Areas and Combined Statistical Areas. In adopting the OMB CBSA geographic designations in RY 2007, we did not provide a separate transition for the CBSA-based wage index since the IPF PPS was already in a transition period from TEFRA payments to PPS payments.

In the RY 2009 IPF PPS notice, we incorporated the CBSA nomenclature changes published in the most recent OMB bulletin that applied to the IPPS hospital wage index used to determine the current IPF wage index and stated that we expected to continue to do the same for all the OMB CBSA nomenclature changes in future IPF PPS rules and notices, as necessary (73 FR 25721).

On February 28, 2013, OMB issued OMB Bulletin No. 13-01 which established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas in the United States (U.S.) 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). These OMB Bulletin changes were reflected in the FY 2015 pre-floor, pre-reclassified IPPS hospital wage index, upon which the FY 2016 IPF wage index was based. We adopted these new OMB CBSA delineations in the FY 2016 IPF wage index and subsequent IPF wage indexes. We refer readers to the FY 2016 IPF PPS final rule (80 FR 46682 through 46689) for a full discussion of our implementation of the OMB labor market area delineations beginning with the FY 2016 wage index.

On July 15, 2015, OMB issued OMB Bulletin No. 15-01, which provided updates to and superseded OMB Bulletin No. 13-01 that was issued on February 28, 2013. The attachment to OMB Bulletin No. 15-01 provided detailed information on the update to statistical areas since February 28, 2013. The updates provided in OMB Bulletin No. 15-01 were based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2012 and July 1, 2013. The complete list of statistical areas incorporating these changes is provided in OMB Bulletin No. 15-01. A copy of this bulletin may be obtained at <https://>

www.whitehouse.gov/omb/information-for-agencies/bulletins/.

OMB Bulletin No. 15–01 established revised delineations for the Nation’s Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas. The bulletin also provided delineations of Metropolitan Divisions as well as delineations of New England City and Town Areas. As discussed in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56913), the updated labor market area definitions from OMB Bulletin 15–01 were implemented under the IPPS beginning on October 1, 2016 (FY 2017). Therefore, we implemented these revisions for the IPF PPS beginning October 1, 2017 (FY 2018), consistent with our historical practice of modeling IPF PPS adoption of the labor market area delineations after IPPS adoption of these delineations (historically the IPF wage index has been based upon the pre-floor, pre-reclassified IPPS hospital wage index from the prior year).

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 IPF PPS final rule (84 FR 38453 through 38454), we adopted the updates set forth in OMB Bulletin No. 17–01 effective October 1, 2019, beginning with the FY 2020 IPF wage index. Given that the loss of the rural adjustment was mitigated in part by the increase in wage index value, and that only a single IPF was affected by this change, we did not believe it was necessary to transition this provider from its rural to newly urban status. We refer readers to the FY 2020 IPF PPS final rule (84 FR 38453 through 38454) for a more detailed discussion about the decision to forego a transition plan in FY 2020.

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 OMB Bulletin No. 18–04 may be

obtained at <https://www.whitehouse.gov/wp-content/uploads/2018/09/Bulletin-18-04.pdf>.

In the FY 2021 IPF PPS final rule (85 FR 47051 through 47059), we adopted the updates set forth in OMB Bulletin No. 18–04 effective October 1, 2020, beginning with the FY 2021 IPF wage index. These updates included material changes to the OMB statistical area delineations which included 34 urban counties that became rural, 47 rural counties that became urban, and 19 counties that moved to a new or modified CBSA.

Given the scope of changes involved in adopting the CBSA delineations for FY 2021, we finalized a 2-year transition policy consistent with our past practice of using transition policies to help mitigate negative impacts on hospitals of certain wage index policy changes. We applied a 5-percent cap on wage index decreases to all IPF providers that had any decrease in their wage indexes, regardless of the circumstance causing the decline, so that an IPF’s final wage index for FY 2021 would not be less than 95 percent of its final wage index for FY 2020, regardless of whether the IPF was part of an updated CBSA. We refer readers to the FY 2021 IPF PPS final rule (85 FR 47058 through 47059) for a more detailed discussion about the wage index transition policy for FY 2021.

On March 6, 2020 OMB issued OMB Bulletin 20–01 (available on the web at <https://www.whitehouse.gov/wp-content/uploads/2020/03/Bulletin-20-01.pdf>). In considering whether to adopt this bulletin, we analyzed whether the changes in this bulletin would have a material impact on the IPF PPS wage index. This bulletin creates only one Micropolitan statistical area. As discussed in further detail in section III.D.1.b.ii, since Micropolitan areas are considered rural for the IPF PPS wage index, this bulletin has no material impact on the IPF PPS wage index. That is, the constituent county of the new Micropolitan area was considered rural effective as of FY 2021 and would continue to be considered rural if we adopted OMB Bulletin 20–01. Therefore, we are not proposing to adopt OMB Bulletin 20–01.

ii. Micropolitan Statistical Areas

OMB defines a “Micropolitan Statistical Area” as a CBSA associated with at least one urban cluster that has a population of at least 10,000, but less than 50,000 (75 FR 37252). We refer to these as Micropolitan Areas. After extensive impact analysis, consistent with the treatment of these areas under the IPPS as discussed in the FY 2005

IPPS final rule (69 FR 49029 through 49032), we determined the best course of action would be to treat Micropolitan Areas as “rural” and include them in the calculation of each state’s IPF PPS rural wage index. We refer the reader to the FY 2007 IPF PPS final rule (71 FR 27064 through 27065) for a complete discussion regarding treating Micropolitan Areas as rural.

c. Proposed Adjustment for Rural Location

In the November 2004 IPF PPS final rule, (69 FR 66954) we provided a 17 percent payment adjustment for IPFs located in a rural area. This adjustment was based on the regression analysis, which indicated that the per diem cost of rural facilities was 17 percent higher than that of urban facilities after accounting for the influence of the other variables included in the regression. This 17 percent adjustment has been part of the IPF PPS each year since the inception of the IPF PPS. For FY 2022, we are proposing to continue to apply a 17 percent payment adjustment for IPFs located in a rural area as defined at § 412.64(b)(1)(ii)(C) (see 69 FR 66954 for a complete discussion of the adjustment for rural locations).

d. Proposed Budget Neutrality Adjustment

Changes to the wage index are made in a budget-neutral manner so that updates do not increase expenditures. Therefore, for FY 2022, we are proposing to continue to apply a budget-neutrality adjustment in accordance with our existing budget-neutrality policy. This policy requires us to update the wage index in such a way that total estimated payments to IPFs 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 IPF PPS rates. We use the following steps to ensure that the rates reflect the FY 2022 update to the wage indexes (based on the FY 2018 hospital cost report data) and the labor-related share in a budget-neutral manner:

Step 1: Simulate estimated IPF PPS payments, using the FY 2021 IPF wage index values (available on the CMS website) and labor-related share (as published in the FY 2021 IPF PPS final rule (85 FR 47043)).

Step 2: Simulate estimated IPF PPS payments using the proposed FY 2022 IPF wage index values (available on the CMS website) and proposed FY 2022 labor-related share (based on the latest available data as discussed previously).

Step 3: Divide the amount calculated in step 1 by the amount calculated in step 2. The resulting quotient is the FY

2022 budget-neutral wage adjustment factor of 1.0014.

Step 4: Apply the FY 2022 budget-neutral wage adjustment factor from step 3 to the FY 2021 IPF PPS Federal per diem base rate after the application of the market basket update described in section III.A of this rule, to determine the FY 2022 IPF PPS Federal per diem base rate.

2. Proposed Teaching Adjustment

a. Background

In the November 2004 IPF PPS final rule, we implemented regulations at § 412.424(d)(1)(iii) to establish a facility-level adjustment for IPFs that are, or are part of, teaching hospitals. The teaching adjustment accounts for the higher indirect operating costs experienced by hospitals that participate in graduate medical education (GME) programs. The payment adjustments are made based on the ratio of the number of full-time equivalent (FTE) interns and residents training in the IPF and the IPF's average daily census (ADC).

Medicare makes direct GME payments (for direct costs such as resident and teaching physician salaries, and other direct teaching costs) to all teaching hospitals including those paid under a PPS, and those paid under the TEFRA rate-of-increase limits. These direct GME payments are made separately from payments for hospital operating costs and are not part of the IPF PPS. The direct GME payments do not address the estimated higher indirect operating costs teaching hospitals may face.

The results of the regression analysis of FY 2002 IPF data established the basis for the payment adjustments included in the November 2004 IPF PPS final rule. The results showed that the indirect teaching cost variable is significant in explaining the higher costs of IPFs that have teaching programs. We calculated the teaching adjustment based on the IPF's "teaching variable," which is $(1 + (\text{the number of FTE residents training in the IPF/the IPF's ADC}))$. The teaching variable is then raised to 0.5150 power to result in the teaching adjustment. This formula is subject to the limitations on the number of FTE residents, which are described in this section of this rule.

We established the teaching adjustment in a manner that limited the incentives for IPFs to add FTE residents for the purpose of increasing their teaching adjustment. We imposed a cap on the number of FTE residents that may be counted for purposes of calculating the teaching adjustment. The cap limits the number of FTE residents

that teaching IPFs may count for the purpose of calculating the IPF PPS teaching adjustment, not the number of residents teaching institutions can hire or train. We calculated the number of FTE residents that trained in the IPF during a "base year" and used that FTE resident number as the cap. An IPF's FTE resident cap is ultimately determined based on the final settlement of the IPF's most recent cost report filed before November 15, 2004 (publication date of the IPF PPS final rule). A complete discussion of the temporary adjustment to the FTE cap to reflect residents due to hospital closure or residency program closure appears in the RY 2012 IPF PPS proposed rule (76 FR 5018 through 5020) and the RY 2012 IPF PPS final rule (76 FR 26453 through 26456). In section III.D.2.b of this proposed rule, we discuss proposed updates to the IPF policy on temporary adjustment to the FTE cap.

In the regression analysis, the logarithm of the teaching variable had a coefficient value of 0.5150. We converted this cost effect to a teaching payment adjustment by treating the regression coefficient as an exponent and raising the teaching variable to a power equal to the coefficient value. We note that the coefficient value of 0.5150 was based on the regression analysis holding all other components of the payment system constant. A complete discussion of how the teaching adjustment was calculated appears in the November 2004 IPF PPS final rule (69 FR 66954 through 66957) and the RY 2009 IPF PPS notice (73 FR 25721). As with other adjustment factors derived through the regression analysis, we do not plan to rerun the teaching adjustment factors in the regression analysis until we more fully analyze IPF PPS data. Therefore, in this FY 2022 proposed rule, we are proposing to continue to retain the coefficient value of 0.5150 for the teaching adjustment to the Federal per diem base rate.

b. Proposed Update to IPF Teaching Policy on IPF Program Closures and Displaced Residents

For FY 2022, we are proposing to change the IPF policy regarding displaced residents from IPF closures and closures of IPF teaching programs. Specifically, we are proposing to adopt conforming changes to the IPF PPS teaching policy to align with the policy changes that the IPPS finalized in the FY 2021 IPPS final rule (85 FR 58865 through 58870). We believe that the IPF IME policy relating to hospital closure and displaced students is susceptible to the same vulnerabilities as IPPS GME policy. Hence, if an IPF with a large

number of residents training in its residency program announces it is closing, these residents will become displaced and will need to find alternative positions at other IPF hospitals or risk being unable to become Board certified. Although we propose to adopt a policy under the IPF PPS that is consistent with an applicable policy under the IPPS, the actual caps under the two payment systems may not be commingled. In other words, the resident cap applicable under the IPPS is separate from the resident cap applicable under the IPF PPS; moreover, a provider cannot add its IPF resident cap to its IPPS resident cap in order to increase the number of residents it receives payment for under either payment system.

Section 124 of the BBRA gives the Secretary broad discretion to determine the appropriate adjustment factors for the IPF PPS. We are proposing to implement the policy discussed in this section to remain consistent with the way that the IPPS teaching policy calculates FTE resident caps in the case of a receiving hospital that obtains a temporary IME and direct GME cap adjustment for assuming the training of displaced residents due to another hospital or residency program's closure. We are also proposing that in the future, we would deviate from IPPS teaching policy as it pertains to counting displaced residents for the purposes of the IPF teaching adjustment only when it is necessary and appropriate for the IPF PPS.

As stated in the November 2004 IPF PPS final rule (69 FR 66922), we implemented regulations at § 412.424(d)(1)(iii) to establish a facility-level adjustment for IPFs that are, or are part of, teaching hospitals. The facility-level adjustment we are providing for teaching hospitals under IPF PPS parallels the IME payments paid under the IPPS. Both payments are add on adjustments to the amount per case and both are based in part on the number of full-time equivalent (FTE) residents training at the facility.

The regulation at 42 CFR 412.424(d)(1)(iii)(F) permits an IPF to temporarily adjust its FTE cap to reflect residents added because of another hospital or program's closure. We first implemented regulations regarding residents displaced by teaching hospital and program closures in the May 6, 2011 IPF PPS final rule (76 FR 26431). In that final rule, we adopted the IPPS definition of "closure of a hospital" at 42 CFR 413.79(h)(1)(i) to apply to IPF closures as well, and to mean that the IPF terminates its Medicare provider agreement as specified in 42 CFR

489.52. In this proposed rule, we are proposing to codify this definition, as well as the definition of an IPF program closure, at § 412.402.

Although not explicitly stated in regulations text, our current policy is that a displaced resident is one that is physically present at the hospital training on the day prior to or the day of hospital or program closure. This longstanding policy derived from the fact that in the regulations text, there are requirements that the receiving hospital identifies the residents' "who have come from the closed IPF" (§ 412.424(d)(1)(iii)(F)(1)(ii)) or "identifies the residents "who have come from another IPF's closed program" (§ 412.424(d)(1)(iii)(F)(2)(i)), and that the IPF that closed its program identifies "the residents who were in training at the time of the program's closure" (§ 412.424(d)(1)(iii)(F)(2)(ii)). We considered the residents who were physically present at the IPF to be those residents who were "training at the time of the program's closure," thereby granting them the status of "displaced residents." Although we did not want to limit the "displaced residents" to only those physically present at the time of closure, it becomes much more administratively challenging for the following groups of residents at closing IPFs/programs to continue their training: (1) Residents who leave the program after the closure is publicly announced to continue training at another IPF, but before the actual closure; (2) residents assigned to and training at planned rotations at other IPFs who will be unable to return to their rotations at the closing IPF or program; and (3) individuals (such as medical students or would-be fellows) who matched into resident programs at the closing IPF or program but have not yet started training at the closing IPF or program. Other groups of residents who, under current policy, are already considered "displaced residents" include—(1) residents who are physically training in the IPF on the day prior to or day of program or IPF closure; and (2) residents who would have been at the closing IPF or IPF program on the day prior to or of closure but were on approved leave at that time, and are unable to return to their training at the closing IPF or IPF program.

We are proposing to amend the IPF policy with regard to closing teaching IPFs and closing residency programs to address the needs of residents attempting to find alternative IPFs in which to complete their training. Additionally, this proposal addresses the incentives of originating and receiving IPFs with regard to ensuring

we appropriately account for their indirect teaching costs by way of an appropriate IPF teaching adjustment based on each program's resident FTEs. We are proposing to change two aspects of the current IPF policy, which are discussed in the following section.

First, rather than link the status of displaced residents for the purpose of the receiving IPF's request to increase their FTE cap to the resident's presence at the closing IPF or program on the day prior to or the day of program or IPF closure, we propose that the ideal day would be the day that the closure was publicly announced, (for example, via a press release or a formal notice to the Accreditation Council on Graduate Medical Education (ACGME)). This would provide greater flexibility for the residents to transfer while the IPF operations or residency programs were winding down, rather than waiting until the last day of IPF or program operation. This would address the needs of the first group of residents as previously described: Residents who would leave the IPF program after the closure was publicly announced to continue training at another IPF, but before the day of actual closure.

Second, by removing the link between the status of displaced residents and their presence at the closing IPF or program on the day prior to or the day of program or IPF closure, we propose to also allow the second and third group of residents who are not physically at the closing IPF/closing program, but had intended to train at (or return to training at, in the case of residents on rotation) to be considered a displaced resident. Thus, we are proposing to revise our teaching policy with regard to which residents can be considered "displaced" for the purpose of the receiving IPF's request to increase their FTE cap in the situation where an IPF announces publicly that it is closing, and/or that it is closing an IPF residency program(s). Specifically, we are proposing to adopt the definitions of "closure of a hospital", "closure of a hospital residency training program", and "displaced resident" as defined at 42 CFR 413.79(h) but with respect to IPFs and for the purposes of accounting for indirect teaching costs.

In addition, we are proposing to change another detail of the IPF teaching policy specific to the requirements for the receiving IPF. To apply for the temporary increase in the FTE resident cap, the receiving IPF would have to submit a letter to its Medicare Administrative Contractor (MAC) within 60 days of beginning the training of the displaced residents. As established under existing regulation at

§ 412.424(d)(1)(iii)(F)(1)(ii) and § 412.424(d)(1)(iii)(F)(2)(i), this letter must identify the residents who have come from the closed IPF or program and have caused the receiving IPF to exceed its cap, and must specify the length of time the adjustment is needed. Moreover, we want to propose clarifications on how the information would be delivered in this letter. Consistent with IPPS teaching policy, we are proposing that the letter from the receiving IPF would have to include: (1) The name of each displaced resident; (2) the last four digits of each displaced resident's social security number; (3) the IPF and program in which each resident was training previously; and (4) the amount of the cap increase needed for each resident (based on how much the receiving IPF is in excess of its cap and the length of time for which the adjustments are needed). We are proposing to require the receiving hospital to only supply the last four digits of each displaced resident's social security number to reduce the amount of personally identifiable information (PII) included in these agreements.

We are also clarifying that, as we previously discussed in the May 6, 2011 IPF PPS final rule (76 FR 26455), the maximum number of FTE resident cap slots that could be transferred to all receiving IPFs is the number of FTE resident cap slots belonging to the IPF that has the closed program or that is closing. Therefore, if the originating IPF is training residents in excess of its cap, then being a displaced resident does not guarantee that a cap slot will be transferred along with that resident. Therefore, we are proposing that if there are more IPF displaced residents than available cap slots, the slots may be apportioned according to the closing IPF's discretion. The decision to transfer a cap slot if one is available would be voluntary and made at the sole discretion of the originating IPF. However, if the originating IPF decides to do so, then it would be the originating IPF's responsibility to determine how much of an available cap slot would go with a particular resident (if any). We also note that, as we previously discussed in the May 6, 2011 IPF PPS final rule (76 FR 25455), only to the extent a receiving IPF would exceed its FTE cap by training displaced residents would it be eligible for a temporary adjustment to its resident FTE cap. Displaced residents are factored into the receiving IPF's ratio of resident FTEs to the facility's average daily census.

3. Proposed Cost of Living Adjustment for IPFs Located in Alaska and Hawaii

The IPF PPS includes a payment adjustment for IPFs located in Alaska and Hawaii based upon the area in which the IPF is located. As we explained in the November 2004 IPF PPS final rule, the FY 2002 data demonstrated that IPFs in Alaska and Hawaii had per diem costs that were disproportionately higher than other IPFs. Other Medicare prospective payment systems (for example: The IPPS and LTCH PPS) adopted a COLA to account for the cost differential of care furnished in Alaska and Hawaii.

We analyzed the effect of applying a COLA to payments for IPFs located in Alaska and Hawaii. The results of our analysis demonstrated that a COLA for IPFs located in Alaska and Hawaii would improve payment equity for these facilities. As a result of this analysis, we provided a COLA in the November 2004 IPF PPS final rule.

A COLA for IPFs located in Alaska and Hawaii is made by multiplying the non-labor-related portion of the Federal per diem base rate by the applicable COLA factor based on the COLA area in which the IPF is located.

The COLA factors through 2009 were published by the Office of Personnel Management (OPM), and the OPM memo showing the 2009 COLA factors is available at <https://www.chcoc.gov/content/nonforeign-area-retirement-equity-assurance-act>.

We note that the COLA areas for Alaska are not defined by county as are the COLA areas for Hawaii. In 5 CFR 591.207, the OPM established the following COLA areas:

- City of Anchorage, and 80-kilometer (50-mile) radius by road, as measured from the Federal courthouse.
- City of Fairbanks, and 80-kilometer (50-mile) radius by road, as measured from the Federal courthouse.
- City of Juneau, and 80-kilometer (50-mile) radius by road, as measured from the Federal courthouse.
- Rest of the state of Alaska.

As stated in the November 2004 IPF PPS final rule, we update the COLA factors according to updates established by the OPM. However, sections 1911 through 1919 of the Non-foreign Area Retirement Equity Assurance Act, as contained in subtitle B of title XIX of the National Defense Authorization Act (NDAA) for FY 2010 (Pub. L. 111–84, October 28, 2009), transitions the Alaska and Hawaii COLAs to locality pay. Under section 1914 of NDAA, locality pay was phased in over a 3-year period beginning in January 2010, with COLA rates frozen as of the date of enactment,

October 28, 2009, and then proportionately reduced to reflect the phase-in of locality pay.

When we published the proposed COLA factors in the RY 2012 IPF PPS proposed rule (76 FR 4998), we inadvertently selected the FY 2010 COLA rates, which had been reduced to account for the phase-in of locality pay. We did not intend to propose the reduced COLA rates because that would have understated the adjustment. Since the 2009 COLA rates did not reflect the phase-in of locality pay, we finalized the FY 2009 COLA rates for RY 2010 through RY 2014.

In the FY 2013 IPPS/LTCH final rule (77 FR 53700 through 53701), we established a new methodology to update the COLA factors for Alaska and Hawaii, and adopted this methodology for the IPF PPS in the FY 2015 IPF final rule (79 FR 45958 through 45960). We adopted this new COLA methodology for the IPF PPS because IPFs are hospitals with a similar mix of commodities and services. We think it is appropriate to have a consistent policy approach with that of other hospitals in Alaska and Hawaii. Therefore, the IPF COLAs for FY 2015 through FY 2017 were the same as those applied under the IPPS in those years. As finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53700 and 53701), the COLA updates are determined every 4 years, when the IPPS market basket labor-related share is updated. Because the labor-related share of the IPPS market basket was updated for FY 2018, the COLA factors were updated in FY 2018 IPPS/LTCH rulemaking (82 FR 38529). As such, we also updated the IPF PPS COLA factors for FY 2018 (82 FR 36780 through 36782) to reflect the updated COLA factors finalized in the FY 2018 IPPS/LTCH rulemaking.

For FY 2022, we are proposing to update the COLA factors published by OPM for 2009 (as these are the last COLA factors OPM published prior to transitioning from COLAs to locality pay) using the methodology that we finalized in the FY 2013 IPPS/LTCH PPS final rule and adopted for the IPF PPS in the FY 2015 IPF final rule. Specifically, we are proposing to update the 2009 OPM COLA factors by a comparison of the growth in the Consumer Price Indices (CPIs) for the areas of Urban Alaska and Urban Hawaii, relative to the growth in the CPI for the average U.S. city as published by the Bureau of Labor Statistics (BLS). We note that for the prior update to the COLA factors, we used the growth in the CPI for Anchorage and the CPI for Honolulu. Beginning in 2018, these indexes were renamed to the CPI for

Urban Alaska and the CPI for Urban Hawaii due to the BLS updating its sample to reflect the data from the 2010 Decennial Census on the distribution of the urban population (<https://www.bls.gov/regions/west/factsheet/2018cpirevisionwest.pdf>, accessed January 22, 2021). The CPI for Urban Alaska area covers Anchorage and Matanuska-Susitna Borough in the State of Alaska and the CPI for Urban Hawaii covers Honolulu in the State of Hawaii. BLS notes that the indexes are considered continuous over time, regardless of name or composition changes.

Because BLS publishes CPI data for only Urban Alaska and Urban Hawaii, using the methodology we finalized in the FY 2013 IPPS/LTCH PPS final rule and adopted for the IPF PPS in the FY 2015 IPF final rule, we are proposing to use the comparison of the growth in the overall CPI relative to the growth in the CPI for those areas to update the COLA factors for all areas in Alaska and Hawaii, respectively. We believe that the relative price differences between these urban areas and the U.S. (as measured by the CPIs mentioned above) are appropriate proxies for the relative price differences between the “other areas” of Alaska and Hawaii and the U.S.

BLS publishes the CPI for All Items for Urban Alaska, Urban Hawaii, and for the average U.S. city. However, consistent with our methodology finalized in the FY 2013 IPPS/LTCH PPS final rule and adopted for the IPF PPS in the FY 2015 IPF final rule, we are proposing to create reweighted CPIs for each of the respective areas to reflect the underlying composition of the IPPS market basket nonlabor-related share. The current composition of the CPI for All Items for all of the respective areas is approximately 40 percent commodities and 60 percent services. However, the IPPS nonlabor-related share is comprised of a different mix of commodities and services. Therefore, we are proposing to create reweighted indexes for Urban Alaska, Urban Hawaii, and the average U.S. city using the respective CPI commodities index and CPI services index and proposed shares of 57 percent commodities/43 percent. We created reweighted indexes using BLS data for 2009 through 2020—the most recent data available at the time of this proposed rulemaking. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38530), we created reweighted indexes based on the 2014-based IPPS market basket (which was adopted for the FY 2018 IPPS update) and BLS data for 2009 through 2016 (the most recent BLS data at the time of the FY 2018

IPPS/LTCH PPS rulemaking), and we updated the IPF PPS COLA factors accordingly for FY 2018.

We continue to believe this methodology is appropriate because we continue to make a COLA for hospitals located in Alaska and Hawaii by multiplying the nonlabor-related portion of the standardized amount by a COLA factor. We note that OPM's COLA factors were calculated with a statutorily mandated cap of 25 percent.

As stated in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38530), under the COLA update methodology we finalized in the FY 2013 IPPS/LTCH PPS final rule, we exercised our discretionary authority to adjust payments to hospitals in Alaska and Hawaii by incorporating this cap. In applying this finalized methodology for updating the COLA factors, for FY 2022, we are proposing to continue to use such a cap, as our policy is based on OPM's COLA

factors (updated by the methodology described above).

Applying this methodology, the COLA factors that we are proposing to establish for FY 2022 to adjust the nonlabor-related portion of the standardized amount for IPFs located in Alaska and Hawaii are shown in the Table 1 below. For comparison purposes, we also are showing the COLA factors effective for FY 2018 through FY 2021.

TABLE 1—COMPARISON OF IPF PPS COST-OF-LIVING ADJUSTMENT FACTORS: IPFS LOCATED IN ALASKA AND HAWAII

Area	FY 2018 through FY 2021	FY 2022 through FY 2025 (proposed)
Alaska:		
City of Anchorage and 80-kilometer (50-mile) radius by road	1.25	1.22
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.25	1.22
City of Juneau and 80-kilometer (50-mile) radius by road	1.25	1.22
Rest of Alaska	1.25	1.24
Hawaii:		
City and County of Honolulu	1.25	1.25
County of Hawaii	1.21	1.22
County of Kauai	1.25	1.25
County of Maui and County of Kalawao	1.25	1.25

The proposed IPF PPS COLA factors for FY 2022 are also shown in Addendum A to this proposed rule, and is available at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html>.

4. Proposed Adjustment for IPFs With a Qualifying Emergency Department (ED)

The IPF PPS includes a facility-level adjustment for IPFs with qualifying EDs. We provide an adjustment to the Federal per diem base rate to account for the costs associated with maintaining a full-service ED. The adjustment is intended to account for ED costs incurred by a psychiatric hospital with a qualifying ED or an excluded psychiatric unit of an IPPS hospital or a CAH, for preadmission services otherwise payable under the Medicare Hospital Outpatient Prospective Payment System (OPPS), furnished to a beneficiary on the date of the beneficiary's admission to the hospital and during the day immediately preceding the date of admission to the IPF (see § 413.40(c)(2)), and the overhead cost of maintaining the ED. This payment is a facility-level adjustment that applies to all IPF admissions (with one exception which we described), regardless of whether a particular patient receives preadmission services in the hospital's ED.

The ED adjustment is incorporated into the variable per diem adjustment

for the first day of each stay for IPFs with a qualifying ED. Those IPFs with a qualifying ED receive an adjustment factor of 1.31 as the variable per diem adjustment for day 1 of each patient stay. If an IPF does not have a qualifying ED, it receives an adjustment factor of 1.19 as the variable per diem adjustment for day 1 of each patient stay.

The ED adjustment is made on every qualifying claim except as described in this section of the proposed rule. As specified in § 412.424(d)(1)(v)(B), the ED adjustment is not made when a patient is discharged from an IPPS hospital or CAH and admitted to the same IPPS hospital's or CAH's excluded psychiatric unit. We clarified in the November 2004 IPF PPS final rule (69 FR 66960) that an ED adjustment is not made in this case because the costs associated with ED services are reflected in the DRG payment to the IPPS hospital or through the reasonable cost payment made to the CAH.

Therefore, when patients are discharged from an IPPS hospital or CAH and admitted to the same hospital's or CAH's excluded psychiatric unit, the IPF receives the 1.19 adjustment factor as the variable per diem adjustment for the first day of the patient's stay in the IPF. For FY 2022, we are proposing to continue to retain the 1.31 adjustment factor for IPFs with qualifying EDs. A complete discussion of the steps involved in the calculation of the ED adjustment factors

are in the November 2004 IPF PPS final rule (69 FR 66959 through 66960) and the RY 2007 IPF PPS final rule (71 FR 27070 through 27072).

F. Other Proposed Payment Adjustments and Policies

1. Outlier Payment Overview

The IPF PPS includes an outlier adjustment to promote access to IPF care for those patients who require expensive care and to limit the financial risk of IPFs treating unusually costly patients. In the November 2004 IPF PPS final rule, we implemented regulations at § 412.424(d)(3)(i) to provide a per-case payment for IPF stays that are extraordinarily costly. Providing additional payments to IPFs for extremely costly cases strongly improves the accuracy of the IPF PPS in determining resource costs at the patient and facility level. These additional payments reduce the financial losses that would otherwise be incurred in treating patients who require costlier care, and therefore, reduce the incentives for IPFs to under-serve these patients. We make outlier payments for discharges in which an IPF's estimated total cost for a case exceeds a fixed dollar loss threshold amount (multiplied by the IPF's facility-level adjustments) plus the Federal per diem payment amount for the case.

In instances when the case qualifies for an outlier payment, we pay 80 percent of the difference between the

estimated cost for the case and the adjusted threshold amount for days 1 through 9 of the stay (consistent with the median LOS for IPFs in FY 2002), and 60 percent of the difference for day 10 and thereafter. The adjusted threshold amount is equal to the outlier threshold amount adjusted for wage area, teaching status, rural area, and the COLA adjustment (if applicable), plus the amount of the Medicare IPF payment for the case. We established the 80 percent and 60 percent loss sharing ratios because we were concerned that a single ratio established at 80 percent (like other Medicare PPSs) might provide an incentive under the IPF per diem payment system to increase LOS in order to receive additional payments.

After establishing the loss sharing ratios, we determined the current fixed dollar loss threshold amount through payment simulations designed to compute a dollar loss beyond which payments are estimated to meet the 2 percent outlier spending target. Each year when we update the IPF PPS, we simulate payments using the latest available data to compute the fixed dollar loss threshold so that outlier payments represent 2 percent of total estimated IPF PPS payments.

2. Proposed Update to the Outlier Fixed Dollar Loss Threshold Amount

In accordance with the update methodology described in § 412.428(d), we are proposing to update the fixed dollar loss threshold amount used under the IPF PPS outlier policy. Based on the regression analysis and payment simulations used to develop the IPF PPS, we established a 2 percent outlier policy, which strikes an appropriate balance between protecting IPFs from extraordinarily costly cases while ensuring the adequacy of the Federal per diem base rate for all other cases that are not outlier cases.

Our longstanding methodology for updating the outlier fixed dollar loss threshold involves using the best available data, which is typically the most recent available data. For this proposed rulemaking, the most recent available data would be the FY 2020 claims. However, during FY 2020, the U.S. healthcare system undertook an unprecedented response to the Public Health Emergency (PHE) declared by the Health and Human Services Secretary on January 31, 2020 in response to the outbreak of respiratory disease caused by a novel (new) coronavirus that has been named “SARS CoV 2” and the disease it causes, which has been named “coronavirus disease 2019” (abbreviated “COVID-19”). Therefore, as discussed

in section VI.C.3 of this proposed rule, we considered whether the most recent available year of claims, FY 2020, or the prior year, FY 2019, would be the best for estimating IPF PPS payments in FY 2021 and FY 2022. We compared the two years’ claims distributions as well as the impact results, and based on that analysis determined that the FY 2019 claims appear to be the best available data at this time. We refer the reader to section VI.C.3 of this proposed rule for a detailed discussion of that analysis.

Based on an analysis of the June 2020 update of FY 2019 IPF claims and the FY 2021 rate increases, we believe it is necessary to update the fixed dollar loss threshold amount to maintain an outlier percentage that equals 2 percent of total estimated IPF PPS payments. We are proposing to update the IPF outlier threshold amount for FY 2022 using FY 2019 claims data and the same methodology that we used to set the initial outlier threshold amount in the RY 2007 IPF PPS final rule (71 FR 27072 and 27073), which is also the same methodology that we used to update the outlier threshold amounts for years 2008 through 2021. Based on an analysis of these updated data, we estimate that IPF outlier payments as a percentage of total estimated payments are approximately 1.8 percent in FY 2021. Therefore, we are proposing to update the outlier threshold amount to \$14,030 to maintain estimated outlier payments at 2 percent of total estimated aggregate IPF payments for FY 2022. This proposed update is a decrease from the FY 2021 threshold of \$14,630. In contrast, using the FY 2020 claims to estimate payments, the proposed outlier fixed dollar loss threshold for FY 2022 would be \$19,840, an increase from the FY 2021 threshold of \$14,630. We refer the reader to section VI.C.3 of this proposed rule for a detailed discussion of the estimated impacts of the proposed update to the outlier fixed dollar loss threshold, and we invite comments on this analysis.

We note that our proposed use of the FY 2019 claims to set the proposed outlier fixed dollar loss threshold for FY 2022 would deviate from what has been our longstanding practice of using the most recent available year of claims, which is FY 2020 data. However, this proposal remains consistent with the established outlier update methodology. As discussed in this section and in section VI.C.3 of this proposed rule, we are proposing to update the outlier fixed dollar loss threshold based on FY 2019 IPF claims in order to maintain the appropriate outlier percentage in FY 2022. We are proposing to deviate from our longstanding practice of using the

most recent available year of claims only because and only to the extent that the COVID-19 PHE appears to have significantly impacted the FY 2020 IPF claims. As we are able to analyze more recent available IPF claims data and better understand both the short-term and long-term effects of the COVID-19 PHE on IPFs, we intend to re-assess the appropriateness of using FY 2019 IPF claims rather than FY 2020 IPF claims for the FY 2022 update.

3. Proposed Update to IPF Cost-to-Charge Ratio Ceilings

Under the IPF PPS, an outlier payment is made if an IPF’s cost for a stay exceeds a fixed dollar loss threshold amount plus the IPF PPS amount. In order to establish an IPF’s cost for a particular case, we multiply the IPF’s reported charges on the discharge bill by its overall cost-to-charge ratio (CCR). This approach to determining an IPF’s cost is consistent with the approach used under the IPPS and other PPSs. In the FY 2004 IPPS final rule (68 FR 34494), we implemented changes to the IPPS policy used to determine CCRs for IPPS hospitals, because we became aware that payment vulnerabilities resulted in inappropriate outlier payments. Under the IPPS, we established a statistical measure of accuracy for CCRs to ensure that aberrant CCR data did not result in inappropriate outlier payments.

As we indicated in the November 2004 IPF PPS final rule (69 FR 66961), we believe that the IPF outlier policy is susceptible to the same payment vulnerabilities as the IPPS; therefore, we adopted a method to ensure the statistical accuracy of CCRs under the IPF PPS. Specifically, we adopted the following procedure in the November 2004 IPF PPS final rule:

- Calculated two national ceilings, one for IPFs located in rural areas and one for IPFs located in urban areas.
- Computed the ceilings by first calculating the national average and the standard deviation of the CCR for both urban and rural IPFs using the most recent CCRs entered in the most recent Provider Specific File (PSF) available.

For FY 2022, we are proposing to continue to follow this methodology.

To determine the rural and urban ceilings, we multiplied each of the standard deviations by 3 and added the result to the appropriate national CCR average (either rural or urban). The upper threshold CCR for IPFs in FY 2022 is 2.0398 for rural IPFs and 1.6126 for urban IPFs, based on CBSA-based geographic designations. If an IPF’s CCR is above the applicable ceiling, the ratio is considered statistically inaccurate,

and we assign the appropriate national (either rural or urban) median CCR to the IPF.

We apply the national median CCRs to the following situations:

- New IPFs that have not yet submitted their first Medicare cost report. We continue to use these national median CCRs until the facility's actual CCR can be computed using the first tentatively or final settled cost report.

- IPFs whose overall CCR is in excess of three standard deviations above the corresponding national geometric mean (that is, above the ceiling).

- Other IPFs for which the MAC obtains inaccurate or incomplete data with which to calculate a CCR.

We are proposing to continue to update the FY 2022 national median and ceiling CCRs for urban and rural IPFs based on the CCRs entered in the latest available IPF PPS PSF. Specifically, for FY 2022, to be used in each of the three situations listed previously, using the most recent CCRs entered in the CY 2021 PSF, we provide an estimated national median CCR of 0.5720 for rural IPFs and a national median CCR of 0.4200 for urban IPFs. These calculations are based on the IPF's location (either urban or rural) using the CBSA-based geographic designations. A complete discussion regarding the national median CCRs appears in the November 2004 IPF PPS final rule (69 FR 66961 through 66964).

IV. Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program

A. Background and Statutory Authority

We refer readers to the FY 2019 IPF PPS final rule (83 FR 38589) for a discussion of the background and statutory authority¹ of the IPFQR Program.

¹ We note that the statute uses the term "rate year" (RY). However, beginning with the annual update of the inpatient psychiatric facility prospective payment system (IPF PPS) that took effect on July 1, 2011 (RY 2012), we aligned the IPF PPS update with the annual update of the ICD codes, effective on October 1 of each year. This change allowed for annual payment updates and the ICD coding update to occur on the same schedule and appear in the same **Federal Register** document, promoting administrative efficiency. To reflect the change to the annual payment rate update cycle, we revised the regulations at 42 CFR 412.402 to specify that, beginning October 1, 2012, the RY update period would be the 12-month period from October 1 through September 30, which we refer to as a "fiscal year" (FY) (76 FR 26435). Therefore, with respect to the IPFQR Program, the terms "rate year," as used in the statute, and "fiscal year" as used in the regulation, both refer to the period from October 1 through September 30. For more information regarding this terminology change, we refer readers to section III. of the RY 2012 IPF PPS final rule (76 FR 26434 through 26435).

B. Covered Entities

In the FY 2013 IPFS/LTCH PPS final rule (77 FR 53645), we established that the IPFQR Program's quality reporting requirements cover those psychiatric hospitals and psychiatric units paid under Medicare's IPF PPS (§ 412.404(b)). Generally, psychiatric hospitals and psychiatric units within acute care and critical access hospitals that treat Medicare patients are paid under the IPF PPS. Consistent with previous regulations, we continue to use the terms "facility" or IPF to refer to both inpatient psychiatric hospitals and psychiatric units. This usage follows the terminology in our IPF PPS regulations at § 412.402. For more information on covered entities, we refer readers to the FY 2013 IPFS/LTCH PPS final rule (77 FR 53645).

C. Previously Finalized Measures and Administrative Procedures

The current IPFQR Program includes 14 measures. For more information on these measures, we refer readers to Table 4 of this proposed rule and the following final rules:

- The FY 2013 IPFS/LTCH PPS final rule (77 FR 53646 through 53652);
- The FY 2014 IPFS/LTCH PPS final rule (78 FR 50889 through 50897);
- The FY 2015 IPF PPS final rule (79 FR 45963 through 45975);
- The FY 2016 IPF PPS final rule (80 FR 46695 through 46714);
- The FY 2017 IPFS/LTCH PPS final rule (81 FR 57238 through 57247);
- The FY 2019 IPF PPS final rule (83 FR 38590 through 38606); and
- The FY 2020 IPF PPS final rule (84 FR 38459 through 38467).

For more information on previously adopted procedural requirements, we refer readers to the following rules:

- The FY 2013 IPFS/LTCH PPS final rule (77 FR 53653 through 53660);
- The FY 2014 IPFS/LTCH PPS final rule (78 FR 50897 through 50903);
- The FY 2015 IPF PPS final rule (79 FR 45975 through 45978);
- The FY 2016 IPF PPS final rule (80 FR 46715 through 46719);
- The FY 2017 IPFS/LTCH PPS final rule (81 FR 57248 through 57249);
- The FY 2018 IPFS/LTCH PPS final rule (82 FR 38471 through 38474);
- The FY 2019 IPF PPS final rule (83 FR 38606 through 38608); and
- The FY 2020 IPF PPS final rule (84 FR 38467 through 38468).

D. Closing the Health Equity Gap in CMS Quality Programs—Request for Information (RFI)

Persistent inequities in health care outcomes exist in the U.S., including

among Medicare patients. 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 facilities, providers, and patients. The following is part of an ongoing effort across CMS to evaluate appropriate initiatives to reduce health disparities. Feedback will be used to inform the creation of a future, comprehensive, RFI focused on closing the health equity gap in CMS programs and policies.

This RFI contains four parts:

- **Background:** This section provides information describing our commitment to health equity, and existing initiatives with an emphasis on reducing health disparities.

- **Current CMS Disparity Methods:** This section describes the methods, measures, and indicators of social risk currently used with the CMS Disparity Methods.

- **Future potential stratification of quality measure results:** This section describes four potential future expansions of the CMS Disparity Methods, including (1) Stratification of Quality Measure Results—Dual Eligibility; (2) Stratification of Quality Measure Results—Race and Ethnicity; (3) Improving Demographic Data Collection; and (4) Potential Creation of a Facility Equity Score to Synthesize Results Across Multiple Social Risk Factors.

- **Solicitation of public comment:** This section specifies 12 requests for feedback on the above topics. We look forward to receiving feedback on these topics, and note our intention for an additional RFI or rulemaking on this topic in the future.

1. Background

Significant and persistent inequities in health care outcomes exist in the U.S. 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; living in a rural area; or being near or below the poverty level, is often associated with worse health outcomes.^{2,3,4,5,6,7,8,9} Such disparities in

² 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.

³ 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.

⁴ Trivedi AN, Nsa W, Hausmann LRM, et al. Quality and Equity of Care in U.S. Hospitals. *New*

health outcomes are the result of 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.^{10 11 12 13 14 15} 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.^{16 17 18 19 20} Studies have also

shown that African Americans are significantly more likely than white Americans to die prematurely from heart disease and stroke.²¹ 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.^{22 23} 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.”²⁴ One important strategy for addressing these important inequities is improving data collection to allow for better measurement and reporting on equity across our programs and policies.

We are 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.²⁵ For the purposes of this proposed 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.”²⁶ We note that this definition was recently established by the current administration, and provides a useful, 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.²⁷ The CMS Equity Plan for Improving Quality in Medicare focuses on three core priority areas which inform our policies and programs: (1) Increasing understanding and awareness of health disparities; (2) developing and disseminating solutions to achieve health equity; and (3) implementing sustainable actions to achieve health equity.²⁸ The CMS Quality Strategy²⁹ and Meaningful Measures Framework³⁰ include elimination of racial and ethnic disparities as a central principle. Our efforts aimed at closing the health equity gap to date have included both providing transparency about health disparities, supporting providers with evidence-informed solutions to achieve health equity, and reporting to providers

England Journal of Medicine. 2014;371(24):2298–2308.

⁵ 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.

⁶ Rural Health Research Gateway. Rural Communities: Age, Income, and Health Status. Rural Health Research Recap. November 2018.

⁷ https://www.minorityhealth.hhs.gov/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf.

⁸ www.cdc.gov/mmwr/volumes/70/wr/mm7005a1.htm.

⁹ 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.

¹⁰ Martino, SC, Elliott, MN, Dembosky, JW, Hambarsoomian, K, Burkhardt, 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.

¹¹ 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.

¹² 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.

¹³ 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.

¹⁴ 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.

¹⁵ 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.

¹⁶ 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.

¹⁷ Centers for Medicare and Medicaid Services. Medicare Hospital Quality Chartbook: Performance Report on Outcome Measures; 2014.

¹⁸ 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.

¹⁹ 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.

²⁰ 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.

²¹ HHS. Heart disease and African Americans. (March 29, 2021). <https://www.minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=19>.

²² <https://www.cms.gov/files/document/medicare-covid-19-data-snapshot-fact-sheet.pdf>.

²³ 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/>.

²⁴ <https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html>.

²⁵ <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf>.

²⁶ <https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-Federal-government>.

²⁷ Centers for Medicare and Medicaid Services Office of Minority Health. The CMS Equity Plan for Improving Quality in Medicare. 2015. https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH_Dwnld-CMS_EquityPlanforMedicare_090615.pdf.

²⁸ Centers for Medicare and Medicaid Services Office of Minority Health. The CMS Equity Plan for Improving Quality in Medicare. 2015. https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH_Dwnld-CMS_EquityPlanforMedicare_090615.pdf.

²⁹ Centers for Medicare Services. CMS Quality Strategy. 2016. <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf>.

³⁰ <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page>.

on gaps in quality through the following reports and programs:

- The *CMS Mapping Medicare Disparities Tool*, which is an interactive map that identifies areas of disparities and a starting point to understand and investigate geographical, racial and ethnic differences in health outcomes for Medicare patients.³¹

- The *Racial, Ethnic, and Gender Disparities in Health Care in Medicare Advantage Stratified Report*, which highlights racial and ethnic differences in health care experiences and clinical care, compares quality of care for women and men, and looks at racial and ethnic differences in quality of care among women and men separately for Medicare Advantage plans.³²

- The *Rural-Urban Disparities in Health Care in Medicare Report*, which details rural-urban differences in health care experiences and clinical care.³³

- The *Standardized Patient Assessment Data Elements* for certain post-acute care Quality Reporting Programs, which now includes data reporting for race and ethnicity and preferred language, in addition to screening questions for social needs (84 FR 42536 through 42588).

- The *CMS Innovation Center's Accountable Health Communities Model*, which include standardized data collection of health-related social needs data.

- The *Guide to Reducing Disparities* which provides an overview of key issues related to disparities in readmissions and reviews sets of activities that can help hospital leaders reduce readmissions in diverse populations.³⁴

- The *CMS Disparity Methods*, which provide hospital-level confidential results stratified by dual eligibility for condition-specific readmission measures currently included in the Hospital Readmission Reduction Program (84 FR 42496 through 42500).

These programs are informed by reports by the National Academies of Science, Engineering and Medicine

³¹ <https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH-Mapping-Medicare-Disparities>.

³² <https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/statistics-and-data/stratified-reporting>.

³³ Centers for Medicare and Medicaid Services. *Rural-Urban Disparities in Health Care in Medicare*. 2019. <https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Rural-Urban-Disparities-in-Health-Care-in-Medicare-Report.pdf>.

³⁴ 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.

(NASEM)³⁵ and the Office of the Assistant Secretary for Planning and Evaluation (ASPE)³⁶ which have examined the influence of social risk factors on several of our quality programs. In this RFI, we address only the sixth initiative listed, the CMS Disparity Methods, which we have implemented for measures in the Hospital Readmissions Reduction Program and are considering in other programs, including the IPFQR Program. We discuss the implementation of these methods to date and present considerations for continuing to improve and expand these methods to provide providers and ultimately consumers with actionable information on disparities in health care quality to support efforts at closing the equity gap.

2. Current CMS Disparity Methods

We first sought public comment on potential confidential and public reporting of IPFQR program measure data stratified by social risk factors in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20121). We initially focused on stratification by dual eligibility, which is consistent with recommendations from ASPE's First Report to Congress which was required by the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014 (Pub. L. 113–185).³⁷ This report found that in the context of value-based purchasing (VBP) programs, dual eligibility was among the most powerful predictors of poor health outcomes among those social risk factors that ASPE examined and tested.

In the FY 2018 IPPS/LTCH PPS final rule we also solicited feedback on two potential methods for illuminating differences in outcomes rates among patient groups within a provider's patient population that would also allow for a comparison of those differences, or disparities, across providers for the Hospital IQR Program (82 FR 38403 through 38409). The first method (the Within-Hospital disparity method) promotes quality improvement by calculating differences in outcome rates among patient groups within a hospital while accounting for their clinical risk factors. This method also

³⁵ National Academies of Sciences, Engineering, and Medicine. 2016. *Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/21858>.

³⁶ <https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicare-value-based-purchasing-programs>.

³⁷ <https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicare-value-based-purchasing-programs>.

allows for a comparison of the magnitude of disparity across hospitals, permitting hospitals to assess how well they are closing disparity gaps compared to other hospitals. The second methodological approach (the Across-Hospital method) is complementary and assesses hospitals' outcome rates for dual-eligible patients only, across hospitals, allowing for a comparison among hospitals on their performance caring for their patients with social risk factors. In the FY 2018 IPPS/LTCH PPS proposed rule under the IPFQR Program (82 FR 20121), we also specifically solicited feedback on which social risk factors provide the most valuable information to stakeholders. Overall, comments supported the use of dual eligibility as a proxy for social risk, although commenters also suggested investigation of additional social risk factors, and we continue to consider which risk factors provide the most valuable information to stakeholders.

Concurrent with our comment solicitation on stratification in the IPFQR Program, we have considered methods for stratifying measure results for other quality reporting programs. For example, FY 2019 IPPS/LTCH PPS final rule (82 FR 41597 through 41601), we finalized plans to provide confidential hospital-specific reports (HSRs) containing stratified results of the Pneumonia Readmission (NQF #0506) and Pneumonia Mortality (NQF #0468) measures including both the Across-Hospital Disparity Method and the Within-Hospital Disparity Method (disparity methods), stratified by dual eligibility. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41554 through 41556), we also removed six condition/procedure specific readmissions measures, including the Pneumonia Readmission measure (NQF #0506) and five mortality measures, including the Pneumonia Mortality measure (NQF #0468) (83 FR 41556 through 41558) from the Hospital IQR Program. However, the Pneumonia Readmission (NQF #0506) and the other condition/procedure measures remained in the Hospital Readmissions Reduction Program. In 2019, we provided hospitals with results of the Pneumonia Readmission measure (NQF #0506) stratified using dual eligibility. We provided this information in annual confidential HSRs for claims-based measures.

We then, in the FY 2020 IPPS/LTCH PPS Final Rule (84 FR 42388 through 42390), finalized the proposal to provide confidential hospital specific reports (HSRs) containing data stratified by dual-eligible status for all six readmission measures included in the

Hospital Readmission Reduction Program.

3. Potential Expansion of the CMS Disparity Methods

We are committed to advancing health equity by improving data collection to better measure and analyze disparities across programs and policies.³⁸ As we previously noted, we have been considering, among other things, expanding our efforts to provide stratified data for additional social risk factors and measures, optimizing the ease-of-use of the results, enhancing public transparency of equity results, and building towards provider accountability for health equity. We are seeking public comment on the potential stratification of quality measures in the IPFQR Program across two social risk factors: Dual eligibility and race/ethnicity.

a. Stratification of Quality Measure Results—Dual Eligibility

As described above, landmark reports by the National Academies of Science, Engineering and Medicine (NASEM)³⁹ and the Office of the Assistant Secretary for Planning and Evaluation (ASPE),⁴⁰ which have examined the influence of social risk factors on several of our quality programs, have shown that in the context of value-based purchasing (VBP) programs, dual eligibility, as an indicator of social risk, is a powerful predictor of poor health outcomes. We note that the patient population of IPFs has a higher percentage of dually eligible patients than the general Medicare population. Specifically, over half (56 percent) of Medicare patients in IPFs are dually eligible⁴¹ while approximately 20 percent of all Medicare patients are dually eligible.⁴² We are considering stratification of quality measure results in the IPFQR Program and are considering which

measures would be most appropriate for stratification and if dual eligibility would be a meaningful social risk factor for stratification.

For the IPFQR Program, we would consider disparity reporting using two disparity methods derived from the Within-Hospital and Across-Hospital methods, described above. The first method (based on the Within-Facility disparity method) would aim to promote quality improvement by calculating differences in outcome rates between dual and non-dual eligible patient groups within a facility while accounting for their clinical risk factors. This method would allow for a comparison of those differences, or disparities, across facilities, so facilities could assess how well they are closing disparity gaps compared to other facilities. The second approach (based on the Across-Facility method) would be complementary and assesses facilities' outcome rates for subgroups of patients, such as dual eligible patients, across facilities, allowing for a comparison among facilities on their performance caring for their patients with social risk factors.

b. Stratification of Quality Measure Results—Race and Ethnicity

The Administration's *Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government* directs agencies to assess potential barriers that underserved communities and individuals may face to enrollment in and access to benefits and services in Federal Programs. As summarized above, studies have shown that among Medicare beneficiaries, racial and ethnic minority persons often experience worse health outcomes, including more frequent hospital readmissions and operative complications. An important part of identifying and addressing inequities in health care is improving data collection to allow us to better measure and report on equity across our programs and policies. We are considering stratification of quality measure results in the IPFQR Program by race and ethnicity and are considering which measures would be most appropriate for stratification.

As outlined in the 1997 Office of Management and Budget (OMB) Revisions to the Standards for the Collection of Federal Data on Race and Ethnicity, the racial and ethnic categories, which may be used for reporting the disparity methods are considered to be social and cultural, not

biological or genetic.⁴³ The 1997 OMB Standard lists five minimum categories of race: (1) American Indian or Alaska Native; (2) Asian; (3) Black or African American; (4) Native Hawaiian or Other Pacific Islander; (5) and White. In the OMB standards, Hispanic or Latino is the only ethnicity category included, and since race and ethnicity are two separate and distinct concepts, persons who report themselves as Hispanic or Latino can be of any race.⁴⁴ Another example, the "Race & Ethnicity—CDC" code system in Public Health Information Network (PHIN) Vocabulary Access and Distribution System (VADS)⁴⁵ permits a much more granular structured recording of a patient's race and ethnicity with its inclusion of over 900 concepts for race and ethnicity. The recording and exchange of patient race and ethnicity at such a granular level can facilitate the accurate identification and analysis of health disparities based on race and ethnicity. Further, the "Race & Ethnicity—CDC" code system has a hierarchy that rolls up to the OMB minimum categories for race and ethnicity and, thus, supports aggregation and reporting using the OMB standard. ONC includes both the CDC and OMB standards in its criterion for certified health IT products.⁴⁶ For race and ethnicity, a certified health IT product must be able to express both detailed races and ethnicities using any of the 900 plus concepts in the "Race & Ethnicity—CDC" code system in the PHIN VADS, as well as aggregate each one of a patient's races and ethnicities to the categories in the OMB standard for race and ethnicity. This approach can reduce burden on providers recording demographics using certified products.

Self-reported race and ethnicity data remain the gold standard for classifying an individual according to race or ethnicity. However, CMS does not consistently collect self-reported race and ethnicity for the Medicare program, but instead gets the data from the Social Security Administration (SSA) and the data accuracy and comprehensiveness have proven challenging despite capabilities in the marketplace via

⁴³ Executive Office of the President Office of Management and Budget, Office of Information and Regulatory Affairs. Revisions to the standards for the classification of Federal data on race and ethnicity. Vol 62. **Federal Register**. 1997:58782–58790.

⁴⁴ <https://www.census.gov/topics/population/hispanic-origin/about.html>.

⁴⁵ <https://phinvads.cdc.gov/vads/ViewValueSet.action?id=67D34BBC-617F-DD11-B38D-00188B398520>.

⁴⁶ ONC criteria for certified health IT products: <https://www.healthit.gov/isa/representing-patient-race-and-ethnicity>.

³⁸ Centers for Medicare Services. CMS Quality Strategy. 2016. <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf>.

³⁹ National Academies of Sciences, Engineering, and Medicine. 2016. Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors. Washington, DC: The National Academies Press. <https://doi.org/10.17226/21858>.

⁴⁰ <https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicare-value-based-purchasing-programs>.

⁴¹ <https://aspe.hhs.gov/basic-report/transitions-care-and-service-use-among-medicare-beneficiaries-inpatient-psychiatric-facilities-issue-brief>.

⁴² <https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/DataStatisticalResources/Downloads/MedicareMedicaidDualEnrollmentEverEnrolledTrendsDataBrief2006-2018.pdf>.

certified health IT products. Historical inaccuracies in Federal data systems and limited collection classifications have contributed to the limited quality of race and ethnicity information in Medicare's administrative data systems.⁴⁷ In recent decades, to address these data quality issues, we have undertaken numerous initiatives, including updating to data taxonomies and conducting direct mailings to some beneficiaries to enable more comprehensive race and ethnic identification.^{48 49} Despite those efforts, studies reveal varying data accuracy in identification of racial and ethnic groups in Medicare administrative data, with higher sensitivity for correctly identifying White and Black individuals, and lower sensitivity for correctly identifying individuals of Hispanic ethnicity or of Asian/Pacific Islander and American Indian/Alaskan Native race.⁵⁰ Incorrectly classified race or ethnicity may result in overestimation or underestimation in the quality of care received by certain groups of beneficiaries.

We continue to work with Federal and private partners to better collect and 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 Collection⁵¹ and supported collection of specialized International Classification of Disease, 10th Edition, Clinical Modification (ICD-10-CM) codes for describing the socioeconomic, cultural, and environmental determinants of health, and sponsored several initiatives to statistically estimate race and ethnicity information

when it is absent.⁵² The Office of the National Coordinator for Health Information Technology (ONC) included social, psychological, and behavioral standards in the 2015 Edition health information technology (IT) certification criteria (2015 Edition), providing interoperability standards (LOINC (Logical Observation Identifiers Names and Codes) and SNOMED CT (Systematized Nomenclature of Medicine—Clinical Terms)) for financial strain, education, social connection and isolation, and others. Additional stakeholder efforts underway to expand capabilities to capture additional social determinants of health data elements include the Gravity Project to identify and harmonize social risk factor data for interoperable electronic health information exchange for EHR fields, as well as proposals to expand the ICD-10 (International Classification of Diseases, Tenth Revision) z-codes, the alphanumeric codes used worldwide to represent diagnoses.⁵³

While development of sustainable and consistent programs to collect data on social determinants of health can be considerable undertakings, we recognize that another method to identify better race and ethnicity data is needed in the short term to address the need for reporting on health equity. In working with our contractors, two algorithms have been developed to *indirectly estimate* the race and ethnicity of Medicare beneficiaries (as described further in the following paragraphs). We feel that using indirect estimation can help to overcome the current limitations of demographic information and enable timelier reporting of equity results until longer term collaborations to improve demographic data quality across the health care sector materialize. The use of indirectly estimated race and ethnicity for conducting stratified reporting does not place any additional collection or reporting burdens on facilities as these data are derived using existing administrative and census-linked data.

Indirect estimation relies on a statistical imputation method for inferring a missing variable or improving an imperfect administrative variable using a related set of information that is more readily

available.⁵⁴ Indirectly estimated data are most commonly used at the population level (such as the facility or health plan-level), where aggregated results form a more accurate description of the population than existing, imperfect data sets. These methods often estimate race and ethnicity using a combination of other data sources which are predictive of self-identified race and ethnicity, such as language preference, information about race and ethnicity in our administrative records, first and last names matched to validated lists of names correlated to specific national origin groups, and the racial and ethnic composition of the surrounding neighborhood. Indirect estimation has been used in other settings to support population-based equity measurement when self-identified data are not available.⁵⁵

As described above, we have previously supported the development of two such methods of indirect estimation of race and ethnicity of Medicare beneficiaries. One indirect estimation approach, developed by our contractor, uses Medicare administrative data, first name and surname matching, derived from the U.S. Census and other sources, with beneficiary language preference, state of residence, and the source of the race and ethnicity code in Medicare administrative data to reclassify some beneficiaries as Hispanic or Asian/Pacific Islander (API).⁵⁶ In recent years, we have also worked with another contractor to develop a new approach, the Medicare Bayesian Improved Surname Geocoding (MBISG), which combines Medicare administrative data, first and surname matching, geocoded residential address linked to the 2010 U.S. Census, and uses both Bayesian updating and multinomial logistic regression to estimate the probability of belonging to each of six racial/ethnic groups.⁵⁷

⁴⁷ Eicheldinger, C., & Bonito, A. (2008). More accurate racial and ethnic codes for Medicare administrative data. *Health Care Financing Review*, 29(3), 27–42.

⁴⁸ Filice CE, Joynr KE. Examining Race and Ethnicity Information in Medicare Administrative Data. *Med Care*. 2017;55(12):e170-e176. doi:10.1097/MLR.0000000000000608.

⁴⁹ Eicheldinger, C., & Bonito, A. (2008). More accurate racial and ethnic codes for Medicare administrative data. *Health Care Financing Review*, 29(3), 27–42.

⁵⁰ 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>.

⁵¹ 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>.

⁵² <https://pubmed.ncbi.nlm.nih.gov/18567241/>, <https://pubmed.ncbi.nlm.nih.gov/30506674/>, Eicheldinger C, Bonito A. More accurate racial and ethnic codes for Medicare administrative data. *Health Care Finance Rev*. 2008;29(3):27–42. Haas A, Elliott MN, Dembosky JW, et al. Imputation of race/ethnicity to enable measurement of HEDIS performance by race/ethnicity. *Health Serv Res*. 2019;54(1):13–23. doi:10.1111/1475-6773.13099.

⁵³ <https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress>.

⁵⁴ IOM. 2009. Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement. Washington, DC: The National Academies Press.

⁵⁵ IOM. 2009. Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement. Washington, DC: The National Academies Press.

⁵⁶ Bonito AJ, Bann C, Eicheldinger C, Carpenter L. Creation of New Race-Ethnicity Codes and Socioeconomic Status (SES) Indicators for Medicare Beneficiaries. Final Report, Sub-Task 2. (Prepared by RTI International for the Centers for Medicare and Medicaid Services through an interagency agreement with the Agency for Healthcare Research and Policy, under Contract No. 500-00-0024, Task No. 21) AHRQ Publication No. 08-0029-EF. Rockville, MD, Agency for Healthcare Research and Quality. January 2008.

⁵⁷ Haas, A., Elliott, M. et al (2018). Imputation of race/ethnicity to enable measurement of HEDIS

The MBISG model is currently used to conduct the national, contract-level, stratified reporting of Medicare Part C & D performance data for Medicare Advantage Plans by race and ethnicity.⁵⁸ Validation testing reveals concordances of 0.88 through 0.95 between indirectly estimated and self-report among individuals who identify as White, Black, Hispanic and API for the MBISG version 2.0 and concordances with self-reported race and ethnicity of 0.96 through 0.99 for these same groups for MBISG version 2.1.⁵⁹ The algorithms under consideration are considerably less accurate for individuals who self-identify as American Indian/Alaskan Native or multiracial.⁶¹ Indirect estimation can be a statistically reliable approach for calculating population-level equity results for groups of individuals (such as the facility-level) and is not intended, nor being considered, as an approach for inferring the race and ethnicity of an individual.

However, despite the high degree of statistical accuracy of the indirect estimation algorithms under consideration there remains the small risk of unintentionally introducing bias. For example, if the indirect estimation is not as accurate in correctly estimating race and ethnicity in certain geographies or populations it could lead to some bias in the method results. Such bias might result in slight overestimation or underestimation of the quality of care received by a given group. We feel this amount of bias is considerably less than

would be expected if stratified reporting was conducted using the race and ethnicity currently contained in our administrative data. Indirect estimation of race and ethnicity is envisioned as an intermediate step, filling the pressing need for more accurate demographic information for the purposes of exploring inequities in service delivery, while allowing newer approaches, as described in the next section, for improving demographic data collection to progress. We are interested in learning more about, and soliciting comments about, the potential benefits and challenges associated with measuring facility equity using an imputation algorithm to enhance existing administrative data quality for race and ethnicity until self-reported information is sufficiently available.

c. Improving Demographic Data Collection

Stratified facility-level reporting using dual eligibility and indirectly estimated race and ethnicity would represent an important advance in our ability to provide equity reports to facilities. However, self-reported race and ethnicity data remain the gold standard for classifying an individual according to race or ethnicity. The CMS Quality Strategy outlines our commitment to strengthening infrastructure and data systems by ensuring that standardized demographic information is collected to identify disparities in health care delivery outcomes.⁶² Collection and sharing of a standardized set of social, psychological, and behavioral data by facilities, including race and ethnicity, using electronic data definitions which permit nationwide, interoperable health information exchange, can significantly enhance the accuracy and robustness of our equity reporting.⁶³ This could potentially include expansion to additional social risk factors, such as disability status, where accuracy of administrative data is currently limited. We are mindful that additional resources, including data collection and staff training may be necessary to ensure that conditions are created whereby all patients are comfortable answering all demographic questions, and that individual preferences for non-response are maintained.

We are also interested in learning about and are soliciting comments on current data collection practices by facilities to capture demographic data elements (such as race, ethnicity, sex, sexual orientation and gender identity (SOGI), primary language, and disability status). Further, we are interested in potential challenges facing facility collection, at the time of admission, of a minimum set of demographic data elements in alignment with national data collection standards (such as the standards finalized by the Affordable Care Act)⁶⁴ and standards for interoperable exchange (such as the U.S. Core Data for Interoperability incorporated into certified health IT products as part of the 2015 Edition of health IT certification criteria).⁶⁵ Advancing data interoperability through collection of a minimum set of demographic data collection, and incorporation of this demographic information into quality measure specifications, has the potential for improving the robustness of the disparity method results, potentially permitting reporting using more accurate, self-reported information, such as race and ethnicity, and expanding reporting to additional dimensions of equity, including stratified reporting by disability status.

d. Potential Creation of a Facility Equity Score To Synthesize Results Across Multiple Social Risk Factors

As we describe in section IV.D.3.a of this proposed rule, we are considering expanding the disparity methods to IPFs and to include two social risk factors (dual eligibility and race/ethnicity). This approach would improve the comprehensiveness of health equity information provided to facilities. Aggregated results from multiple measures and multiple social risk factors, from the CMS Disparity Methods, in the format of a summary score, can improve the usefulness of the equity results. In working with our contractors, we recently developed an equity summary score for Medicare Advantage contract/plans, the Health Equity Summary Score (HESS), with application to stratified reporting using two social risk factors: dual eligibility and race and as described in *Incentivizing Excellent Care to At-Risk Groups with a Health Equity Summary Score*.⁶⁶

performance by race/ethnicity. *Health Services Research*, 54:13–23.

⁵⁸ The Office of Minority Health (2020). Racial, Ethnic, and Gender Disparities in Health Care in Medicare Advantage. The Centers for Medicare and Medicaid Services, (pg vii). <https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/statistics-and-data/stratified-reporting>.

⁵⁹ Haas, A., Elliott, M. et al (2018). Imputation of race/ethnicity to enable measurement of HEDIS performance by race/ethnicity. *Health Services Research*, 54:13–23.

⁶⁰ MBISG 2.1 validation results performed under contract #GS-10F-0012Y/HHS-500-2016-00097G). Pending public release of the 2021 Part C and D Performance Data Stratified by Race, Ethnicity, and Gender Report, available at: <https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/statistics-and-data/stratified-reporting>.

⁶¹ Haas, A., Elliott, M. et al (2018). Imputation of race/ethnicity to enable measurement of HEDIS performance by race/ethnicity. *Health Services Research*, 54:13–23 and Bonito AJ, Bann C, Eicheldinger C, Carpenter L. Creation of New Race-Ethnicity Codes and Socioeconomic Status (SES) Indicators for Medicare Beneficiaries. Final Report, Sub-Task 2. (Prepared by RTI International for the Centers for Medicare and Medicaid Services through an interagency agreement with the Agency for Healthcare Research and Policy, under Contract No. 500-00-0024, Task No. 21) AHRQ Publication No. 08-0029-EF. Rockville, MD, Agency for Healthcare Research and Quality. January 2008.

⁶² The Centers for Medicare & Medicaid Services. CMS Quality Strategy. 2016. <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf>.

⁶³ The Office of the National Coordinator for Health Information Technology. United State Core Data for Interoperability Draft Version 2. 2021. <https://www.healthit.gov/isa/sites/isa/files/2021-01/Draft-USCDI-Version-2-January-2021-Final.pdf>.

⁶⁴ https://minorityhealth.hhs.gov/assets/pdf/checked/1/Fact_Sheet_Section_4302.pdf.

⁶⁵ https://www.healthit.gov/sites/default/files/2020-08/2015EdCures_Update_CCG_USCDI.pdf.

⁶⁶ Agniel D, Martino SC, Burkhart Q, et al. Incentivizing Excellent Care to At-Risk Groups with

The HESS calculates standardized and combined performance scores blended across the two social risk factors. The HESS also combines results of the within-plan (similar to the Within-Facility method) and across-plan method (similar to the Across-Facility method) across multiple performance measures.

We are considering building a “Facility Equity Score,” not yet developed, which would be modeled off the HESS but adapted to the context of risk-adjusted facility outcome measures and potentially other IPF quality measures. We envision that the Facility Equity Score would synthesize results for a range of measures and using multiple social risk factors, using measures and social risk factors, which would be reported to facilities as part of the CMS Disparity Methods. We believe that creation of the Facility Equity Score has the potential to supplement the overall measure data already reported on the *Care Compare* or successor website, by providing easy to interpret information regarding disparities measured within individual facilities and across facilities nationally. A summary score would decrease burden by minimizing the number of measure results provided and providing an overall indicator of equity.

The Facility Equity Score under consideration would potentially:

- Summarize facility performance across multiple social risk factors (initially dual eligibility and indirectly estimated race and ethnicity, as described above); and
- Summarize facility performance across the two disparity methods (that is, the Within-Facility Disparity Method and the Across-Facility Disparity Method) and potentially for multiple measures.

Prior to any future public reporting, if we determine that a Facility Equity Score can be feasibly and accurately calculated, we would provide results of the Facility Equity Score, in confidential facility specific reports, which facilities and their QIN–QIOs would be able to download. Any potential future proposal to display the Facility Equity Score on the *Care Compare* or successor website would be made through future RFI or rulemaking.

c. Solicitation of Public Comment

We are soliciting public comments on the possibility of stratifying IPFQR Program measures by dual eligibility and race and ethnicity. We are also

soliciting public comments on mechanisms of incorporating co-occurring disability status into such stratification as well. We are soliciting public comments on the application of the within-facility or across-facility disparities methods IPFQR Program measures if we were to stratify IPFQR Program measures. We are also seeking comment on the possibility of facility collection of standardized demographic information for the purposes of potential future quality reporting and measure stratification. In addition, we are soliciting public comments on the potential design of a facility equity score for calculating results across multiple social risk factors and measures, including race and disability. Any data pertaining to these areas that are recommended for collection for measure reporting for a CMS program and any potential public disclosure on *Care Compare* or successor website would be addressed through a separate and future notice- and-comment rulemaking. We plan to continue working with ASPE, facilities, the public, and other key stakeholders on this important issue to identify policy solutions that achieve the goals of attaining health equity for all patients and minimizing unintended consequences. We look forward to receiving feedback on these topics. We also note our intention for additional RFIs or rulemaking on this topic in the future.

Specifically, we are soliciting public comment on the following:

Future Potential Stratification of Quality Measure Results

- The possible stratification of facility-specific reports for IPFQR program measure data by dual-eligibility status given that over half of the patient population in IPFs are dually eligible, including, which measures would be most appropriate for stratification;
- The potential future application of indirect estimation of race and ethnicity to permit stratification of measure data for reporting facility-level disparity results until more accurate forms of self-identified demographic information are available;
- Appropriate privacy safeguards with respect to data produced from the indirect estimation of race and ethnicity to ensure that such data are properly identified if/when it is shared with providers.
- Ways to address the challenges of defining and collecting accurate and standardized self-identified demographic information, including information on race and ethnicity and disability, for the purposes of reporting,

measure stratification and other data collection efforts relating to quality.

- Recommendations for other types of readily available data elements for measuring disadvantage and discrimination for the purposes of reporting, measure stratification and other data collection efforts relating to quality, in addition, or in combination with race and ethnicity.
- Recommendations for types of quality measures or measurement domains to prioritize for stratified reporting by dual eligibility, race and ethnicity, and disability.
- Examples of approaches, methods, research, and/or considerations for use of data-driven technologies that do not facilitate exacerbation of health inequities, recognizing that biases may occur in methodology or be encoded in datasets.

Improving Demographic Data Collection

- Experiences of users of certified health IT regarding local adoption of practices for collection of social, psychological, and behavioral data elements, the perceived value of using these data for improving decision-making and care delivery, and the potential challenges and benefits of collecting more granular, structured demographic information, such as the “Race & Ethnicity—CDC” code system.
- The possible collection of a minimum set of social, psychological, and behavioral data elements by hospitals at the time of admission using structured, interoperable data standards, for the purposes of reporting, measure stratification and other data collection efforts relating to quality.

Potential Creation of a Facility Equity Score To Synthesize Results Across Multiple Social Risk Factors

- The possible creation and confidential reporting of a Facility Equity Score to synthesize results across multiple social risk factors and disparity measures.
- Interventions facilities could institute to improve a low facility equity score and how improved demographic data could assist with these efforts.

E. Measure Adoption

We strive to put consumers and caregivers first, ensuring they are empowered to make decisions about their own healthcare along with their clinicians using information from data-driven insights that are increasingly aligned with meaningful quality measures. We support technology that reduces burden and allows clinicians to focus on providing high-quality healthcare for their patients. We also

support innovative approaches to improve quality, accessibility, and affordability of care while paying particular attention to improving clinicians' and beneficiaries' experiences when interacting with our programs. In combination with other efforts across the Department of Health and Human Services (HHS), we believe the IPFQR Program helps to incentivize facilities to improve healthcare quality and value while giving patients and providers the tools and information needed to make the best decisions for them. Consistent with these goals, our objective in selecting quality measures is to balance the need for information on the full spectrum of care delivery and the need to minimize the burden of data collection and reporting. We have primarily focused on measures that evaluate critical processes of care that have significant impact on patient outcomes and support CMS and HHS priorities for improved quality and efficiency of care provided by IPFs. When possible, we also propose to incorporate measures that directly evaluate patient outcomes and experience. We refer readers to section VIII.F.4.a. of the FY 2013 IPPS/LTCH PPS final rule (77 FR 53645 through 53646) for a detailed discussion of the considerations taken into account in selecting quality measures.

1. Measure Selection Process

Before being proposed for inclusion in the IPFQR Program, measures are placed on a list of measures under consideration (MUC), which is published annually on behalf of CMS by the National Quality Forum (NQF). Following publication on the MUC list, the Measure Applications Partnership (MAP), a multi-stakeholder group convened by the NQF, reviews the measures under consideration for the IPFQR Program, among other Federal programs, and provides input on those measures to the Secretary. We consider the input and recommendations provided by the MAP in selecting all measures for the IPFQR Program. In our evaluation of the IPFQR Program measure set, we identified two measures that we believe are appropriate to propose for the IPFQR Program.

2. Proposed Adoption of COVID-19 Vaccination Coverage Among Health Care Personnel (HCP)⁶⁷ Measure for the FY2023 Payment Determination and Subsequent Years

a. Background

On January 31, 2020, the Secretary declared a public health emergency (PHE) for the U.S. in response to the global outbreak of SARS-CoV-2, a novel (new) coronavirus that causes a disease named "coronavirus disease 2019" (COVID-19).⁶⁸ COVID-19 is a contagious respiratory illness⁶⁹ that can cause serious illness and death. Older individuals and those with underlying medical conditions are considered to be at higher risk for more serious complications from COVID-19.⁷⁰

As of April 2, 2021, the U.S. has reported over 30 million cases of COVID-19 and over 550,000 COVID-19 deaths.⁷¹ Hospitals and health systems saw significant surges of COVID-19 patients as community infection levels increased.⁷² From December 2, 2020 through January 30, 2021, more than 100,000 Americans were in the hospital with COVID-19 at the same time.⁷³

Evidence indicates that COVID-19 primarily spreads when individuals are in close contact with one another.⁷⁴ 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.⁷⁵ Thus, the CDC advises that infections mainly occur through exposure to respiratory droplets when a person is in close contact with someone who has COVID-19.⁷⁶ Experts believe that COVID-19 spreads less commonly through contact with a contaminated surface (although that is not thought to be a common way that COVID-19 spreads),⁷⁷ and that in certain circumstances, infection can occur through airborne transmission.⁷⁸ 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.⁷⁹ 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, or from patient to patient given the close contact that may occur during the provision of care.⁸⁰ The CDC has emphasized that health care settings, including long-term care settings, can be high-risk places for COVID-19 exposure and transmission.⁸¹

Vaccination is a critical part of the nation's strategy to effectively counter the spread of COVID-19 and ultimately help restore societal functioning.⁸² On

⁶⁷ This measure was previously titled, "SARS-CoV-2 Vaccination Coverage among Healthcare Personnel."

⁶⁸ 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>.

⁶⁹ 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>.

⁷⁰ 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>.

⁷¹ Centers for Disease Control and Prevention. (2020). CDC COVID Data Tracker. Accessed on April 3, 2021 at: https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days.

⁷² 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>.

⁷³ U.S. Currently Hospitalized | The COVID Tracking Project <https://covidtracking.com/data/charts/us-currently-hospitalized>.

⁷⁴ Centers for Disease Control and Prevention. (2021). How COVID-19 Spreads. Accessed on April 3, 2021 at: <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html>.

⁷⁵ Centers for Disease Control and Prevention. (2021). How COVID-19 Spreads. Accessed on April 3, 2021 at: <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html>.

⁷⁶ Centers for Disease Control and Prevention. (2021). How COVID-19 Spreads. Accessed on April 3, 2021 at: <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html>.

⁷⁷ Centers for Disease Control and Prevention. (2021). How COVID-19 Spreads. Accessed on April 3, 2021 at: <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html>.

⁷⁸ Centers for Disease Control and Prevention. (2021). How COVID-19 Spreads. Accessed on April 3, 2021 at: <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html>.

⁷⁹ Centers for Disease Control and Prevention. (2021). When to Quarantine. Accessed on April 3, 2021 at: <https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html>.

⁸⁰ 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 April 2, 2021 at: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/faq.html#Transmission>.

⁸¹ 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.

⁸² Centers for Disease Control and Prevention. (2020). COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations. Accessed on April 3, 2021 at: <https://www.cdc.gov/vaccines/imz->

December 11, 2020, the FDA issued the first Emergency Use Authorization (EUA) for a COVID-19 vaccine in the U.S.⁸³ Subsequently, the FDA issued EUAs for additional COVID-19 vaccines.⁸⁴

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.⁸⁵

As part of its national strategy to address COVID-19, the Biden 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.⁸⁶ 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 HCP providing direct care to patients with COVID-19, and individuals at highest risk for developing severe illness from COVID-19.⁸⁷ For example, the CDC's Advisory 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.⁸⁸ Research suggests most states followed this recommendation,⁸⁹ and HCP began receiving the vaccine in mid-December of 2020.⁹⁰

There are approximately 18 million healthcare workers in the U.S.⁹¹ As of April 3, 2021 the CDC reported that over 162 million doses of COVID-19 vaccine had been administered, and approximately 60 million people had received a complete vaccination course as described in IV.1.b.i of this proposed rule.⁹² President Biden indicated on March 2, 2021 that the U.S. is on track to have sufficient vaccine supply for every adult by the end of May 2021.⁹³

We believe it is important to require that IPFs report HCP vaccination in their facilities in order to assess whether they are taking steps to protect health care workers and to help sustain the ability of IPFs to continue serving their communities throughout the PHE and beyond. Therefore, we are proposing a new measure, COVID-19 Vaccination Coverage Among HCP, beginning with the FY 2023 program year. For that program year, IPFs would be required to report data on the measure for the fourth quarter of 2021 (October 1, 2021 through December 31, 2021). For more information about the proposed reporting period, see section V.E.2.c of

this proposed rule. The measure would assess the proportion of an IPF's health care workforce that has been vaccinated against COVID-19.

Although at this time data to show the effectiveness of COVID-19 vaccines to prevent asymptomatic infection or transmission of SARS-CoV-2 are limited, we believe IPFs should report the level of vaccination among their HCP as part of their efforts to assess and reduce the risk of transmission of COVID-19 within their facilities. HCP vaccination can potentially reduce illness that leads to work absence and limit disruptions to care.⁹⁴ Data from influenza vaccination demonstrates that provider uptake of the vaccine is associated with that provider recommending vaccination to patients,⁹⁵ and we believe HCP COVID-19 vaccination in IPFs could similarly increase uptake among that patient population. We also believe that publishing the HCP vaccination rates will 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 measure addresses the quality priority of "Promote Effective Prevention and Treatment of Chronic Disease" through the Meaningful Measure Area of "Preventive Care."

b. Overview of Measure

The COVID-19 Vaccination Coverage Among HCP measure ("COVID-19 HCP vaccination measure") is a process measure developed by the CDC to track COVID-19 vaccination coverage among HCP in facilities such as IPFs.

(1). Measure Specifications

The denominator is the number of HCP eligible to work in the IPF for at least 1 day during the reporting period, excluding persons with contraindications to COVID-19 vaccination that are described by the CDC.⁹⁶

The numerator is the cumulative number of HCP eligible to work in the health care facility for at least 1 day

managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf.

⁸³ 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>.

⁸⁴ U.S. Food and Drug Administration. (2020). Moderna COVID-19 Vaccine EUA Letter of Authorization. Available at <https://www.fda.gov/media/144636/download>; U.S. Food and Drug Administration. (2021). Janssen COVID-19 Vaccine EUA Letter of Authorization. Available at <https://www.fda.gov/media/146303/download>.

⁸⁵ 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> and S. Food and Drug Administration. (2020). Moderna COVID-19 Vaccine EUA Letter of Authorization. Available at <https://www.fda.gov/media/144636/download>; U.S. Food and Drug Administration. (2021). Janssen COVID-19 Vaccine EUA Letter of Authorization. Available at <https://www.fda.gov/media/146303/download>.

⁸⁶ <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/>.

⁸⁷ Health and Human Services, Department of Defense. (2020) From the Factory to the Frontlines: The Operation Warp Speed 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.

⁸⁸ 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.

⁸⁹ 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/>.

⁹⁰ Associated Press. "Healing is Coming: U.S. Health Workers Start Getting Vaccine. December 15, 2020. Accessed on December 16 at: <https://apnews.com/article/us-health-workers-coronavirus-vaccine-56df745388a9fc12ae93c6f9a0d0e81f>.

⁹¹ <https://www.cdc.gov/niosh/topics/healthcare/default.html#:~:text=HEALTHCARE%20WORKERS,-Related%20Pages&text=Healthcare%20is%20the%20fastest%20growing,of%20the%20healthcare%20work%20force>

⁹² CDC. COVID Data Tracker. COVID-19 Vaccinations in the United States. Accessed on 2/18/21 at: <https://covid.cdc.gov/covid-data-tracker/#vaccinations>.

⁹³ The White House. Remarks by President Biden on the Administration's COVID-19 Vaccination Efforts. Accessed March 18, 2021 at: <https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/03/02/remarks-by-president-biden-on-the-administrations-covid-19-vaccination-efforts/>.

⁹⁴ Centers for Disease Control and Prevention. Overview of Influenza Vaccination among Health Care Personnel. October 2020. (2020) Accessed March 16, 2021 at: <https://www.cdc.gov/flu/toolkit/long-term-care/why.htm>.

⁹⁵ Measure Application Committee Coordinating Committee Meeting Presentation. March 15, 2021. (2021) Accessed March 16, 2021 at: http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx.

⁹⁶ Centers for Disease Control and Prevention. Contraindications and precautions. <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Contraindications>.

during the reporting period and who received a completed vaccination course against COVID-19 since the vaccine was first available or on a repeated interval if revaccination on a regular basis is needed.⁹⁷ Vaccination coverage for the purposes of this measure is defined as the estimated percentage of HCP eligible to work at the IPF for at least 1 day who received a completed vaccination course. A completed vaccination course may require one or more doses depending on the EUA for the specific vaccine used.

The finalized specifications for this measure will be available at <https://www.cdc.gov/nhsn/nqf/index.html>.

(2). Review by the Measure Applications Partnership

The COVID-19 HCP vaccination measure was included on the publicly available “List of Measures under Consideration for December 21, 2020,”⁹⁸ a list of measures under consideration for use in various Medicare programs. When the Measure Applications Partnership (MAP) Hospital Workgroup convened on January 11, 2021, it reviewed the MUC List and the COVID-19 HCP vaccination 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 IPFQR Program measure set by providing transparency about an important COVID-19 intervention to help prevent infections in HCP and patients.⁹⁹ The MAP also stated that collecting information on COVID-19 vaccination coverage among HCP and providing feedback to facilities will allow facilities to benchmark coverage rates and improve coverage in their facility, and that reducing rates of COVID-19 in HCP may reduce transmission among patients and reduce instances of staff shortages due to illness.¹⁰⁰

In its preliminary recommendations, the MAP Hospital Workgroup did not support this measure for rulemaking,

⁹⁷ Measure Application Partnership Coordinating Committee Meeting Presentation. March 15, 2021. (2021) Accessed March 16, 2021 at: http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx.

⁹⁸ <https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94212>.

⁹⁹ Measure Applications Partnership. MAP Preliminary Recommendations 2020–2021. Accessed on January 24, 2021 at: http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx.

¹⁰⁰ Measure Applications Partnership. MAP Preliminary Recommendations 2020–2021. Accessed on January 24, 2021 at: http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx.

subject to potential for mitigation.¹⁰¹ To mitigate its concerns, the MAP believed that the measure needed well-documented evidence, finalized specifications, testing, and NQF endorsement prior to implementation.¹⁰² Subsequently, the MAP Coordinating Committee met on January 25, 2021, and reviewed the COVID-19 Vaccination Coverage Among HCP measure. In the 2020–2021 MAP Final Recommendations, the MAP offered conditional support for rulemaking contingent on CMS bringing the measures back to MAP once the specifications are further refined.¹⁰³ The MAP specifically stated, “the incomplete specifications require immediate mitigation and further development should continue.”¹⁰⁴ The spreadsheet of final recommendations no longer cited concerns regarding evidence, testing, or NQF endorsement.¹⁰⁵ In response to the MAP final recommendation request that CMS bring the measure back to the MAP once the specifications are further refined, CMS and the CDC met with MAP Coordinating committee on March 15th. Additional information was provided to address vaccine availability, alignment of the COVID-19 Vaccination Coverage Among HCP as closely as possible with the data collection for the Influenza HCP vaccination measure (NQF 0431) and clarification related to how HCP are defined. At this meeting, CMS and the CDC presented preliminary findings from the testing of the numerator of COVID-19 Vaccination Coverage Among HCP, which is currently in process. These preliminary findings show numerator data should be feasible and reliable. Testing of the numerator of the number of healthcare personnel vaccinated involves a comparison of the data collected through NHSN and independently reported through the Federal pharmacy partnership program for delivering vaccination to LTC facilities. These are two completely

¹⁰¹ Measure Applications Partnership. MAP Preliminary Recommendations 2020–2021. Accessed on January 24, 2021 at: http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx.

¹⁰² Measure Applications Partnership. MAP Preliminary Recommendations 2020–2021. Accessed on January 24, 2021 at: http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx.

¹⁰³ Measure Applications Partnership. 2020–2021 MAP Final Recommendations. Accessed on February 3, 2021 at: http://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx.

¹⁰⁴ Measure Applications Partnership. 2020–2021 MAP Final Recommendations. Accessed on February 23, 2021 at: http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx.

¹⁰⁵ *Ibid*.

independent data collection systems. In initial analyses of the first month of vaccination, the number of healthcare workers vaccinated in approximately 1,200 facilities, which had data from both systems the number of healthcare personnel vaccinated was highly correlated between these 2 systems with a correlation coefficient of nearly 90 percent in the second two weeks of reporting.¹⁰⁶ The MAP further noted that the measure would add value to the program measure set by providing visibility into an important intervention to limit COVID-19 infections in healthcare personnel and the patients for whom they provide care.¹⁰⁷

We value the recommendations of the MAP and considered these recommendations carefully. Section 1890A(a)(4) of the Act requires the Secretary to take into consideration input from multi-stakeholder groups in selecting certain quality and efficiency measures. While we value input from the MAP, we believe it is important to propose the measure as quickly as possible to address the urgency of the COVID-19 PHE and its impact on vulnerable populations, including IPFs. CMS continues to engage with the MAP to mitigate concerns and appreciates the MAP’s conditional support for the measure.

(3). NQF Endorsement

Under section 1886(s)(4)(D)(i) of the Act, unless the exception of clause (ii) applies, measures selected for the quality reporting program must have been endorsed by the entity with a contract under section 1890(a) of the Act. The NQF currently holds this contract. Section 1886(s)(4)(D)(ii) of the Act provides an exception to the requirement for NQF endorsement of measures: 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.

This measure is not NQF endorsed and has not been submitted to NQF for

¹⁰⁶ For more information on testing results and other measure updates, please see the Meeting Materials (including Agenda, Recording, Presentation Slides, Summary, and Transcript) of the March 15, 2021 meeting available at <https://www.qualityforum.org/ProjectMaterials.aspx?projectId=75367>.

¹⁰⁷ Measure Applications Partnership. 2020–2021 MAP Final Recommendations. Accessed on February 23, 2021 at: http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx.

endorsement consideration. CMS will consider the potential for future NQF endorsement as part of its ongoing work with the MAP.

Because this measure is not NQF-endorsed, we considered other available measures. We found no other feasible and practical measures on the topic of COVID-19 vaccination among HCP, therefore, we believe the exception in Section 1186(s)(4)(D)(ii) of the Act applies.

c. Data Collection, Submission and Reporting

Given the time-sensitive nature of this measure considering the PHE, we are proposing that IPFs would be required to begin reporting data on the proposed COVID-19 Vaccination Coverage Among HCP measure beginning October 1, 2021 for the FY 2023 IPFQR Program year. Thereafter, we propose annual reporting periods.

To report this measure facilities would report COVID-19 vaccination data to the NHSN for at least one week each month, beginning in October 2021 for the October 1, 2021 through December 31, 2021 reporting period affecting FY 2023 payment determination and continuing for each quarter in subsequent years. For more details on data submission, we refer readers to section V.J.2.a of this proposed rule.

If our proposal to adopt this measure is finalized, IPFs would report the measure through the CDC National Healthcare Safety Network (NHSN) web-based surveillance system.¹⁰⁸ While the IPFQR Program does not currently require use of the NHSN web-based surveillance system, we have previously required use of this system. We refer readers to the FY 2015 IPF PPS final rule in which we adopted the Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) measure for additional information on reporting through the NHSN web-based surveillance system (79 FR 45968 through 45970).

IPFs would report COVID-19 vaccination data in the NHSN Healthcare Personnel Safety (HPS) Component by reporting the number of HCP eligible to have worked at the facility that week (denominator) and the number of those HCP who have received a completed vaccination course of a COVID-19 vaccination (numerator). For additional information about the data

reporting requirements, see V.J.4. of this proposed rule.

We invite public comment on our proposal to add a new measure, COVID-19 Vaccination Coverage Among HCP, to the IPFQR Program for the FY 2023 payment determination and subsequent years.

3. Proposed Adoption of the Follow-Up After Psychiatric Hospitalization (FAPH) Measure for the FY 2024 Payment Determination and Subsequent Years

a. Background

We are proposing one new measure, Follow-Up After Psychiatric Hospitalization (FAPH), for the FY 2024 payment determination and subsequent years. The FAPH measure would use Medicare fee-for-service (FFS) claims to determine the percentage of inpatient discharges from an inpatient psychiatric facility (IPF) stay with a principal diagnosis of select mental illness or substance use disorders (SUDs) for which the patient received a follow-up visit for treatment of mental illness or SUD. Two rates would be calculated for this measure: (1) The percentage of discharges for which the patient received follow-up within 7 days of discharge, and; (2) the percentage of discharges for which the patient received follow-up within 30 days of discharge.

The proposed FAPH measure is an expanded and enhanced version of the Follow-Up After Hospitalization for Mental Illness (FUH, NQF #0576) measure currently in the IPFQR Program. We are proposing to adopt the FAPH measure and replace the FUH measure and refer readers to section IV.F.2.d of this proposed rule for our proposal to remove the FUH measure contingent on adoption of the FAPH measure. The FUH (NQF #0576) measure uses Medicare FFS claims to determine the percentage of inpatient discharges from an IPF stay with a principal diagnosis of select mental illness diagnoses for which the patient received a follow-up visit for treatment of mental illness, and it excludes patients with primary substance use diagnoses. During the 2017 comprehensive review of NQF #0576, the NQF Behavioral Health Standing Committee (BHSC) recommended expanding the measure population to include patients hospitalized for drug and alcohol disorders, because these patients also require follow-up care after they are discharged. In 2018, CMS began development of a measure to expand the IPFQR FUH population to include patients with principal SUD diagnoses

to address the NQF BHSC recommendation and the CMS Meaningful Measures priority to promote treatment of SUDs. The FAPH measure would expand the number of discharges in the denominator by about 35 percent over the current FUH measure by adding patients with SUD or dementia, populations that also benefit from timely follow-up care.

Furthermore, compared to the criteria for provider type in the current FUH measure, the FAPH measure does not limit the provider type for the follow-up visit if it is billed with a diagnosis of mental illness or SUD. During the measure's testing, the most frequent provider types for the FAPH measure were family or general practice physicians, internal medicine physicians, nurse practitioners, and physician assistants. The technical expert panel (TEP) convened by our contractor agreed that these provider types should be credited by the measure for treating mental illness and SUD and confirmed that this is aligned with integrated care models that aim to treat the whole patient. The TEP further noted that in areas where there are shortages of mental health or SUD clinicians, other types of providers are often the only choice for follow-up treatment. Allowing visits to these types of providers to count towards the numerator allows the measure to capture the rates of appropriate follow-up care more accurately in areas with provider shortages.

Performance on the FAPH measure indicates that follow-up rates for patients hospitalized with mental illness or SUD are less than optimal and that room for improvement is ample. The clinical benefits of timely follow-up care after hospitalization, including reduced risk of readmission and improved adherence to medication, are well-documented in the published literature.^{109 110 111 112 113 114 115}

¹⁰⁹ Tong, L., Arnold, T., Yang, J., Tian, X., Erdmann, C., & Esposito, T. (2018). The association between outpatient follow-up visits and all-cause non-elective 30-day readmissions: A retrospective observational cohort study. *PLoS one*, 13(7), e0200691. <https://doi.org/10.1371/journal.pone.0200691>.

¹¹⁰ Terman, S.W., Reeves, M.J., Skolarus, L.E., & Burke, J.F. (2018). Association Between Early Outpatient Visits and Readmissions After Ischemic Stroke. *Circulation. Cardiovascular quality and outcomes*, 11(4), e004024. <https://doi.org/10.1161/CIRCOUTCOMES.117.004024>.

¹¹¹ First Outpatient Follow-Up After Psychiatric Hospitalization: Does One Size Fit All? (2014). *Psychiatric Services*, 66(6), 364–372. <https://doi.org/10.1176/appi.ps.201400081>.

¹¹² Terman, S.W., Reeves, M.J., Skolarus, L.E., & Burke, J.F. (2018). Association Between Early Outpatient Visits and Readmissions After Ischemic Stroke. *Circulation. Cardiovascular quality and*

¹⁰⁸ 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.

Behavioral health patients in particular have a number of risk factors that underscore the need for timely follow-up and continuity of care: Behavioral health patients have higher baseline hospitalization rates, higher hospital readmission rates, and higher health care costs as compared with the general population of patients.^{116 117} Among patients with serious mental illness, 90 percent have comorbid clinical conditions such as hypertension, cardiovascular disease, hyperlipidemia, or diabetes.¹¹⁸ Among patients hospitalized for general medical conditions, those who also have a mental illness are 28 percent more likely to be readmitted within 30 days than their counterparts without a psychiatric comorbidity.¹¹⁹ The high prevalence of clinical comorbidities among behavioral health patients, combined with the compounding effect of mental illness on patients with general medical conditions, suggests that behavioral health patients are uniquely vulnerable and supports the intent of the measure to increase follow-up after hospitalization.

In addition, clinical practice guidelines stress the importance of continuity of care between settings for patients with mental illness and SUD. For the treatment of SUD patients, the 2010 guidelines of the American

Psychiatric Association (APA) state: “It is important to intensify the monitoring for substance use during periods when the patient is at a high risk of relapsing, including during the early stages of treatment, times of transition to less intensive levels of care, and the first year after active treatment has ceased.”¹²⁰ This statement is accompanied by a grade of [I], which indicates the highest level of APA endorsement: “recommended with substantial clinical evidence.”

Evidence supports that outpatient follow-up care and interventions after hospital discharges are associated with a decreased risk of readmissions for patients with mental illness.^{121 122} IPFs can influence rates of follow-up care for patients hospitalized for mental illness or SUD. Three studies reported that with certain interventions—such as pre-discharge transition interviews, appointment reminder letters or reminder phone calls, meetings with outpatient clinicians before discharge, and meetings with inpatient staff familiar to patients at the first post-discharge appointment—facilities achieved 30-day follow-up rates of 88 percent or more.^{123 124 125} This is substantially higher than the national rate of about 52 percent observed in the current FUH measure for Medicare FFS discharges between July 1, 2016, and June 30, 2017.¹²⁶ Medicare FFS data from July 1, 2016, to June 30, 2017,

show the national 7-day follow-up rate to be 35.5 percent and the 30-day rate to be 61.0 percent. These data reveal wide variation in follow-up rates across facilities, with a 16.9 percent absolute difference between the 25th and 75th percentiles for the 7-day rate and a 17.4 percent absolute difference for the 30-day rate. If all facilities achieved the benchmark follow-up rates for their Medicare FFS patients (as calculated using the AHRQ Achievable Benchmarks of Care method),¹²⁷ 53,841 additional discharges would have a 7-day follow-up visit, and 47,552 would have a 30-day follow-up visit.¹²⁸

During the development process, we used the CMS Quality Measures Public Comment Page to ask for public comments on the measure.¹²⁹ We accepted public comments from Friday, January 25, 2019, to Wednesday, February 13, 2019. During this period, we received comments from 29 organizations or individuals. Many commenters acknowledged the importance of developing a measure that assesses acute care providers for follow-up post-hospitalization. Some commenters expressed skepticism about the measure’s appropriateness as a tool for evaluating the performance of discharging IPFs due to factors beyond the IPFs’ control that can affect whether a patient receives timely post-discharge follow-up care. Ten stakeholders expressed support for the measure based on the expanded list of qualifying diagnoses in the denominator and the inclusion of more patients who could benefit from post-discharge follow-up visits.¹³⁰

We reviewed the comments we received with the TEP, whose members shared similar feedback regarding the importance of follow-up for patients with both mental health diagnoses and substance use disorders, as well as concerns about the ability of IPFs to influence follow-up care. We agree with commenters that some factors that influence follow-up are outside of a facility’s control. However, as described, in section IV.E.3.a, we believe that there are interventions (such as pre-discharge transition interviews, appointment reminder letters or reminder phone calls, meetings with outpatient

outcomes, 11(4), e004024. <https://doi.org/10.1161/CIRCOUTCOMES.117.004024>.

¹¹³ Jackson, C., Shahsahebi, M., Wedlake, T., & DuBard, C.A. (2015). Timeliness of outpatient follow-up: An evidence-based approach for planning after hospital discharge. *Annals of family medicine*, 13(2), 115–122. <https://doi.org/10.1370/afm.1753>.

¹¹⁴ Hernandez, A.F., Greiner, M.A., Fonarow, G.C., Hammill, B.G., Heidenreich, P.A., Yancy, C.W., Peterson, E.D., & Curtis, L.H. (2010). Relationship between early physician follow-up and 30-day readmission among Medicare beneficiaries hospitalized for heart failure. *JAMA*, 303(17), 1716–1722. <https://doi.org/10.1001/jama.2010.533>.

¹¹⁵ Nadereh Pourat, Xiao Chen, Shang-Hua Wu and Anna C. Davis. Timely Outpatient Follow-up Is Associated with Fewer Hospital Readmissions among Patients with Behavioral Health Conditions. *The Journal of the American Board of Family Medicine*. May 2019, 32 (3) 353–361; DOI: <https://doi.org/10.3122/jabfm.2019.03.180244>.

¹¹⁶ Germack, H.D., et al. (2019, January). Association of comorbid serious mental illness diagnosis with 30-day medical and surgical readmissions. *JAMA Psychiatry*.

¹¹⁷ First Outpatient Follow-Up After Psychiatric Hospitalization: Does One Size Fit All? (2014). *Psychiatric Services*, 66(6), 364–372. <https://doi.org/10.1176/appi.ps.201400081>.

¹¹⁸ First Outpatient Follow-Up After Psychiatric Hospitalization: Does One Size Fit All? (2014). *Psychiatric Services*, 66(6), 364–372. <https://doi.org/10.1176/appi.ps.201400081>.

¹¹⁹ Benjenk, I., & Chen, J. (2018). Effective mental health interventions to reduce hospital readmission rates: A systematic review. *Journal of hospital management and health policy*, 2, 45. <https://doi.org/10.21037/jhmp.2018.08.05>.

¹²⁰ American Psychiatric Association. Practice guideline for the treatment of patients with substance use disorders. 2010. http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/substanceuse.pdf.

¹²¹ Kurdyak P, Vigod SN, Newman A, Giannakeas V, Mulsant BH, Stukel T. Impact of Physician Follow-Up Care on Psychiatric Readmission Rates in a Population-Based Sample of Patients With Schizophrenia. *Psychiatr Serv*. 2018;69(1):61–68. doi: 10.1176/appi.ps.201600507.

¹²² Marcus SC, Chuang CC, Ng-Mak DS, Olfson M. Outpatient follow-up care and risk of hospital readmission in schizophrenia and bipolar disorder. *Psychiatr Serv*. 2017;68(12):1239–1246. doi: 10.1176/appi.ps.201600498.

¹²³ Batscha C, McDevitt J, Weiden P, Dancy B. The effect of an inpatient transition intervention on attendance at the first appointment post discharge from a psychiatric hospitalization. *J Am Psychiatr Nurses Assoc*. 2011;17(5):330–338. doi: 10.1177/1078390311417307.

¹²⁴ Agarin T, Okorafor E, Kailasam V, et al. Comparing kept appointment rates when calls are made by physicians versus behavior health technicians in inner city hospital: Literature review and cost considerations. *Community Ment Health J*. 2015;51(3):300–304. doi: 10.1007/s10597-014-9812-x.

¹²⁵ Olfson M, Mechanic D, Boyer CA, Hansell S. Linking inpatients with schizophrenia to outpatient care. *Psychiatr Serv*. 1998;49(7):911–917. doi: 10.1176/ps.49.7.911. Quality AFHRA. 2017 National Healthcare Quality and Disparities Report. Rockville, MD: Services USDoHaH; 2018.

¹²⁶ <https://data.cms.gov/provider-data/archived-data/hospitals/>.

¹²⁷ <https://nhqrnet.ahrq.gov/inhqrdr/resources/methods#Benchmarks>.

¹²⁸ Quality AFHRA. 2017 National Healthcare Quality and Disparities Report. Rockville, MD: Services USDoHaH; 2018.

¹²⁹ <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/IPF-Follow-Up-After-Psychiatric-Hospitalization-Public-Comment-Summary.pdf>.

¹³⁰ Mathematica. FAPH public comment summary. April 2019.

clinicians before discharge, and meetings with inpatient staff familiar to patients at the first post-discharge appointment) that allow facilities to improve their follow-up adherence. We remain committed to monitoring follow-up to improve health outcomes and view this measure as an expansion of our ability to measure appropriate follow-up care established by FUH.

b. Overview of Measure

(1). Measure Calculation

The FAPH measure would be calculated by dividing the number of discharges that meet the numerator criteria by the number that meet the denominator criteria. Two rates are reported for this measure: The 7-day rate and the 30-day rate.

(a) Numerator

The first rate that would be reported for this measure includes discharges from a psychiatric facility that are followed by an outpatient visit for treatment of mental illness or SUD within 7 days. The second rate reported for this measure would include discharges from a psychiatric facility that are followed by an outpatient visit for treatment of mental illness or SUD within 30 days. Outpatient visits are defined as outpatient visits, intensive outpatient encounters, or partial hospitalization and are defined by the Current Procedural Terminology (CPT), Healthcare Common Procedure Coding System (HCPCS), and Uniform Billing (UB) Revenue codes. Claims with codes for emergency room visits do not count toward the numerator.

(b) Denominator

The denominator includes discharges paid under the IPF prospective payment system during the performance period for Medicare FFS patients with a principal diagnosis of mental illness or SUD. Specifically, the measure includes IPF discharges for which the patient was:

- Discharged with a principal diagnosis of mental illness or SUD that would necessitate outpatient follow-up care,
- Alive at the time of discharge,
- Enrolled in Medicare Parts A and B during the month of the discharge date and at least one month after the discharge date to ensure that data are available to capture the index admission and follow-up visits, and
- Age 6 or older on the date of discharge, because follow-up treatment for mental illness or SUD might not always be recommended for younger children.

The denominator excludes IPF discharges for patients who:

- Were admitted or transferred to acute and non-acute inpatient facilities within the 30-day follow-up period, because admission or transfer to other institutions could prevent an outpatient follow-up visit from taking place,
- Were discharged against medical advice, because the IPF could have limited opportunity to complete treatment and prepare for discharge,
- Died during the 30-day follow-up period, or
- Use hospice services or elect to use a hospice benefit at any time during the measurement year regardless of when the services began, because hospice patients could require different follow-up services.

The FAPH measure differs from FUH mostly in the expansion of the measure population to include SUD and other mental health diagnoses in the measure's denominator, but it includes some additional differences:

- The FAPH measure simplifies the exclusion of admission or transfer to acute or non-acute inpatient facilities within 30 days after discharge by aligning with the HEDIS® Inpatient Stay Value Set used in both the HEDIS® FUH and the HEDIS® Follow-Up After Emergency Department Visit for Alcohol and Other Drug Abuse or Dependence (FUA) measures to identify acute and non-acute inpatient stays. A discharge is excluded from the FAPH measure if it is followed by an admission or a transfer with one of the codes in the value set.
- The FAPH measure uses Medicare UB Revenue codes (rather than inpatient discharge status code, which the FUH measure uses) to identify discharge or transfer to other health care institutions. This is to align better with the intent of the HEDIS® FUH and HEDIS® FUA measures.
- The FAPH measure allows mental illness or SUD diagnoses in any position on the follow-up visit claim to count toward the numerator and does not require that it be in the primary position as the FUH measure does.

(2) Measure Reliability and Validity

In 2019, CMS used the final measure specifications to complete reliability and validity testing, which revealed that the FAPH measure provides reliable and valid facility-level rates of follow-up after psychiatric hospitalization. We evaluated measure reliability based on a signal-to-noise analysis,¹³¹ in which a score of 0.0 implies that all variation is

¹³¹ For additional information on reliability tests see http://www.qualityforum.org/Measuring_Performance/Improving_NQF_Process/Measure_Testing_Task_Force_Final_Report.aspx.

attributed to measurement error (noise), and a score of 1.0 implies that all measure score variation is caused by a real difference in performance across IPFs. Using that approach, we established a minimum denominator size of 40 discharges to attain an overall reliability score of 0.7 for both the 7-day and the 30-day rate. These analyses revealed that the measure can reliably distinguish differences in performance between IPFs with adequate denominator size.

We evaluated the validity of the measure based on its correlation to two conceptually related measures in the IPFQR Program: The 30-Day All-Cause Unplanned Readmission After Psychiatric Discharge from an IPF (IPF Readmission) measure, and the Medication Continuation Following Inpatient Psychiatric Discharge (Medication Continuation) measure. We observed a weak negative correlation between FAPH and the IPF Readmission measure for both 7-day (-0.11) and 30-day (-0.18) measure rates. This negative correlation is expected because a higher score is indicative of better quality of care for the FAPH, while a lower score is indicative of better quality of care for the IPF readmission measure (that is, a lower rate of unplanned readmissions). High rates of follow-up after visits after discharge and low rates of unplanned readmissions both indicate good care coordination during the discharge process. We observed a weak positive correlation between the 7-day FAPH measure rate and the Medication Continuation measure (0.32), and between the 30-day FAPH measure rate and the Medication Continuation measure (0.42). This result is expected because for both the FAPH and the Medication Continuation measures higher scores are indicative of better-quality care. Follow-up visits after discharge and continuation of medication after discharge both indicate good care coordination during the discharge process. After reviewing these results and the proposed measure specifications, all 13 TEP members who were present agreed that the measure had face validity.¹³²

¹³² Face validity is defined as a subjective determination by experts that the measure appears to reflect quality of care, done through a systematic and transparent process, that explicitly addresses whether performance scores resulting from the measure as specified can be used to distinguish good from poor quality, with degree of consensus and any areas of disagreement provided/discussed: https://www.qualityforum.org/Measuring_Performance/Scientific_Methods_Panel/Docs/Evaluation_Guidance.aspx.

(3) Review by the Measure Applications Partnership and NQF

Under section 1890A(a)(2) of the Act, this measure was included in a publicly available document: “List of Measures Under Consideration for December 1, 2019,” available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Downloads/Measures-under-Consideration-List-for-2018.pdf>.

On January 15, 2020, the MAP Coordinating Committee rated the measure as “Conditional Support for Rulemaking” contingent upon NQF endorsement. We submitted the measure to the NQF for endorsement in the spring 2020 cycle. However, some members of the NQF Behavioral Health and Substance Use Standing Committee were concerned about the measure’s exclusions for patients who died during the 30-day follow-up period or who were transferred. In addition, some members objected to combining persons with a diagnosis of SUD and those with a diagnosis for a mental health disorder into a single measure of follow-up care. Therefore, the NQF declined to endorse this measure. We noted that the exclusions for patients who died or who were admitted or transferred to an acute or non-acute inpatient facility during the 30-day follow up period align with the FUH measure currently in the IPFQR Program.

Section 1886(s)(4)(D)(ii) of the Act authorizes the Secretary to specify a measure for the IPFQR Program that is not endorsed by NQF. The exception to the requirement to specify an endorsed measure states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization.

The FAPH measure is not NQF endorsed. We have reviewed NQF-endorsed and other consensus-endorsed measures related to follow-up care and identified the FUH measure (NQF #0576) currently in the IPFQR Program and Continuity of Care after Inpatient or Residential Treatment for SUD (NQF #3453). We believe that the FAPH measure is an improvement over the current FUH measure and over the Continuity of Care after Inpatient or Residential Treatment of Substance Use Disorder because we believe that it is

important to ensure appropriate access to follow-up treatment for the largest patient population possible and the FAPH measure applies to a larger patient population than either of the measures we considered. Therefore, we propose to adopt the FAPH measure described in this section for the FY 2024 payment determination and subsequent years.

c. Data Collection, Submission and Reporting

FAPH uses Medicare FFS Part A and Part B claims that are received by Medicare for payment purposes. The measure links Medicare FFS claims submitted by IPFs and subsequent outpatient providers for Medicare FFS IPF discharges. Therefore, no additional data collection would be required from IPFs. For additional information on data submission for this measure, see section IV.J.2.b of this proposed rule. The performance period used to identify cases in the denominator is 12 months. Data from this period and 30 days afterward are used to identify follow-up visits in the numerator. Consistent with other claims-based measures in the IPFQR Program, the performance period for this measure is July 1 through June 30. For example, for the FY 2024 payment determination, the performance period will include discharges between July 1, 2021 and June 30, 2022.¹³³

We invite public comment on our proposal to add a new measure, Follow-Up After Psychiatric Hospitalization, to the IPFQR Program, beginning with the FY 2024 payment determination and subsequent years.

F. Removal or Retention of IPFQR Program Measures

1. Background

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38463 through 38465), we adopted considerations for removing or retaining measures within the IPFQR Program and criteria for determining when a measure is “topped out.” In the FY 2019 IPF PPS final rule (83 FR 38591 through 38593), we adopted one additional measure removal factor. We are not proposing any changes to these removal factors, topped-out criteria, or retention factors and refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38463 through 38465) and the FY 2019 IPF PPS final rule (83 FR 38591

¹³³ If data availability or operational issues prevent use of this performance period, we would announce the updated performance period through subregulatory communications including announcement on a CMS website and/or on our applicable listservs.

through 38593) for more information. We will continue to retain measures from each previous year’s IPFQR Program measure set for subsequent years’ measure sets, except when we specifically propose to remove or replace a measure. We will continue to use the notice-and-comment rulemaking process to propose measures for removal or replacement, as we described upon adopting these factors in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38464 through 38465).

In our continual evaluation of the IPFQR Program measure set under our Meaningful Measures Framework and according to our measure removal and retention factors, we identified four measures that we believe are appropriate to propose removing from the IPFQR Program for the FY 2024 payment determination and subsequent years. Our discussion of these measures follows.

2. Measures for Removal

a. Proposal To Remove Alcohol Use Brief Intervention Provided or Offered and Alcohol Use Brief Intervention (SUB–2/2a) Beginning With FY 2024 Payment Determination

We are proposing to remove the Alcohol Use Brief Intervention Provided or Offered and Alcohol Use Brief Intervention (SUB–2/2a) measure from the IPFQR Program beginning with the FY 2024 payment determination under our measure removal Factor 8, “The costs associated with a measure outweigh the benefit of its continued use in the program.” We adopted the Alcohol Use Brief Intervention Provided or Offered and Alcohol Use Brief Intervention (SUB–2/2a) measure in the FY 2016 IPF PPS final rule (80 FR 46699 through 46701) because we believe it is important to address the common comorbidity of alcohol use among IPF patients. This measure requires facilities to chart-abstract measure data on a sample of IPF patient records, in accordance with established sampling policies (80 FR 46717 through 46719).

We have previously stated our intent to move away from chart-abstracted measures to reduce information collection burden in this and other CMS quality programs (78 FR 50808; 79 FR 50242; 80 FR 49693). When we adopted the SUB–2/2a measure to the IPFQR Program, the benefits of this measure were high because facility performance was not consistent. Therefore, the measure provided a means of distinguishing facility performance and incentivized facilities to improve rates of treatment for this common comorbidity. Between the FY 2018

payment determination (the first year that SUB–2/2a was included in the IPFQR Program measure set) and the FY 2019 payment determination, we saw substantial performance improvement on the SUB–2 measure (which is the portion of the SUB–2/2a measure that assess whether the facility provided or offered a brief intervention for alcohol use). However, for the FY 2019 and FY 2020 payment determinations, that

improvement has leveled off to consistently high performance, as indicated in Table 2. These data further show that at this time there is little room for improvement in the SUB 2 measure, and that the quality improvement benefits from the measure have greatly diminished. We continue to believe that alcohol use is an important comorbidity to address in the IPF setting, and that brief interventions are

a key component of addressing this comorbidity. However, based on these data, we believe that most IPFs routinely offer alcohol use brief interventions, and that IPFs will continue to offer these interventions to patients, regardless of whether the SUB–2/2a measure is in the IPFQR Program measure set, because it has become an embedded part of their clinical workflows.

TABLE 2—PERFORMANCE ANALYSIS FOR ALCOHOL USE BRIEF INTERVENTION PROVIDED OR OFFERED (SUB–2)

Year	Mean	Median	75th percentile	90th percentile	Truncated coefficient of variation (TCV)
2016 (2018 Payment Determination)	66.96	77	96	100	0.49
2017 (2019 Payment Determination)	77.11	88	99	100	0.28
2018 (2020 Payment Determination)	79.49	91	100	100	0.25

While the measure does not meet our criteria for “topped-out” status because of the TCV higher than 0.1, we believe that this measure no longer meaningfully supports the program objectives of informing beneficiary choice and driving improvement in IPF interventions for alcohol use because it is no longer showing significant improvement in facility performance (that is, in providing or offering alcohol use brief interventions). Furthermore, as we stated in the FY 2019 IPF PPS final rule, costs are multi-faceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining the program (83 FR 38592). For example, it may be costly for health care providers to maintain general administrative knowledge to report this measure. Additionally, CMS must expend resources in maintaining information collection systems, analyzing reported data, and providing public reporting of the collected information.

Here, IPF information collection burden and related costs associated with reporting the SUB 2/2a measure to CMS are high because it is a chart-abstracted measure. Furthermore, CMS incurs costs associated with the program oversight of the measure for public display. As a result, we believe that the costs and burdens associated with this chart-abstracted measure outweigh the benefit of its continued use in the program.

Therefore, we are proposing to remove the Alcohol Use Brief

Intervention Provided or Offered and Alcohol Use Brief Intervention (SUB–2/2a) measure from the IPFQR Program beginning with the FY 2024 payment determination. We welcome public comments on our proposal to remove the SUB–2/2a measure from the IPFQR Program.

b. Proposal To Remove Tobacco Use Brief Intervention Provided or Offered and Tobacco Use Brief Intervention (TOB–2/2a) Beginning With FY 2024 Payment Determination

We are proposing to remove the Tobacco Use Brief Intervention Provided or Offered and Tobacco Use Brief Intervention (TOB–2/2a) measure from the IPFQR Program beginning with the FY 2024 payment determination under our measure removal Factor 8, “The costs associated with a measure outweigh the benefit of its continued use in the program.” We adopted the Tobacco Use Brief Intervention Provided or Offered and Tobacco Use Brief Intervention (TOB–2/2a) measure in the FY 2015 IPF PPS final rule (79 FR 45971 through 45972) because we believe it is important to address the common comorbidity of tobacco use among IPF patients. Like SUB–2/2a described in the previous subsection, this measure requires facilities to chart-abstract measure data on a sample of IPF patient records, in accordance with established sampling policies (80 FR 46717 through 46719). When we introduced the TOB–2/2a measure to

the IPFQR Program, the benefits of this measure were high, because facility performance was not consistent and therefore the measure provided a means of distinguishing facility performance and incentivized facilities to improve rates of treatment for this common comorbidity. Between the FY 2017 payment determination (the first year that TOB–2/2a was included in the IPFQR Program’s measure set) and the FY 2019 payment determination we saw substantial performance improvement on TOB–2. However, between the FY 2019 and FY 2020 payment determinations, that improvement has leveled off to consistently high performance, as indicated in Table 3. These data further show that currently there is little room for improvement in the TOB–2 measure, and that the quality improvement benefits from the measure have greatly diminished. We continue to believe that tobacco use is an important comorbidity to address in the IPF setting, and that brief interventions are a key component of addressing this comorbidity. However, based on these data, we believe that most IPFs routinely offer tobacco use brief interventions, and that IPFs will continue to offer these interventions to patients, regardless of whether the TOB–2/2a measure is in the IPFQR Program measure set, because it has become an embedded part of their clinical workflows.

TABLE 3—PERFORMANCE ANALYSIS FOR TOBACCO USE BRIEF INTERVENTION PROVIDED OR OFFERED (TOB–2)

Year	Mean	Median	75th percentile	90th percentile	Truncated coefficient of variation (TCV)
2015 (2017 Payment Determination)	63.83	71.5	91	99	0.49
2016 (2018 Payment Determination)	74.72	84	95	100	0.28
2017 (2019 Payment Determination)	79.04	88	97	100	0.22
2018 (2020 Payment Determination)	79.08	88	98	100	0.22

While the measure does not meet our criteria for “topped-out” status because of the TCV higher than 0.1, we believe that this measure no longer meaningfully supports the program objectives of informing beneficiary choice and driving improvement in IPF interventions for tobacco use because it is no longer showing significant improvement in facility performance (that is, in providing or offering tobacco use brief interventions). Furthermore, as we stated in the FY 2019 IPF PPS final rule, costs are multi-faceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining the program (83 FR 38592). For example, it may be costly for health care providers to maintain general administrative knowledge to report this measure. Additionally, CMS must expend resources in maintaining information collection systems, analyzing reported data, and providing public reporting of the collected information. Here, IPF information collection burden and related costs associated with reporting this measure to CMS are high because the measure is a chart-abstracted measure. Furthermore, CMS incurs costs associated with the program oversight of the measure for public display. As a result, we believe that the costs and burdens associated with this chart-abstracted measure outweigh the benefit of its continued use in the program.

Therefore, we are proposing to remove the Tobacco Use Brief Intervention Provided or Offered and Tobacco Use Brief Intervention (TOB–2/2a) measure from the IPFQR Program beginning with the FY 2024 payment determination. We welcome public comments on our proposal to remove the TOB–2/2a measure from the IPFQR Program.

c. Proposal To Remove Timely Transmission of Transition Record (Discharges From an Inpatient Facility to Home/Self Care or Any Other Site of Care) Beginning With FY 2024 Payment Determination

We are proposing to remove the

Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) measure from the IPFQR Program beginning with the FY 2024 payment determination under our measure removal Factor 8, “The costs associated with a measure outweigh the benefit of its continued use in the program.”

We adopted the Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) measure in the FY 2016 IPF PPS final rule (80 FR 46706 through 46709) because more timely communication of vital information regarding the inpatient hospitalization results in better care, reduction of systemic medical errors, and improved patient outcomes. The Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) measure builds on the Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) measure, which requires facilities to provide a discharge record with 11 specified elements to patients at discharge.

We continue to believe that the 11 elements required by the Transition Record with Specified Elements measure provide meaningful information about the quality of care provided by IPFs, and we are therefore not proposing to remove that measure from the IPFQR Program. However, we believe that the benefits of requiring facilities to transmit the discharge record with 11 specified elements to the next level care provided within 24 hours, as required by the Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) measure, have been reduced. Reporting this measure requires facilities to chart-abstract measure data on a sample of IPF patient records, in accordance with established sampling policies (80 FR 46717 through 46719). On May 1, 2020, we updated the Conditions of Participation (CoPs) for

IPFs participating in the Medicare program in the Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally Facilitated Exchanges, and Health Care Providers final rule (85 FR 25588).

In the May 1, 2020 update to the CoPs, we adopted a requirement for psychiatric hospitals that possess EHR systems with the technical capacity to generate information for electronic patient event notifications to send electronic patient event notifications of a patient’s admission, discharge, and/or transfer to another health care facility or to another community provider at the time of a patient’s discharge or transfer. Because these updated CoP requirements overlap with, but are not the same as, the requirements for the Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) measure (which requires transmission of a discharge record with 11 specified elements to the next level care provider within 24 hours of the patient’s discharge rather than requiring notification regarding the patient’s inpatient stay to be transmitted at discharge), we believe that the adoption of these updated CoPs increases the costs of the Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) measure while decreasing its benefit. Specifically, we believe that the costs of this measure are increased because facilities to which the new CoPs apply (that is, facilities that possess EHR or other administrative systems with the technical capacity to generate information for electronic patient event notifications) could bear increased cost if they separately implement the patient event notifications meeting both the criteria for the updated CoPs and the capacity to share a transition record that meets the requirements of our measure. We

note that the updated CoPs do not include the level of detail regarding data to be transferred at discharge that our Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) measure requires. While the set of information in the CoP notification policy is a minimal set of information, we believe that it would continue to be appropriate for providers to transmit the transition record that they will continue to be providing to patients under our Transition Record Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) measure.

We believe the different requirements regarding both timeliness of notification and contents of notification could lead some providers to send two separate discharge notifications to meet the separate requirements. Further, we believe that the benefits of the measure are reduced because all facilities to which the new CoPs apply will be sending patient discharge information to the next level of care provider as required by the CoPs. Therefore, the benefits of this measure are reduced because it is less likely to ensure that these facilities provide patient discharge information to the next level care provider, and it is less likely to provide information to help consumers differentiate quality between facilities. While these updated CoPs do not directly address transmission of patient event notifications for facilities that do not possess EHR systems with patient

event notification capabilities, such facilities should continue to transmit data using their existing infrastructure and timelines.

Because we believe that the costs are now increased and the benefits are now reduced, we believe that the costs and burdens associated with this chart-abstracted measure outweigh the benefit of its continued use in the IPFQR Program.

Therefore, we are proposing to remove the Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) measure from the IPFQR Program beginning with the FY 2024 payment determination. We welcome public comments on our proposal to remove the Timely Transmission of Transition Record measure from the IPFQR Program.

d. Proposal To Remove Follow-Up After Hospitalization for Mental Illness (FUH, NQF #0576) Beginning With FY 2024 Payment Determination

If we finalize adoption of the Follow-Up After Psychiatric Hospitalization measure described in Section IV.E.3, we believe that our current measure removal Factor 3 would apply to the existing Follow-Up After Hospitalization for Mental Illness (FUH, NQF #0576) measure. Measure removal Factor 3 applies when a “measure can be replaced by a more broadly applicable measure (across settings or populations) or a measure that is more proximal in time to desired patient outcomes for the particular topics.” We adopted removal factor 3 in the FY 2017

IPPS/LTCH PPS final rule (82 FR 38463 through 38465). The proposed FAPH measure expands the patient population from patients with mental illness to also include patients with primary SUD diagnoses while addressing the same important aspect of care transitions. Because this FAPH measure uses the same methodology to address the same element of care for a broader patient population than the FUH measure, we believe that it is more broadly applicable across populations.

Therefore, we are proposing to remove the FUH measure under measure removal Factor 3 only if we finalize our proposal to adopt of the FAPH measure. We note that if we do not adopt the FAPH measure, we will retain the FUH measure because we believe this measure addresses an important clinical topic. We welcome public comments on our proposal to remove FUH if we adopt FAPH.

G. Summary of Previously Finalized and Newly Proposed Measures

1. Previously Finalized and Newly Proposed Measures for the FY 2023 Payment Determination and Subsequent Years

There are 14 previously finalized measures for the FY 2023 payment determination and subsequent years. In this proposed rule, we are proposing to adopt one measure for the FY 2023 payment determination and subsequent years. The 15 measures which would be in the program if this proposal is finalized are shown in Table 4.

TABLE 4—IPFQR PROGRAM MEASURE SET FOR THE FY 2023 PAYMENT DETERMINATION AND SUBSEQUENT YEARS IF MEASURE ADOPTION IS FINALIZED AS PROPOSED

NQF #	Measure ID	Measure
0640	HBIPS-2	Hours of Physical Restraint Use.
0641	HBIPS-3	Hours of Seclusion Use.
0560	HBIPS-5	Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification.
0576	FUH	Follow-Up After Hospitalization for Mental Illness.
N/A *	SUB-2 and SUB-2a	Alcohol Use Brief Intervention Provided or Offered and SUB-2a Alcohol Use Brief Intervention.
N/A *	SUB-3 and SUB-3a	Alcohol and Other Drug Use Disorder Treatment Provided or Offered at Discharge and SUB-3a Alcohol and Other Drug Use Disorder Treatment at Discharge.
N/A *	TOB-2 and TOB-2a	Tobacco Use Treatment Provided or Offered and TOB-2a Tobacco Use Treatment.
N/A *	TOB-3 and TOB-3a	Tobacco Use Treatment Provided or Offered at Discharge and TOB-3a Tobacco Use Treatment at Discharge.
1659	IMM-2	Influenza Immunization.
N/A *	N/A	Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care).
N/A *	N/A	Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or any Other Site of Care).
N/A	N/A	Screening for Metabolic Disorders.
2860	N/A	Thirty-Day All-Cause Unplanned Readmission Following Psychiatric Hospitalization in an Inpatient Psychiatric Facility.
3205	Med Cont	Medication Continuation Following Inpatient Psychiatric Discharge.

TABLE 4—IPFQR PROGRAM MEASURE SET FOR THE FY 2023 PAYMENT DETERMINATION AND SUBSEQUENT YEARS IF MEASURE ADOPTION IS FINALIZED AS PROPOSED—Continued

NQF #	Measure ID	Measure
TBD	COVID HCP	COVID-19 Healthcare Personnel (HCP) Vaccination Measure.

* Measure is no longer endorsed by the NQF but was endorsed at time of adoption. Section 1886(s)(4)(D)(ii) of the Act authorizes the Secretary to specify a measure that is not endorsed by the NQF as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We attempted to find available measures for each of these clinical topics that have been endorsed or adopted by a consensus organization and found no other feasible and practical measures on the topics for the IPF setting.

2. Previously Finalized and Newly Proposed Measures for the FY 2024 Payment Determination and Subsequent Years

There are 14 previously finalized measures for the FY 2024 payment

determination and subsequent years. In this proposed rule, we are proposing to adopt one measure for the FY 2023 payment determination and subsequent years. Additionally, we are proposing to remove three measures and replace one measure for the FY 2024 payment

determination and subsequent years. The 12 measures which would be in the program for FY 2024 payment determination and subsequent years if these proposals are finalized are shown in Table 5.

TABLE 5—IPFQR PROGRAM MEASURE SET FOR THE FY 2024 PAYMENT DETERMINATION AND SUBSEQUENT YEARS IF ADOPTIONS AND REMOVALS ARE FINALIZED AS PROPOSED

NQF #	Measure ID	Measure
0640	HBIPS-2	Hours of Physical Restraint Use.
0641	HBIPS-3	Hours of Seclusion Use.
0560	HBIPS-5	Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification.
N/A	FAPH	Follow-Up After Psychiatric Hospitalization.
1659	IMM-2	Influenza Immunization.
N/A *	SUB-3 and SUB-3a	Alcohol and Other Drug Use Disorder Treatment Provided or Offered at Discharge and SUB-3a Alcohol and Other Drug Use Disorder Treatment at Discharge.
N/A *	TOB-3 and TOB-3a	Tobacco Use Treatment Provided or Offered at Discharge and TOB-3a Tobacco Use Treatment at Discharge.
N/A *	N/A	Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care).
N/A	N/A	Screening for Metabolic Disorders.
2860	N/A	Thirty-Day All-Cause Unplanned Readmission Following Psychiatric Hospitalization in an Inpatient Psychiatric Facility.
3205	Med Cont	Medication Continuation Following Inpatient Psychiatric Discharge.
TBD	COVID HCP	COVID-19 Healthcare Personnel (HCP) Vaccination Measure.

* Measure is no longer endorsed by the NQF but was endorsed at time of adoption. Section 1886(s)(4)(D)(ii) of the Act authorizes the Secretary to specify a measure that is not endorsed by the NQF as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We attempted to find available measures for each of these clinical topics that have been endorsed or adopted by a consensus organization and found no other feasible and practical measures on the topics for the IPF setting.

H. Considerations for Future Measure Topics

As we have previously indicated, we seek to develop a comprehensive set of quality measures to be available for widespread use for informed decision-making and quality improvement in the IPF setting (79 FR 45974 through 45975). Therefore, through future rulemaking, we intend to propose new measures for development or adoption that will help further our goals of achieving better healthcare and improved health for individuals who obtain inpatient psychiatric services through the widespread dissemination and use of quality information. In 2017, we introduced the Meaningful Measures Framework as a tool to foster operational efficiencies and reduce costs including collection and reporting

burden while producing quality measurement that is more focused on meaningful outcomes (83 FR 38591). As we continue to evolve the Meaningful Measures Framework, we have stated that we intend to better address health care priorities and gaps, emphasize digital quality measurement, and promote patient perspectives.¹³⁴ As we work to align the IPFQR Program’s measure set with these priorities, we have identified the following areas that we believe are important to stakeholders, but which are not covered in the current IPFQR Program measure set: Patient Experience of Care, Functional Outcomes Measurement, and digital measures. As described in the following subsections, we are seeking

¹³⁴ <https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization>.

public comment on each of these topics and other future measure considerations which stakeholders believe are important.

1. Patient Experience of Care Data Collection Instrument

When we finalized removal of the Assessment of Patient Experience of Care attestation measure in the FY 2019 IPF PPS final rule (83 FR 38596) we stated that we believed we had collected sufficient information to inform development of a patient experience of care measure that would capture data on the results of such a survey. In the FY 2020 IPF PPS proposed rule (84 FR 16986 through 16987), we solicited input on how providers had implemented the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey in their

facilities. We also sought public comment on other potential surveys that commenters believed would be appropriate to adopt for the IPFQR Program. We received many comments on this subject, and many of these comments expressed that there is not one survey used predominantly across IPFs (84 FR 38467). Additional commenters expressed concerns that the HCAHPS survey may not be appropriate for the IPF setting because it does not include some of the unique aspects of inpatient psychiatric care including, group therapy, non-physician providers, and involuntary admissions. While we did not solicit public comment on this issue in the FY 2021 IPF PPS proposed rule, we received many comments addressing this issue (85 FR 47043). We continue to seek to identify a minimally burdensome patient experience of care instrument that would be appropriate for the IPF setting. Therefore, we are seeking public comment on instruments currently in use in the IPF setting, input on whether the HCAHPS survey may be appropriate for this setting, and information on how facilities that currently use the HCAHPS survey have addressed challenges with using this survey within this setting (that is, concerns regarding unique aspects of inpatient psychiatric care).

2. Functional Outcomes Instrument for Use in a Patient Reported Outcomes Measure

When we introduced the Meaningful Measures Framework, we stated that we wanted to focus on meaningful outcomes (83 FR 38591). As we have assessed the IPFQR Program measure set against the Meaningful Measures Framework, we have identified functional outcomes as a potential gap area in the IPFQR Program's measure set. Therefore, we are evaluating whether a patient reported outcomes measure that assesses functional outcomes, such as global functioning, interpersonal problems, psychotic symptoms, alcohol or drug use, emotional lability, and self-harm, would be an appropriate measure to include in the IPFQR program measure set. If we were to develop such a measure, we would develop a measure that compares a patient's responses to a standardized functional outcomes assessment instrument at admission with the patient's results on the same assessment instrument at discharge. We are seeking public comment on the value of such a measure in the IPFQR program measure set, what would be an appropriate functional outcome assessment instrument to use in the potential development of such a measure, and

any additional topics or concepts stakeholders believe would be appropriate for patient reported outcomes measures.

3. Measures for Electronic Data Reporting

As we seek to improve digital measurement across our quality reporting and value-based payment programs, we are considering measures both within and appropriate to adopt for the IPFQR Program measure set that would be appropriate for digital data collection. In our assessment of the current measure set, we identified the Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) measure as a potential option for digital data collection. We are seeking stakeholder input on the current data collection burden associated with this measure, concerns regarding potential electronic specification and data collection for this measure, and other measures that may be appropriate for electronic data collection, either those currently in the IPFQR Program measure set, or those that we could adopt in the future.

I. Public Display and Review Requirements

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53653 through 53654), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50897 through 50898), and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57248 through 57249) for discussion of our previously finalized public display and review requirements. In this proposed rule, we are not proposing any changes to these requirements.

J. Form, Manner, and Timing of Quality Data Submission for the FY 2022 Payment Determination and Subsequent Years

1. Procedural Requirements for the FY 2023 Payment Determination and Subsequent Years

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53654 through 53655), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50898 through 50899), and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38471 through 38472) for our previously finalized procedural requirements. In this proposed rule, we are proposing to use the term "QualityNet security official" instead of "QualityNet system administrator," proposing to revise § 412.434(b)(3) by replacing the term "QualityNet system administrator" with

the term "QualityNet security official," and clarifying our policy under the previously finalized requirement that hospitals "[i]dentify a QualityNet Administrator who follows the registration process located on the QualityNet website" (77 FR 53654).

a. Proposal To Update Reference to QualityNet System Administrator and to No Longer Require Active Account To Qualify for Payment

The previously finalized QualityNet security administrator requirements, including those for setting up a QualityNet account and the associated timelines, are described in the FY 2013 IPPS/LTCH final rule (77 FR 53654).

In this proposed rule, we propose to use the term "QualityNet security official" instead of "QualityNet system administrator" to denote the exercise of authority invested in the role and align with the Hospital Outpatient Quality Reporting Program and other programs. The term "security official" would refer to "the individual(s)" who have responsibilities for security and account management requirements for a facility's QualityNet account. To clarify, this proposed update in terminology would not change the individual's responsibilities or add burden.

We invite public comment on our proposal to replace the term "QualityNet system administrator" with "QualityNet security official."

Additionally, we are proposing to no longer require IPFs to maintain an active QualityNet security official account to qualify for payment. As we reviewed the requirements for the security official role and the basic user¹³⁵ role to identify the most appropriate language to describe the distinguishing authority invested in the security official role, we recognized that the QualityNet security official is not required for submitting data—a basic user can serve in this role—but remains necessary to set up QualityNet basic user accounts and for security purposes. Therefore, consistent with our proposal to adopt the security official term to differentiate the unique security authority and responsibilities of the role from the data submission responsibilities of the basic user role, we would continue to require a QualityNet basic user account to meet

¹³⁵ We also noted that a basic user is a QualityNet user who (1) does not have the registration access described for security officials, (2) has the appropriate data entry roles and permissions for program participation, (3) can submit and review measures and non-measure data, (4) signs and submits the Data Accuracy Completeness Acknowledgement (DACA) form, and (5) refreshes their QualityNet account password every 180 days to ensure that the facility's IPFQR Program Notice of Participation status is "Participating."

IPFQR Program requirements, including data submission and administrative requirements, while recommending, but not requiring, that hospitals maintain an active QualityNet security official account.

We welcome public comments on our proposal to no longer require facilities to maintain an active QualityNet security official account to qualify for payment.

b. Proposal To Update Reference to QualityNet Administrator in Code of Federal Regulations

In this proposed rule, we propose to revise our regulation at § 412.434(b)(3) by replacing “QualityNet system administrator” with “QualityNet security official.” The term “QualityNet security official” refers to the individual(s) who have responsibilities for security and account management requirements for a hospital’s QualityNet account. To clarify, this proposed update in terminology would not change the individual’s responsibilities or add burden. If finalized, the revised paragraph (b)(3) would read: “Contact information for the inpatient psychiatric facility’s chief executive officer and QualityNet security official, including each individual’s name, email address, telephone number, and physical mailing address.”

We invite public comment on our proposal to replace the term “QualityNet system administrator” with “QualityNet security official” at § 412.434(b)(3).

2. Data Submission Requirements

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53655 through 53657), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50899 through 50900), and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38472 through 38473) for our previously finalized data submission requirements. In this proposed rule, we are proposing to adopt one measure for the FY 2023 payment determination and subsequent years and one measure for the FY 2024 payment determination and subsequent years. Data submission requirements for each of these measures are described in the following subsections. Additionally, we are proposing to adopt patient level data submission for certain chart abstracted measures beginning with data submitted for the FY 2023 payment determination and subsequent years; details of this proposal are in subsection c. of this section.

a. Data Submission Requirements for FY 2023 Payment Determination and Subsequent Years

The measure we are proposing for FY 2023 payment determination and subsequent years (the COVID–19 HCP—Vaccination measure) requires facilities to report data on the number of HCP who have received completed vaccination course of a COVID–19 vaccine through the CDC’s National Healthcare Safety Network (NHSN). Specific details on data submission for this measure can be found in the CDC’s Overview of the Healthcare Safety Component, available at https://www.cdc.gov/nhsn/PDFs/slides/NHSN-Overview-HPS_Aug2012.pdf. For each CMS Certification Number (CCN), a percentage of the HCP who received a completed vaccine course of the COVID–19 vaccination will be calculated and publicly reported, so that the public will know what percentage of the HCP have been vaccinated in each IPF.

For the COVID–19 HCP Vaccination measure, we are proposing that facilities would report the numerator and denominator for the COVID–19 HCP vaccination measure to the NHSN for at least one week each month, beginning in October 2021 for the October 1, 2021 through December 31, 2021 reporting period affecting the FY 2023 payment determination. If facilities report more than one week of data in a month, the most recent week’s data would be used to calculate the measure. Each quarter, the CDC would calculate a single quarterly result of COVID–19 vaccination coverage which would summarize the data submitted by IPFs for each of the three weeks of data submitted over the three month period. If finalized, CMS would publicly report the CDC’s quarterly summary of COVID–19 vaccination coverage for IPFs.

We invite public comment on our proposal to require facilities to report the COVID–19 HCP vaccination measure.

b. Data Submission Requirements for FY 2024 Payment Determination and Subsequent Years

Because the Follow-Up After Psychiatric Hospitalization (FAPH) measure would be calculated by CMS using Medicare Fee-for-Service claims, there will be no additional data submission requirements for the FY 2024 payment determination and subsequent years. Therefore, we are not proposing any changes to our data submission policies associated with the proposal to adopt this measure.

c. Proposal To Adopt Patient-Level Reporting for Certain Chart-Abstracted Measures Beginning With FY 2024 Payment Determination and Subsequent Years

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53655 through 53657), we finalized that IPFs participating in the IPFQR Program must submit data to the Web-Based Measures Tool found in the Inpatient Psychiatric Facility section of the QualityNet website’s secure portal between July 1 and August 15 of each year. We noted that the data input forms within the Quality Net secure portal require submission of aggregate data for each separate quarter. In the FY 2014 IPPS/LTCH PPS final rule, we clarified our intent to require that IPFs submit aggregate data on measures on an annual basis via the Web-Based Measures Tool found in the IPF section of the Quality Net website’s secure portal and that the forms available require aggregate data for each separate quarter (78 FR 50899 through 50900). In the FY 2016 IPF PPS final rule (80 FR 46716), we updated our data submission requirements to require facilities to report data for chart-abstracted measures to the Web-Based Measures Tool on an aggregate basis by year, rather than by quarter. Additionally, we discontinued the requirement for reporting by age group. We updated these policies in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38472 through 38473) to change the specification of the submission deadline from exact dates to a 45-day submission period beginning at least 30 days following the end of the data collection period.

In the FY 2019 IPF PPS final rule (83 FR 38607), we observed that reporting aggregate measure data increases the possibility of human error, such as making typographical errors while entering data, which cannot be detected by CMS or by data submission systems. We noted that unlike patient-level data reporting, aggregate measure data reporting does not allow for data accuracy validation, thereby lowering the ability to detect error. We stated that we were considering requiring patient-level data reporting (data regarding each patient included in a measure and whether the patient was included in each numerator and denominator of the measure) of IPFQR measure data in the future. We sought public comment on including patient-level data collection in the IPFQR program. Several commenters expressed support for patient-level data collection, observing that it provides greater confidence in the data’s validity and reliability. Other

commenters recommended that CMS use a system that has already been tested and used for IPF data reporting or work with IPFs in selecting a system so that any selected system would avoid additional burden.

We believe that patient-level data reporting would improve the accuracy of the submitted and publicly reported data without increasing burden. As we considered the current IPFQR measure set, we determined that patient-level

reporting of the Hours of Physical Restraint Use (HBIPS–2, NQF #0640) measure and Hours of Seclusion Use (HBIPS–2, NQF #0641) measure would be appropriate for the numerators of these measures only, because these measures are calculated with a denominator of 1,000 hours rather than a denominator of patients who meet specific criteria for inclusion in the measure. Therefore, we are proposing to require reporting patient-level

information for the numerators of these measures only. For the remainder of the chart-abstracted measures in the IPFQR Program we are proposing to require patient-level reporting of the both the numerator and the denominator. Table 6 lists the proposed FY 2023 IPFQR measure set categorized by whether we would require patient-level data submission through the QualityNet secure portal.

TABLE 6—PATIENT-LEVEL DATA SUBMISSION REQUIREMENTS FOR FY 2024 IPFQR PROGRAM MEASURE SET

NQF #	Measure ID	Measure	Patient-level data submission
0640	HBIPS–2	Hours of Physical Restraint Use	Yes, numerator only.
0641	HBIPS–3	Hours of Seclusion Use	Yes, numerator only.
0560	HBIPS–5	Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification.	Yes.
0576	FUH	Follow-Up After Hospitalization for Mental Illness	No (claims-based).
N/A *	SUB–2 and SUB–2a	Alcohol Use Brief Intervention Provided or Offered and SUB–2a Alcohol Use Brief Intervention.	Yes.
N/A *	SUB–3 and SUB–3a	Alcohol and Other Drug Use Disorder Treatment Provided or Offered at Discharge and SUB–3a Alcohol and Other Drug Use Disorder Treatment at Discharge.	Yes.
N/A *	TOB–2 and TOB–2a	Tobacco Use Treatment Provided or Offered and TOB–2a Tobacco Use Treatment.	Yes.
N/A *	TOB–3 and TOB–3a	Tobacco Use Treatment Provided or Offered at Discharge and TOB–3a Tobacco Use Treatment at Discharge.	Yes.
1659	IMM–2	Influenza Immunization	Yes.
N/A *	N/A	Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care).	Yes.
N/A *	N/A	Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or any Other Site of Care).	Yes.
N/A	N/A	Screening for Metabolic Disorders	Yes.
2860	N/A	Thirty-Day All-Cause Unplanned Readmission Following Psychiatric Hospitalization in an Inpatient Psychiatric Facility.	No (claims-based).
3205	Med Cont	Medication Continuation Following Inpatient Psychiatric Discharge.	No (claims-based).
TBD	COVID HCP	COVID–19 Healthcare Personnel (HCP) Vaccination Measure	No (calculated for HCP).

* Measure is no longer endorsed by the NQF but was endorsed at time of adoption. Section 1886(s)(4)(D)(ii) of the Act authorizes the Secretary to specify a measure that is not endorsed by the NQF as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We attempted to find available measures for each of these clinical topics that have been endorsed or adopted by a consensus organization and found no other feasible and practical measures on the topics for the IPF setting.

Submission of aggregate data requires facilities to abstract patient-level data, then calculate measure performance prior to submitting data through the QualityNet website’s secure portal. For measures for which we would require patient-level data submission, we would allow facilities to submit data using a tool such as the CMS Abstraction & Reporting Tool (CART). This is the tool we use in our other quality reporting and value-based purchasing programs, and therefore, we believe that many facilities may already have familiarity with using this tool to abstract and report data. Additionally, the tool has been specifically designed to facilitate data reporting and minimize provider burden.

We note that under aggregate data reporting, facilities submit aggregate

numerators and aggregate denominators for all measures to CMS in the Hospital Quality Reporting (HQR) system. These aggregate numerators and denominators are generally calculated by manually abstracting the medical record of each included patient using the algorithm, a paper tool, or a vendor abstraction tool. After each required medical record has been abstracted, the numerator and denominator results are added up and submitted as aggregate values in the HQR system. Under our patient level data reporting proposal, facilities would still manually abstract the medical record using either a vendor abstraction tool or an abstraction tool provided by CMS. The vendor abstraction tool or the CMS tool would then produce an individual XML file for each of the cases abstracted. Instead of submitting the

aggregate data, the facility will log into HQR and upload batches of XML files that contain patient level data for each measure with data from all patients whose records were abstracted, and CMS would calculate the aggregate numerators, aggregate denominators, and measure rates from those XML file submissions. Because facilities must abstract patient-level data as one step in calculating measure results, we do not believe that requiring patient-level data submission will increase provider costs or burden associated with measure submission.

Because we believe that patient-level data will improve the data accuracy without increasing provider burden, we are now proposing to adopt patient-level data reporting for numerators only for the Hours of Physical Restraint Use

(HBIPS–2, NQF #0640) and the Hours of Seclusion Use (HBIPS–3, NQF #0631) for numerators and denominators for the following 9 chart-abstracted IPFQR Program measures as detailed in Table 6: Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification (NQF #0560); Alcohol Use Brief Intervention Provided or Offered and SUB–2a Alcohol Use Brief Intervention; Alcohol and Other Drug Use Disorder Treatment Provided or Offered at Discharge and SUB–3a Alcohol and Other Drug Use Disorder Treatment at Discharge, Tobacco Use Treatment Provided or Offered and TOB–2a Tobacco Use Treatment, Tobacco Use Treatment Provided or Offered at Discharge and TOB–3a Tobacco Use Treatment at Discharge, Influenza Immunization (NQF #1659), Transition Record with Specified Elements Received by Discharged Patients (discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care), Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or any Other Site of Care), and Screening for Metabolic Disorders.

We believe that it is appropriate to transition to patient-level reporting incrementally. This would allow facilities to become familiar with the data submission systems and to provide feedback on any challenges they face in reporting data to us. Therefore, we are proposing to allow voluntary patient-level data submission for the FY 2023 payment determination (that is, data submitted during CY 2022). We note that because participation in patient-level reporting for these chart-abstracted measures would be voluntary for this one-year period, facilities would be able to choose whether to submit measure data in aggregate or at the patient level, and would not face a payment reduction as long as they submit all measure data either at the patient level or in aggregate for each measure for which reporting is required, and as long as they met all other IPFQR Program requirements. Therefore, we are proposing to allow voluntary patient-level reporting prior to requiring such data submission for one year prior to the FY 2024 payment determination. If we transition to patient-level reporting, we will ensure that facilities have guidance available through our standard communications channels (that is, listserv announcements, educational webinars, and training material on the QualityNet website).

We are also proposing to require patient-level data submission for these chart-abstracted measures for the FY 2024 payment determination (that is,

data submitted during CY 2023) and subsequent years.

We welcome comment on our proposals to allow voluntary patient-level data reporting for these chart-abstracted measures for the FY 2023 payment determination and then to require patient-level data reporting for the FY 2024 payment determination and subsequent years.

3. Considerations for Data Validation Pilot

As discussed in section IV.J.4 and in the FY 2019 IPF PPS final rule, we are concerned about the limitations of aggregate data submission (83 FR 28607). One such concern was that the ability to detect error is lower for aggregate measure data reporting than for patient-level data reporting (that is, data regarding each patient included in a measure and whether the patient was included in the numerator and denominator of the measure). We note that if we finalize our proposal to adopt patient-level data requirements, we would be able to adopt a data validation policy for the IPFQR Program in the future. We believe that it would be appropriate to develop such a policy incrementally through adoption of a data validation pilot prior to national implementation of data validation within the IPFQR Program. We seek public input on elements of a potential data validation pilot, for example, the number of measures to validate, number of participating facilities, whether the pilot should be mandatory or voluntary, potential thresholds for determining measure accuracy, or any other policies that commenters believe would be appropriate to include in a data validation pilot or eventual data validation policy.

4. Reporting Requirements for the FY 2022 Payment Determination and Subsequent Years

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53656 through 53657), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50900 through 50901), and the FY 2015 IPF PPS final rule (79 FR 45976 through 45977) for our previously finalized reporting requirements. In this proposed rule, we are not proposing any changes to these policies.

5. Quality Measure Sampling Requirements

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53657 through 53658), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50901 through 50902), the FY 2016 IPF PPS final rule (80 FR 46717 through 46719), and the

FY 2019 IPF PPS final rule (83 FR 38607 through 38608) for discussions of our previously finalized sampling policies. We note that neither the measure we are proposing to remove (FUH–NQF #0576) nor the measure we are proposing to adopt (FAPH) if we remove the FUH–NQF #0576 are affected by our sampling policies because these are both calculated by CMS using Medicare Fee-for-Service claims and, therefore, apply to all Medicare patients in the denominator. Furthermore, the denominator of the COVID–19 Healthcare Personnel Vaccination measure we are proposing to adopt in this proposed rule is all healthcare personnel, and therefore, this measure is not eligible for sampling. In this proposed rule, we are not proposing any changes to our previously finalized sampling policies.

6. Non-Measure Data Collection

We refer readers to the FY 2015 IPF PPS final rule (79 FR 45973), the FY 2016 IPF PPS final rule (80 FR 46717), and the FY 2019 IPF PPS final rule (83 FR 38608) for our previously finalized non-measure data collection policies. In this proposed rule, we are not proposing any changes to these policies.

7. Data Accuracy and Completeness Acknowledgement (DACA) Requirements

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53658) for our previously finalized DACA requirements. In this proposed rule, we are not proposing any changes to these policies.

K. Reconsideration and Appeals Procedures

We refer readers to 42 CFR 412.434 for the IPFQR Program's reconsideration and appeals procedures. In this proposed rule, we are not proposing any changes to these policies.

L. Extraordinary Circumstances Exceptions (ECE) Policy

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53659 through 53660), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50903), the FY 2015 IPF PPS final rule (79 FR 45978), and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38473 through 38474) for our previously finalized ECE policies. In this proposed rule, we are not proposing any changes to these policies.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), we are required to provide 60-day notice

in the **Federal Register** and solicit public comment before a “collection of information” (as defined under 5 CFR 1320.3(c) of the PRA’s implementing regulations) requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of the section 3506(c)(2)(A)—required issues for the following

information collection requirements (ICRs).

A. Proposed ICRs for the (IPFQR) Program

The following proposed requirement and burden changes will be submitted to OMB for approval under control number 0938–1171 (CMS–10432).

1. Wage Estimates

In the FY 2020 IPF PPS final rule (84 FR 38468), which was the most recent rule in which we adopted updates to the IPFQR Program, we estimated that reporting measures for the IPFQR Program could be accomplished by a Medical Records and Health Information Technician (BLS Occupation Code: 29–2071) with a median hourly wage of \$18.83/hr. (May 2017). Since then, BLS (the Bureau of Labor Statistics) has revised their wage data (May 2019) to \$20.50/hr.¹³⁶ In response, we are proposing to adjust our

cost estimates using the updated median wage rate figure of \$20.50/hr., an increase of \$1.67/hr.

Under OMB Circular A–76, in calculating direct labor, agencies should not only include salaries and wages, but also “other entitlements” such as fringe benefits and overhead.¹³⁷ Consistent with our past approach, we continue to calculate the cost of fringe benefits and overhead at 100 percent of the median hourly wage (81 FR 57266). This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and methods of estimating these costs vary widely from study to study. Therefore, using these assumptions, we estimate an hourly labor cost increase from \$37.66/hr (\$18.83/hr base salary + \$18.83/hr fringe benefits and overhead) to \$41.00/hr (\$20.50/hr base salary + \$20.50/hr fringe benefits and overhead). Table 7 presents these assumptions.

TABLE 7—WAGE ASSUMPTIONS FOR THE IPFQR PROGRAM

Occupation title	Occupation code	Median hourly wage (\$/hr)	Fringe benefits and overhead (\$/hr)	Adjusted hourly wage (\$/hr)
Medical Records and Health Information Technician	29–2071	20.50	20.50	41.00

2. ICRs Regarding the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program

In subsection 2.a., we restate our currently approved burden estimates. In subsection 2.b., we estimate the proposed adjustments in burden associated with the updated BLS wage rate, our facility estimates, and our case estimates. In subsection 2.c., we estimate the changes in burden associated with the proposals in this rule. Finally, in subsection 2.d., we provide an overview of the total estimated burden.

a. Currently Approved Burden

For a detailed discussion of the burden for the IPFQR Program requirements that we have previously adopted, we refer readers to the following rules:

- The FY 2013 IPPS/LTCH PPS final rule (77 FR 53673);
- The FY 2014 IPPS/LTCH PPS final rule (78 FR 50964);
- The FY 2015 IPF PPS final rule (79 FR 45978 through 45980);
- The FY 2016 IPF PPS final rule (80 FR 46720 through 46721);
- The FY 2017 IPPS/LTCH PPS final rule (81 FR 57265 through 57266);

- The FY 2018 IPPS/LTCH PPS final rule (82 FR 38507 through 38508);
- The FY 2019 IPF PPS final rule (83 FR 38609 through 38612); and
- The FY 2020 IPF PPS final rule (84 FR 38468 through 38476).

Tables 8, 9, and 10 provide an overview of our currently approved burden. These tables use our previous estimate of \$37.66 (\$18.83 base salary plus \$18.83 fringe benefits and overhead) hourly labor cost. For more information on our currently approved burden estimates, please see PRA Supporting Statement A on the Office of Information and Regulatory Affairs website.¹³⁸

TABLE 8—CURRENTLY APPROVED MEASURE COLLECTION AND REPORTING BURDEN

NQF #	Measure ID	Measure description	Estimated cases (per facility)	Time per case (hours)	Annual time per facility (hours)	Number IPFs	Total annual time (hours)	Total annual cost (\$)
0640	HBIPS–2	Hours of Physical Restraint Use	1,283	0.25	320.75	1,679	538,539.25	20,281,388
0641	HBIPS–3	Hours of Seclusion Use	1,283	0.25	320.75	1,679	538,539.25	20,281,388
0560	HBIPS–5	Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification.	609	0.25	152.25	1,679	255,627.75	9,626,941
N/A	SUB–2 and SUB–2a.	Alcohol Use Brief Intervention Provided or Offered.	609	0.25	152.25	1,679	255,627.75	9,626,941

¹³⁶ <https://www.bls.gov/oes/current/oes292098.htm> (Accessed on March 30, 2021).

¹³⁷ http://www.whitehouse.gov/omb/circulars_a076_a76_incl_tech_correction.

¹³⁸ https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201908-0938-011.

TABLE 8—CURRENTLY APPROVED MEASURE COLLECTION AND REPORTING BURDEN—Continued

NQF #	Measure ID	Measure description	Estimated cases (per facility)	Time per case (hours)	Annual time per facility (hours)	Number IPFs	Total annual time (hours)	Total annual cost (\$)
N/A	SUB-3 and SUB-3a.	Alcohol and Other Drug Use Disorder Treatment Provided or Offered at Discharge and Alcohol and Other Drug Use Disorder Treatment at Discharge.	609	0.25	152.25	1,679	255,627.75	9,626,941
0576	FUH	Follow-Up After Hospitalization for Mental Illness*.	0	0	0	0	0	0
N/A	TOB-2 and TOB-2a.	Tobacco Use Treatment Provided or Offered and Tobacco Use Treatment.	609	0.25	152.25	1,679	255,627.75	9,626,941
N/A	TOB-3 and TOB-3a.	Tobacco Use Treatment Provided or Offered at Discharge and Tobacco Use Treatment at Discharge.	609	0.25	152.25	1,679	255,627.75	9,626,941
1659	IMM-2	Influenza Immunization	609	0.25	152.25	1,679	255,627.75	9,626,941
0647	N/A	Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care).	609	0.25	152.25	1,679	255,627.75	9,626,941
0648	N/A	Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care).	609	0.25	152.25	1,679	255,627.75	9,626,941
N/A	N/A	Screening for Metabolic Disorders	609	0.25	152.25	1,679	255,627.75	9,626,941
2860	N/A	Thirty-day all-cause unplanned readmission following psychiatric hospitalization in an IPF*.	0	0	0	0	0	0
3205	Med Cont	Medication Continuation Following Inpatient Psychiatric Discharge*.	0	0	0	0	0	0
Total			8,047	Varies	2,011.75	1,679	3,377,728	127,205,245

* CMS will collect these data using Medicare Part A and Part B claims; therefore, these measures will not require facilities to submit data on any cases.

TABLE 9—CURRENTLY APPROVED NON-MEASURE DATA COLLECTION AND REPORTING BURDEN

Tasks	Number IPFs	Annual time per facility (hours)	Total annual time (hours)	Wage rate (\$/hr)	Cost per IPF (\$)	Total annual cost for all IPFs (\$)
Non-measure Data Collection and Submission	1,679	2.0	3,358	37.66	75.32	126,462

TABLE 10—CURRENTLY APPROVED TOTAL BURDEN

Requirement	Respondents	Responses	Time (hours)	Cost (\$)
Measure Data Collection and Reporting	1,679	13,510,913 (8,047 responses or cases per facility * 1,679 facilities).	3,377,728	127,205,245
Non-Measure Data Collection and Reporting	1,679	6,716 (4 * responses per facility * 1,679 facilities) 4.	3,358	126,462
Notice of Participation, Data Accuracy Acknowledgment, and Vendor Authorization Form*.	N/A	N/A	N/A	N/A
Total	1,679	13,517,629	3,381,086	127,331,707

* The 15 minutes per measure for chart abstraction under Measure Data Collection and Reporting also includes the time for completing and submitting any forms.

b. Proposed Adjustments in Burden Due to Updated Wage, Facility Count, and Case Count Estimates

In the FY 2020 IPF PPS final rule (84 FR 38468), which is the most recent rule, that updated the IPFQR Program

policies, we estimated that there were 1,679 participating IPFs and that (for measures that require reporting on the entire patient population) these facilities will report on an average of 1,283 cases per facility. In this FY 2022 rule, we are proposing to update our

facility count and case estimates by using the most recent data available. Specifically, we estimate that there are now approximately 1,634 facilities (a decrease of 45 facilities) and an average of 1,346 cases per facility (an increase of 63 cases per facility). Tables 11, 12,

and 13, depict the effects of these updates, as well as the wage rate update to \$41.00/hr described in section V.A.1 of the preamble of this proposed rule, on our previously estimated burden.

TABLE 11—MEASURE COLLECTION AND REPORTING BURDEN BASED ON UPDATED CASES PER FACILITY, FACILITY COUNTS, AND WAGE RATE

NQF #	Measure ID	Measure description	Estimated cases (per facility)	Time per case (hours)	Annual time per facility (hours)	Number IPFs	Total annual time (hours)	Total annual cost (\$)
0640	HBIPS-2	Hours of Physical Restraint Use	1,346	0.25	336.50	1,634	549,841	22,543,481
0641	HBIPS-3	Hours of Seclusion Use	1,346	0.25	336.50	1,634	549,841	22,543,481
0560	HBIPS-5	Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification.	* 609	0.25	152.25	1,634	248,776.5	10,199,836.50
N/A	SUB-2 and SUB-2a.	Alcohol Use Brief Intervention Provided or Offered and Alcohol Use Brief Intervention Provided.	* 609	0.25	152.25	1,634	248,776.5	10,199,836.50
N/A	SUB-3 and SUB-3a.	Alcohol and Other Drug Use Disorder Treatment Provided or Offered at Discharge and Alcohol and Other Drug Use Disorder Treatment at Discharge.	* 609	0.25	152.25	1,634	248,776.5	10,199,836.50
0576	FUH	Follow-Up After Hospitalization for Mental Illness*.	0	0	0	0	0	0
N/A	TOB-2 and TOB-2a.	Tobacco Use Treatment Provided or Offered and Tobacco Use Treatment.	* 609	0.25	152.25	1,634	248,776.5	10,199,836.50
N/A	TOB-3 and TOB-3a.	Tobacco Use Treatment Provided or Offered at Discharge and Tobacco Use Treatment at Discharge.	* 609	0.25	152.25	1,634	248,776.5	10,199,836.50
1659	IMM-2	Influenza Immunization	* 609	0.25	152.25	1,634	248,776.5	10,199,836.50
0647	N/A	Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care).	* 609	0.25	152.25	1,634	248,776.5	10,199,836.50
0648	N/A	Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care).	* 609	0.25	152.25	1,634	248,776.5	10,199,836.50
N/A	N/A	Screening for Metabolic Disorders.	* 609	0.25	152.25	1,634	248,776.5	10,199,836.50
2860	N/A	Thirty-day all-cause unplanned readmission following psychiatric hospitalization in an IPF*.	0	0	0	0	0	0
3205	Med Cont	Medication Continuation Following Inpatient Psychiatric Discharge*.	0	0	0	0	0	0
N/A	COVID-19 HCP	COVID-19 Vaccination Rate Among Healthcare Personnel.	**0	0	0	0	0	0
N/A	FAPH	Follow-Up After Psychiatric Hospitalization.	0	0	0	0	0	0
Total			8,173	Varies	2,043.25	1,634	3,338,671	136,885,491

*Under our previously finalized “global sample” (80 FR 46717 through 46718) we allow facilities to apply the same sampling methodology to all measures eligible for sampling. In the FY 2016 IPF PPS final rule (80 FR 46718), we finalized that facilities with between 609 and 3,056 cases that choose to participate in the global sample would be required to report data for 609 cases. Because facilities are only required to submit data on a number specified by the global sampling methodology, rather than abstracting data for all patients or applying measure specific sampling methodologies, we believe that the number of cases under the global sample is a good approximation of facility burden associated with these measures. Therefore, for the average IPF discharge rate of 1,346 discharges versus the previously estimated 1,283, the global sample continues to require abstraction of 609 records.

**The COVID-19 HCP measure will be calculated using data submitted to the CDC under a separate OMB Control Number (0920-1317).

TABLE 12—NON-MEASURE DATA COLLECTION AND REPORTING BURDEN BASED ON UPDATED CASES PER FACILITY, FACILITY COUNTS, AND WAGE RATE

Tasks	Number IPFs	Annual time per facility (hours)	Total annual time (hours)	Wage rate (\$/hr)	Cost per IPF (\$)	Total annual cost for all IPFs (\$)
Non-measure Data Collection and Submission	1,634	2.0	3,268	41.00	82.00	133,988

TABLE 13—TOTAL BURDEN BASED ON UPDATED CASES PER FACILITY, FACILITY COUNTS, AND WAGE RATE

Requirement	Respondents	Responses	Time (hours)	Cost (\$)
Measure Data Collection and Reporting	1,634	13,354,682 (8,173 responses per facility * 1,634 facilities).	3,338,671	136,885,491
Non-Measure Data Collection and Reporting	1,634	6,536 (4 responses per facility * 1,634 facilities).	3,268	133,988
Total	1,634	13,361,218	3,341,939	137,019,479

c. Changes in Burden Due to This Proposed Rule

(1). Updates Due to Proposed Measure Adoptions

In section IV.E of this preamble, we are proposing to adopt the following two measures:

- COVID-19 HCP Vaccination for FY 2023 Payment Determination and Subsequent Years; and
- Follow-Up After Psychiatric Hospitalization (FAPH) for FY 2024 Payment Determination and Subsequent Years.

We are proposing to adopt the COVID-19 HCP Vaccination measure beginning with an initial reporting period from October 1 to December 31, 2021 affecting the FY 2023 payment determination followed by annual reporting beginning with the FY 2024 payment determination and subsequent years. IPFs would submit data through the CDC NHSN. The NHSN is a secure, internet-based system maintained by the CDC and provided free. 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 (NCVIA).¹³⁹

Although the burden as associated with the COVID-19 HCP Vaccination measure is not accounted for under the CDC PRA package currently approved under OMB control number 0920-1317 due to the NCVIA waiver, the cost and burden information is discussed here and will be included 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 IPF on average approximately 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. This burden is comprised of administrative hours and wages. We believe it would take an Administrative Assistant¹⁴⁰ between 45 minutes and 1 hour and 15 minutes to enter this data into NHSN. For the CY 2021 reporting period (consisting of October 1, 2021 through December 31, 2021) 3 months are required. For the CY 2021 reporting period/FY 2023 payment determination, IPFs would incur an additional burden between 2.25 hours (0.75 hours * 3 months) and 3.75 hours (1.25 hours * 3 months) per IPF. For all 1,634 IPFs, the total burden would range from 3,676.5 (2.25 hours * 1,634 IPFs) and 6,127.5 hours (3.75 hours * 1,634 IPFs). Each IPF would incur an estimated cost of between \$27.47 (0.75 hour * \$36.62/hr) and \$45.78 (1.25 hours * \$36.63/hr) monthly and between \$82.40 (2.25 hours * \$36.62/hr) and \$137.33 (3.75 hours * \$36.62/hr) in total over the CY 2021 reporting period to complete this task. Thereafter, 12 months of data are required annually. Therefore, IPFs would incur an additional annual burden between 9 hours (0.75 hours/month * 12 months) and 15 hours (1.25 hours/month * 12 months) per IPF and between 14,706 hours (9 hours/IPF * 1,634 IPFs) and 24,510 hours (15 hours/IPF * 1,634 IPFs) for all IPFs. Each IPF would incur an estimated cost of between \$329.58 (9 hours * \$36.62/hr) and \$549.30 annually (15 hours * \$36.62/hr). The estimated cost across all 1,634 IPFs would be between \$134,641.6 (\$82.40/IPF * 1,634 IPFs) and \$224,397.22 (\$137.33/IPF * 1,634 IPFs) for the CY 2021 reporting period. The estimated cost across all 1,634 IPFs would be between \$538,533.72 (\$329.58/IPF * 1,634 IPFs) and \$897,556.2 (\$549.30/IPF * 1,634 IPFs) annually thereafter.

We recognize that many healthcare facilities are also reporting other COVID-19 data to HHS. We believe the benefits of requiring IPFs to report data on the COVID-19 HCP Vaccination measure to assess whether they are taking steps to limit the spread of COVID-19 among their healthcare workers and to help sustain the ability of IPFs 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 the NHSN.

We further note that as described in section IV.E.C of this preamble, we will calculate performance on the FAPH measure using Medicare Part A and Part B claims that facilities and other providers submit for payment. Since this is a claims-based measure, there is no additional burden outside of submitting the claim. The claim submission is approved by OMB under control number 0938-0050 (CMS-2552-10). This rule does not propose any changes under that control number.

(2). Updates Due to Proposed Measure Removals

In section IV.F. of this preamble, we are proposing to remove the following four measures for the FY 2024 payment determination and subsequent years:

- SUB-2—Alcohol Use Brief Intervention Provided or Offered and the subset measure SUB-2a Alcohol Use Brief Intervention Provided;
- TOB-2—Tobacco Use Brief Intervention Provided or Offered and the subset measure TOB-2a Tobacco Use Brief Intervention;
- Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care); and
- FUH—Follow-Up After Hospitalization for Mental Illness (NQF #0576).

For the FY 2024 payment determination, data on CY 2022 performance would be reported during the summer of 2023. Therefore, we are applying the burden reduction that would occur to the FY 2023 burden calculation. Three of these measures

¹³⁹ Section 321 of the National Childhood Vaccine Injury Act (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.

¹⁴⁰ <https://www.bls.gov/oes/current/oes436013.htm> (accessed on March 30, 2021). The hourly rate of \$36.62 includes an adjustment of 100 percent of the median hourly wage to account for the cost of overhead, including fringe benefits.

(SUB-2/2a, TOB-2/2a, and the Timely Transmission measure) fall under our previously finalized “global sample” (80 FR 46717 through 46718) and, therefore, would require abstraction of 609 records. We estimate that removing each of these three measures would result in a decrease in burden of 152.25 hours per facility, or 248,776.5 hours (152.25 hours × 1,634 facilities) across all IPFs. Therefore, the decrease in costs for each measure is approximately \$6,242.25 per

IPF (\$41.00hr * 152.25 hours), or \$10,199,836.50 across all IPFs (\$6,242.25/facility * 1,634 facilities). For all three of these chart-abstracted measures the total decrease in burden is approximately 456.75 hours per IPF (3 measures * 152.25 hours per measure) or 746,329.5 hours across all IPFs (3 measures * 248,776.5 hours per measure). This equates to \$18,726.75 per IPF (3 measures * \$6,242.25 per measure), or \$30,599,509.50 across all

IPFs (3 measures * \$10,199,836.50 per measure).

We have previously estimated that the FUH (NQF #0576) measure does not have any reporting burden because it is calculated from Medicare FFS claims. Therefore, we do not anticipate a reduction in facility burden associated with the removal of this measure. Table 14 describes our estimated reduction in burden associated with removing these four measures.

TABLE 14—BURDEN UPDATES DUE TO PROPOSED MEASURE REMOVALS

NQF #	Measure ID	Measure description	Estimated cases (per facility)	Time per case (hours)	Annual time per facility (hours)	Number IPFs	Total annual time (hours)	Total annual cost (\$)
N/A	SUB-2 and SUB-2a.	Alcohol Use Brief Intervention Provided or Offered.	(609)	0.25	152.25	1,634	(248,776.5)	(10,199,836.5)
0576	FUH	Follow-Up After Hospitalization for Mental Illness*.	0	0	0	1,634	0	0
N/A	TOB-2 and TOB-2a.	Tobacco Use Treatment Provided or Offered and Tobacco Use Treatment.	(609)	0.25	152.25	1,634	(248,776.5)	(10,199,836.5)
0648	N/A	Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care).	(609)	0.25	152.25	1,634	(248,776.5)	(10,199,836.5)
Total			(1,827)	Varies	(456.75)	1,634	(746,329.5)	(30,599,509.50)

* CMS will collect these data using Medicare Part A and Part B claims; therefore, these measures will not require facilities to submit data on any cases.

(3). Updates Due to Proposed Administrative Policies

(a). Updates Associated With Proposed Updated Reference to QualityNet System Administrator

In section IV.J.1.a of this preamble, we proposed to use the term “QualityNet security official” instead of “QualityNet system administrator.” Because this proposed update would not change the individual’s responsibilities, we do not believe there would be any changes to the information collection burden as a result of this update. We also do not believe that removing the requirement for facilities to have an active

QualityNet security official account to qualify for payment updates will affect burden because we continue to recommend that facilities maintain an active QualityNet security official account.

(b). Updates Associated With Proposed Adoption of Patient-Level Reporting for Certain Chart Abstracted Measures

In section IV.J.2.c of this preamble, we propose to adopt patient-level data submission for the eleven chart-abstracted measures currently in the IPFQR Program measure set (for more details on these measures we refer readers to Table 6). Because submission

of aggregate data requires facilities to abstract patient-level data, then calculate measure performance prior to submitting data through the QualityNet website’s secure portal, facilities must already abstract patient-level data. Therefore, we do not believe that submitting data that facilities must already calculate through a tool that facilities already have experience using will change provider burden.

d. Overall Burden Summary

Table 15 summarizes the estimated burden associated with the IPFQR Program if the proposals in this rule are finalized.

TABLE 15—TOTAL ESTIMATED IPFQR PROGRAM BURDEN

Measure/response description	Estimated responses per facility	Time per response (hours)	Annual time per facility (hours)	Total annual time (hours)	Total annual cost (\$)
Hours of Physical Restraint Use	1,346	0.25	336.50	549,841	\$22,543,481
Hours of Seclusion Use	1,346	0.25	336.50	549,841	22,543,481
Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification	* 609	0.25	152.25	248,776.5	10,199,836.50
Alcohol and Other Drug Use Disorder Treatment Provided or Offered at Discharge and Alcohol and Other Drug Use Disorder Treatment at Discharge	* 609	0.25	152.25	248,776.5	10,199,836.50
Tobacco Use Treatment Provided or Offered at Discharge and Tobacco Use Treatment at Discharge	* 609	0.25	152.25	248,776.5	10,199,836.50
Influenza Immunization	* 609	0.25	152.25	248,776.5	10,199,836.50
Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care)	* 609	0.25	152.25	248,776.5	10,199,836.50
Screening for Metabolic Disorders	* 609	0.25	152.25	248,776.5	10,199,836.50
Thirty-day all-cause unplanned readmission following psychiatric hospitalization in an IPF	** 0	0	0	0	0
Medication Continuation Following Inpatient Psychiatric Discharge	** 0	0	0	0	0
COVID-19 Vaccination Rate Among Healthcare Personnel	*** 0	0	0	0	0
Follow-Up After Psychiatric Hospitalization	** 0	0	0	0	0

TABLE 15—TOTAL ESTIMATED IPFQR PROGRAM BURDEN—Continued

Measure/response description	Estimated responses per facility	Time per response (hours)	Annual time per facility (hours)	Total annual time (hours)	Total annual cost (\$)
Non-Measure Data Collection and Reporting	4	0.5	2.0	3,268	133,988
Total	6,346	N/A	1,588.5	2,595,609	106,419,969

* Under our previously finalized “global sample” (80 FR 46717 through 46718) we allow facilities to apply the same sampling methodology to all measures eligible for sampling. In the FY 2016 IPF PPS final rule (80 FR 46718), we finalized that facilities with between 609 and 3,056 cases that choose to participate in the global sample would be required to report data for 609 cases. Because facilities are only required to submit data on a number specified by the global sampling methodology, rather than abstracting data for all patients or applying measure specific sampling methodologies, we believe that the number of cases under the global sample is a good approximation of facility burden associated with these measures. Therefore, for the average IPF discharge rate of 1,346 discharges versus the previously estimated 1,283, the global sample continues to require abstraction of 609 records.

** CMS will collect these data using Medicare Part A and Part B claims; therefore, these measures will not require facilities to submit data on any cases.

*** The COVID-19 HCP measure will be calculated using data submitted to the CDC under a separate OMB Control Number (0920-1317).

The total change in burden associated with this proposed rule (including all updates to wage rate, case counts, facility numbers, and the measures and administrative policies) is a reduction of 785,477 hours and \$20,911,738 from our currently approved burden of 3,381,086 hours and \$127,331,707. We refer readers to Table 16 for details.

TABLE 16—SUMMARY OF PROPOSED REQUIREMENTS AND ANNUAL BURDEN ESTIMATES UNDER OMB CONTROL NUMBER 0938-1171 (CMS-10432)

Program changes	Number respondents	Total responses	Time per response (hr)	Total time (hr)	Labor cost per hour (\$/hr)	Total cost (\$)
Active Burden	1,679	13,517,629	Varies	3,381,086	37.66	127,331,707
Total Burden Under CMS-1750-P	1,634	10,375,900	Varies	2,595,609	41.00	106,419,969
PROPOSED CHANGES	(45)	(3,141,729)	Varies	(785,477)	+3.34	(20,911,738)

B. Submission of PRA-Related Comments

We have submitted a copy of this proposed rule to OMB for its review of the rule’s information collection and recordkeeping requirements. The requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections previously discussed, visit CMS’s website at: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html> or call the Reports Clearance Office at (410) 786-1326.

We invite public comments on these information collection requirements. If you wish to comment, identify the rule (CMS-1750-P) and, where applicable, the preamble section, and the ICR section. See this rule’s **DATES** and **ADDRESSES** sections for the comment due date and for additional instructions.

VI. Regulatory Impact Analysis

A. Statement of Need

This rule proposes updates to the prospective payment rates for Medicare inpatient hospital services provided by IPFs for discharges occurring during FY 2022 (October 1, 2021 through September 30, 2022). We are proposing to apply the 2016-based IPF market basket increase of 2.3 percent, less the productivity adjustment of 0.2 percentage point as required by

1886(s)(2)(A)(i) of the Act for a proposed total FY 2022 payment rate update of 2.1 percent. In this proposed rule, we are proposing to update the IPF labor-related share and update the IPF wage index to reflect the FY 2022 hospital inpatient wage index.

B. Overall Impact

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

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

economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

We estimate that this rulemaking is likely to be economically significant as measured by the \$100 million threshold, and hence, if finalized as proposed, a major rule under the Congressional Review Act. Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking.

We estimate that the total impact of these changes for FY 2022 payments compared to FY 2021 payments will be a net increase of approximately \$90 million. This reflects an \$80 million increase from the update to the payment rates (+\$90 million from the 4th quarter 2020 IGI forecast of the 2016-based IPF market basket of 2.3 percent, and –\$10 million for the productivity adjustment

of 0.2 percentage point), as well as a \$10 million increase as a result of the update to the outlier threshold amount. Outlier payments are estimated to change from 1.8 percent in FY 2021 to 2.0 percent of total estimated IPF payments in FY 2022.

C. Detailed Economic Analysis

In this section, we discuss the historical background of the IPF PPS and the impact of this proposed rule on the Federal Medicare budget and on IPFs.

1. Budgetary Impact

As discussed in the November 2004 and RY 2007 IPF PPS final rules, we applied a budget neutrality factor to the Federal per diem base rate and ECT payment per treatment to ensure that total estimated payments under the IPF PPS in the implementation period would equal the amount that would have been paid if the IPF PPS had not been implemented. The budget neutrality factor includes the following components: Outlier adjustment, stop-loss adjustment, and the behavioral offset. As discussed in the RY 2009 IPF PPS notice (73 FR 25711), the stop-loss adjustment is no longer applicable under the IPF PPS.

As discussed in section III.D.1 of this proposed rule, we are updating the wage index and labor-related share in a budget neutral manner by applying a wage index budget neutrality factor to the Federal per diem base rate and ECT payment per treatment. Therefore, the budgetary impact to the Medicare program of this proposed rule will be due to the market basket update for FY 2022 of 2.3 percent (see section III.A.4 of this proposed rule) less the productivity adjustment of 0.2 percentage point required by section 1886(s)(2)(A)(i) of the Act and the update to the outlier fixed dollar loss threshold amount.

We estimate that the FY 2022 impact will be a net increase of \$90 million in payments to IPF providers. This reflects an estimated \$80 million increase from

the update to the payment rates and a \$10 million increase due to the update to the outlier threshold amount to set total estimated outlier payments at 2.0 percent of total estimated payments in FY 2022. This estimate does not include the implementation of the required 2.0 percentage point reduction of the market basket update factor for any IPF that fails to meet the IPF quality reporting requirements (as discussed in section V.A. of this proposed rule).

2. Impact on Providers

To show the impact on providers of the changes to the IPF PPS discussed in this proposed rule, we compare estimated payments under the IPF PPS rates and factors for FY 2022 versus those under FY 2021. We determined the percent change in the estimated FY 2022 IPF PPS payments compared to the estimated FY 2021 IPF PPS payments for each category of IPFs. In addition, for each category of IPFs, we have included the estimated percent change in payments resulting from the update to the outlier fixed dollar loss threshold amount; the updated wage index data including the updated labor-related share; and the market basket update for FY 2022, as adjusted by the productivity adjustment according to section 1886(s)(2)(A)(i) of the Act.

Our longstanding methodology uses the best available data as the basis for our estimates of payments. Typically, this is the most recent update of the latest available fiscal year of IPF PPS claims, and for this proposed rulemaking, that would be the FY 2020 claims. However, as discussed in section III.F.2 of this proposed rule, the U.S. healthcare system undertook an unprecedented response to the COVID-19 PHE during FY 2020. Therefore, we considered whether the most recent available year of claims, FY 2020, or the prior year, FY 2019, would be the best for estimating IPF PPS payments in FY 2021 and FY 2022.

To illustrate the impacts of the FY 2022 changes in this proposed rule, our

analysis presents a side-by-side comparison of payments estimated using FY 2019 claims versus payments estimated using FY 2020 claims. We begin with FY 2019 IPF PPS claims (based on the 2019 MedPAR claims, June 2020 update) and FY 2020 IPF PPS claims (based on the 2020 MedPAR claims, December 2020 update). We estimate FY 2021 IPF PPS payments using these 2019 and 2020 claims, the finalized FY 2021 IPF PPS Federal per diem base rates, and the finalized FY 2021 IPF PPS patient and facility level adjustment factors (as published in the FY 2021 IPF PPS final rule (85 FR 47042 through 47070)). We then estimate the FY 2021 outlier payments based on these simulated FY 2021 IPF PPS payments using the same methodology as finalized in the FY 2021 IPF PPS final rule (85 FR 47061 through 47062) where total outlier payments are maintained at 2 percent of total estimated FY 2021 IPF PPS payments.

Each of the following changes is added incrementally to this baseline model in order for us to isolate the effects of each change:

- The proposed update to the outlier fixed dollar loss threshold amount.
- The proposed FY 2022 IPF wage index, the proposed FY 2022 labor-related share, and the proposed updated COLA factors.
- The proposed market basket update for FY 2022 of 2.3 percent less the productivity adjustment of 0.2 percentage point in accordance with section 1886(s)(2)(A)(i) of the Act for a payment rate update of 2.1 percent.

Our proposed column comparison in Table 17 illustrates the percent change in payments from FY 2021 (that is, October 1, 2020, to September 30, 2021) to FY 2022 (that is, October 1, 2021, to September 30, 2022) including all the payment policy changes in this proposed rule. For each column, Table 17 presents a side-by-side comparison of the results using FY 2019 and FY 2020 IPF PPS claims.

TABLE 17—FY 2022 IPF PPS PROPOSED PAYMENT IMPACTS
[Percent change in columns 3 through 5]

Facility by type	Number of facilities		Outlier		Wage index FY22, LRS, and COLA		Total percent change ¹	
	FY 2019 Claims	FY 2020 Claims	FY 2019 Claims	FY 2020 Claims	FY 2019 Claims	FY 2020 Claims	FY 2019 Claims	FY 2020 Claims
(1)	(2)		(3)		(4)		(5)	
All Facilities	1,526	1,536	0.2	-0.7	0.0	0.0	2.3	1.4
Total Urban	1,226	1,238	0.2	-0.7	0.0	0.0	2.3	1.3
Urban unit	742	738	0.3	-1.1	-0.1	-0.1	2.3	0.9
Urban hospital	484	500	0.1	-0.2	0.0	0.0	2.2	1.9
Total Rural	300	298	0.1	-0.5	0.1	0.1	2.4	1.8
Rural unit	240	237	0.1	-0.6	0.0	0.0	2.2	1.5
Rural hospital	60	61	0.1	-0.2	0.5	0.5	2.7	2.4

TABLE 17—FY 2022 IPF PPS PROPOSED PAYMENT IMPACTS—Continued
[Percent change in columns 3 through 5]

Facility by type	Number of facilities		Outlier		Wage index FY22, LRS, and COLA		Total percent change ¹	
	FY 2019 Claims	FY 2020 Claims	FY 2019 Claims	FY 2020 Claims	FY 2019 Claims	FY 2020 Claims	FY 2019 Claims	FY 2020 Claims
(1)	(2)		(3)		(4)		(5)	
By Type of Ownership:								
Freestanding IPFs:								
Urban Psychiatric Hospitals:								
Government	117	123	0.3	-1.1	-0.2	-0.2	2.2	0.7
Non-Profit	93	95	0.1	-0.3	-0.3	-0.2	1.9	1.6
For-Profit	274	282	0.0	-0.1	0.1	0.2	2.3	2.2
Rural Psychiatric Hospitals:								
Government	31	32	0.1	-0.4	0.5	0.6	2.8	2.2
Non-Profit	12	12	0.2	-0.7	0.0	0.1	2.3	1.5
For-Profit	17	17	0.0	0.0	0.6	0.6	2.7	2.7
IPF Units:								
Urban:								
Government	109	108	0.4	-2.1	0.1	0.1	2.7	0.0
Non-Profit	482	480	0.3	-1.1	-0.1	-0.1	2.3	0.9
For-Profit	151	150	0.1	-0.5	-0.1	-0.1	2.2	1.5
Rural:								
Government	58	57	0.1	-0.2	0.3	0.2	2.5	2.1
Non-Profit	133	130	0.2	-0.8	0.0	0.0	2.2	1.2
For-Profit	49	50	0.1	-0.4	-0.2	-0.2	2.0	1.4
By Teaching Status:								
Non-teaching	1,329	1,339	0.1	-0.6	0.0	0.0	2.2	1.5
Less than 10% interns and residents to beds								
.....	106	106	0.3	-1.2	0.0	0.0	2.4	0.9
10% to 30% interns and residents to beds								
.....	70	70	0.4	-1.6	0.0	0.0	2.4	0.5
More than 30% interns and residents to beds								
.....	21	21	0.4	-1.9	-0.1	-0.1	2.4	0.1
By Region:								
New England	106	106	0.2	-0.8	-0.3	-0.4	2.0	1.0
Mid-Atlantic	215	217	0.3	-1.3	-0.2	-0.2	2.1	0.5
South Atlantic	241	243	0.1	-0.5	0.7	0.7	2.9	2.3
East North Central	245	245	0.1	-0.4	-0.1	-0.1	2.2	1.5
East South Central	152	155	0.1	-0.5	-0.7	-0.7	1.5	0.8
West North Central	110	110	0.2	-0.9	0.2	0.2	2.6	1.4
West South Central	225	227	0.1	-0.4	-0.3	-0.3	1.9	1.4
Mountain	103	102	0.1	-0.4	0.1	0.1	2.3	1.8
Pacific	129	131	0.2	-0.9	0.4	0.5	2.8	1.6
By Bed Size:								
Psychiatric Hospitals:								
Beds: 0–24	85	90	0.1	-0.3	0.1	0.1	2.3	1.9
Beds: 25–49	79	83	0.1	-0.2	-0.5	-0.4	1.7	1.4
Beds: 50–75	84	87	0.0	-0.1	0.1	0.3	2.3	2.3
Beds: 76 +	296	301	0.1	-0.3	0.1	0.1	2.3	2.0
Psychiatric Units:								
Beds: 0–24	540	531	0.2	-0.8	0.0	-0.1	2.3	1.2
Beds: 25–49	258	259	0.2	-0.9	0.0	0.0	2.4	1.2
Beds: 50–75	115	115	0.3	-1.1	-0.2	-0.3	2.2	0.7
Beds: 76 +	69	70	0.3	-1.6	0.0	0.0	2.2	0.4

¹ This column includes the impact of the updates in column (3) and (4) above, and of the proposed IPF market basket increase factor for FY 2022 (2.3 percent), reduced by 0.2 percentage point for the productivity adjustment as required by section 1886(s)(2)(A)(i) of the Act. Note, the products of these impacts may be different from the percentage changes shown here due to rounding effects.

3. Impact Results

Table 17 displays the results of our analysis. The table groups IPFs into the categories listed here based on characteristics provided in the Provider of Services file, the IPF PSF, and cost report data from the Healthcare Cost Report Information System:

- Facility Type.
- Location.
- Teaching Status Adjustment.
- Census Region.
- Size.

The top row of the table shows the overall impact on the 1,526 IPFs included in the analysis for FY 2019 claims or the 1,536 IPFs included in the analysis for FY 2020 claims. In column

2, we present the number of facilities of each type that had information available in the PSF and also had claims in the MedPAR dataset for FY 2019 or FY 2020. The number of providers in each category therefore differs slightly between the two years.

In column 3, we present the effects of the update to the outlier fixed dollar loss threshold amount. Based on the FY 2019 claims, we would estimate that IPF outlier payments as a percentage of total IPF payments are 1.8 percent in FY 2021. Alternatively, based on the FY 2020 claims, we would estimate that IPF outlier payments as a percentage of total IPF payments are 2.7 percent in FY 2021.

Thus, we are proposing to adjust the outlier threshold amount in this proposed rule to set total estimated outlier payments equal to 2.0 percent of total payments in FY 2022. Based on the FY 2019 claims, the estimated change in total IPF payments for FY 2022 would include an approximate 0.2 percent increase in payments because we would expect the outlier portion of total payments to increase from approximately 1.8 percent to 2.0 percent. Alternatively, based on the FY 2020 claims, the estimated change in total IPF payments for FY 2022 would include an approximate 0.7 percent decrease in payments because we would expect the outlier portion of total

payments to decrease from approximately 2.7 percent to 2.0 percent.

The overall impact of the estimated increase or decrease to payments due to updating the outlier fixed dollar loss threshold (as shown in column 3 of Table 17), across all hospital groups, is 0.2 percent based on the FY 2019 claims, or -0.7 percent based on the FY 2020 claims. If we decrease the outlier fixed dollar loss threshold based on the FY 2019 claims, the largest increase in payments due to this change is estimated to be 0.4 percent for urban, government-owned IPF units and also 0.4 percent for teaching IPFs with 10 percent or more interns and residents to beds. These same provider types, along with IPF units having more than 75 beds, would experience the largest estimated decrease in payments if we instead increase the outlier fixed dollar loss threshold based on the FY 2020 claims distribution.

In column 4, we present the effects of the budget-neutral update to the IPF wage index, the Labor-Related Share (LRS), and the proposed updated COLA factors discussed in section III.D.3. This represents the effect of using the concurrent hospital wage data as discussed in section III.D.1.a of this proposed rule. That is, the impact represented in this column reflects the proposed updated COLA factors and the update from the FY 2021 IPF wage index to the proposed FY 2022 IPF wage index, which includes basing the FY 2022 IPF wage index on the FY 2022 pre-floor, pre-reclassified IPPS hospital wage index data and updating the LRS from 77.3 percent in FY 2021 to 77.1 percent in FY 2022. We note that there is no projected change in aggregate payments to IPFs, as indicated in the first row of column 4; however, there will be distributional effects among different categories of IPFs. We also note that when comparing the results using FY 2019 and FY 2020 claims, the distributional effects are very similar. For example, we estimate the largest increase in payments to be 0.7 percent for IPFs in the South Atlantic region, and the largest decrease in payments to be -0.7 percent for IPFs in the East South Central region, based on either the FY 2019 or FY 2020 claims.

Finally, column 5 compares the total proposed changes reflected in this proposed rule for FY 2022 to the estimates for FY 2021 (without these changes). The average estimated increase for all IPFs is approximately 2.3 percent based on the FY 2019 claims, or 1.4 percent based on the FY 2020 claims. These estimated net increases include the effects of the 2016-

based market basket update of 2.3 percent reduced by the productivity adjustment of 0.2 percentage point, as required by section 1886(s)(2)(A)(i) of the Act. They also include the overall estimated 0.2 percent increase or 0.7 percent decrease in estimated IPF outlier payments as a percent of total payments from updating the outlier fixed dollar loss threshold amount. In addition, column 5 includes the distributional effects of the proposed updates to the IPF wage index, the labor-related share, and the proposed updated COLA factors, whose impacts are displayed in column 4. Based on the FY 2020 claims distribution, the increase to estimated payments due to the market basket update factor are offset in large part for some provider types by the increase to the outlier fixed dollar loss threshold.

In summary, comparing the impact results for the FY 2019 and FY 2020 claims, the largest difference in the results is due to the update to the outlier fixed dollar loss threshold. Therefore, we examined the differences between the FY 2019 and FY 2020 claims distributions to better understand the disparity in the estimate of outlier payments as a percentage of total PPS payments between the two years, which is driving the divergent results in column 3 of Table 17.

The calculation of the estimated outlier percentage has two components: Estimated outlier payments and estimated total PPS payments. As discussed in section III.F.1 of this proposed rule, we make outlier payments for discharges in which an IPF's estimated total cost for a case exceeds a fixed dollar loss threshold amount (multiplied by the IPF's facility-level adjustments) plus the Federal per diem payment amount for the case. Therefore, estimated outlier payments are a function of both estimated IPF costs and estimated IPF Federal per diem payment amounts per case. As such, we looked at changes in estimated costs, estimated Federal per diem payment amounts, estimated outlier payments, and estimated total PPS payments in order to understand the differences in the estimated outlier percentage when using the FY 2019 and FY 2020 claims data. To facilitate the comparison between our FY 2019 and FY 2020 datasets, we inflated all estimated costs to the midpoint of FY 2021 and estimated all payments based on the finalized FY 2021 IPF PPS patient and facility level adjustment factors (as published in the FY 2021 IPF PPS final rule (85 FR 47042 through 47070)). In summary, we found that estimated outlier payments using the FY

2020 claims dataset are 26 percent higher than the estimated outlier payments using the FY 2019 claims dataset, due to estimated costs per stay that were relatively higher than estimated Federal per diem payment amounts per stay. Estimated total payments using the FY 2020 claims dataset are 14 percent lower than the estimated total payments using the FY 2019 claims dataset. Therefore, both the estimated outlier payments and estimated total payments are contributing to the differences in the estimated outlier payment percentage of 2.7 percent using the FY 2020 claims dataset and 1.8 percent using the FY 2019 claims dataset. We discuss estimated total payments and estimated outlier payments in more detail below.

As stated above, we observed a reduction of estimated total PPS payments of approximately 14 percent using the FY 2020 claims dataset relative to estimated total PPS payments in our FY 2019 claims dataset. The reduction in estimated total PPS payments corresponds with a roughly 15 percent decline in covered IPF days and a roughly 17 percent decline in covered IPF stays. The consistency between the decline in IPF stays and IPF days indicates the overall length of stay is fairly consistent in the FY 2019 claims dataset and FY 2020 claims dataset.

An important consideration for how we estimate the percentage of estimated outlier payments in FY 2022 is whether we expect this lower level of total payments to persist in future years. We note that although there has been a downward trend in IPF stays and total payments in recent years, the decrease from FY 2019 to FY 2020 is 2 to 3 times greater than the decreases in recent prior years. Looking on a monthly basis at the claims in our FY 2020 claims dataset, we observed that estimated total PPS payments per month declined sharply, nearly 28 percent, from January 2020 to April 2020. Estimated total PPS payments per month decreased overall by approximately 21 percent from January 2020 to September 2020. The lower estimated total PPS payments per month were a result of both lower covered IPF days and covered IPF stays. The COVID-19 PHE was declared on January 31, 2020, and continued through the end of FY 2020, with an initial surge in cases occurring in many places in the early months of the PHE. Based on the timing of the declines in covered IPF stays and covered IPF days, we believe they are related to the response to the COVID-19 PHE. Therefore, we do not anticipate that decreases in total PPS payments,

covered IPF days, and covered IPF stays of the same magnitude as observed in FY 2020 are likely to occur in FY 2022. We are seeking comments on this analysis. Specifically, we are requesting comments from stakeholders about likely explanations for the declines in total PPS payments, covered IPF days, and covered IPF stays in FY 2020.

Next, we looked at estimated outlier payments. Estimated outlier payments were approximately 26 percent higher using the FY 2020 claims data compared to estimated outlier payments using the FY 2019 claims data despite overall covered IPF stays being approximately 17 percent lower using the FY 2020 claims data. As stated above, we make outlier payments for discharges in which an IPF's estimated total cost for a case exceeds a fixed dollar loss threshold amount (multiplied by the IPF's facility-level adjustments) plus the Federal per diem payment amount for the case. We examined estimated IPF costs and estimated IPF Federal per diem payment amounts in order to understand the increase in estimated outlier payments. Overall, estimated costs were approximately 12 percent lower when using the FY 2020 claims dataset. However, estimated Federal per diem payment amounts were approximately 15 percent lower. In other words, both estimated costs and estimated Federal per diem payments declined along with the number of stays, but, importantly, estimated Federal per diem payment amounts decreased by a greater amount. When we account for the number of stays, we can see that estimated costs and Federal per diem payment amounts per stay were greater in FY 2020 than in FY 2019, but the increase in estimated cost per stay was greater. Estimated Federal per diem payment amounts per stay were approximately 2.5 percent higher using the FY 2020 claims dataset than estimated Federal per diem payment amounts per stay using the FY 2019 claims dataset. However, estimated costs per stay were about 6.0 percent higher than estimated Federal per diem payments per stay using the FY 2019 claims dataset. In other words, we observed that estimated costs per stay increased by more than estimated IPF Federal per diem payment amounts per stay when the FY 2020 claims dataset was used. As a result, total estimated costs were approximately 12 percent lower but total estimated Federal per diem payments were approximately 15 percent lower. This difference between estimated costs and estimated Federal per diem payments contributed to the 26 percent greater estimated outlier

payments using the FY 2020 claims dataset.

We wanted to understand whether there were monthly trends in estimated costs and estimated Federal per diem payment amounts that would explain why estimated costs increased more than estimated Federal per diem payment amounts from FY 2019 to FY 2020, and if any of these monthly trends might be related to the COVID-19 PHE. Looking on a monthly basis, we observed that estimated cost per stay and estimated IPF Federal per diem payment per stay generally moved in line with average length of stay until July 2020, however estimated costs remained relatively higher than estimated payments from July 2020 until September 2020. Discharges in our dataset occurring in February and March 2020 had an average length of stay that was roughly 6 percent shorter than for discharges occurring in April 2020, and for May 2020, average length of stay was approximately 4 percent shorter than in the preceding month. We observed comparable peaks and valleys in average cost per stay and average estimated IPF Federal per diem payment per stay. However, the changes in average cost per stay were smaller, around a 3 percent increase from March 2020 to April 2020 and a 3.4 decrease percent from April 2020 to May 2020. Additionally, we observed that estimated cost per stay declined less than average length of stay and estimated IPF Federal per diem payment per stay from July 2020 to September 2020, declining approximately 0.6 percent compared to 1.4 percent for length of stay and 1.5 percent for estimated IPF Federal per diem payment per stay. In other words, we observed that from July 2020 to September 2020, the declines in estimated payments were greater than the declines in estimated costs, and therefore the gap between costs and payments increased during this period.

Looking specifically at estimated outlier cases on a monthly basis, we observed a similar trend from March 2020 to May 2020 in average length of stay, estimated IPF Federal per diem payment per stay, and estimated cost per stay to those we observed in all FY 2020 claims in our dataset. However, from July 2020 to September 2020, estimated cost per stay, estimated IPF Federal per diem payment per stay, and average length of stay all increased. Estimated cost per stay and estimated length of stay increased approximately 3.9 percent and 2.0 percent, whereas estimated IPF Federal per diem payment per stay increased by a lower amount, approximately 2.4 percent.

Additionally, we observed that estimated outlier payment per outlier stay was approximately 50 percent higher in July 2020 than it was in May 2020. In September 2020 estimated outlier payment per outlier stay was approximately 62 percent higher than May 2020. In other words, we observed that the divergence in estimated costs and estimated payments in our FY 2020 dataset corresponded with the increase in estimated outlier payment per stay.

Because the IPF PPS is a per diem payment system, we also looked at whether increased length of stay was contributing to the increased estimated outlier payment per case. Among estimated outlier cases, we calculated the estimated outlier payment per covered IPF day. We observed that estimated outlier payment per covered day was nearly 69 percent greater in July 2020 than it was in May 2020, and remained at a higher level through the end of the year than at the start of the year. Compared to January 2020, average length of stay for estimated outlier cases in September 2020 was approximately 10 percent lower, whereas estimated outlier payment per outlier stay was approximately 52 percent higher. Therefore, we concluded that increased length of stay among estimated outlier cases does not appear to be driving the increase in estimated outlier payments.

We examined the distribution of DRGs throughout the FY 2020 claims in our dataset but did not observe variation that would explain the substantial increases in estimated outlier payments. In general, the majority of IPF cases have a DRG of 885 (Psychoses). The percentage of claims with this DRG remained very similar from FY 2019 (74.5 percent) to FY 2020 (75.2 percent), and this percentage did not appear to diverge or fluctuate meaningfully during FY 2020. We also looked at comorbidities and observed that the percentage of cases with a comorbidity increased slightly, from approximately 3.6 percent in our FY 2019 dataset to 3.8 percent in our FY 2020 dataset. In general, most IPF cases in both FY 2019 and FY 2020 did not have any IPF comorbidities. Among cases with at least one comorbidity, the number of cases for each comorbidity category declined in FY 2020, with the exception of Chronic Obstructive Pulmonary Disorder. We note that this is the IPF comorbidity category in which the COVID-19 diagnosis code, U07.1, falls. However, cases with this comorbidity category remained a relatively small percentage of all IPF cases, approximately 0.8 percent in FY 2019 and approximately 1.3 percent in FY 2020. Additionally, among estimated

outlier cases, those with at least one comorbidity received approximately 58 percent less estimated outlier pay per covered day than those without any comorbidities. This makes intuitive sense, because cases with an IPF comorbidity would receive a payment adjustment corresponding to the appropriate IPF comorbidity category, therefore reducing the difference between estimated IPF Federal per diem payments and costs for those cases. Therefore, it does not seem likely that cases with IPF comorbidities were the main driver of the increases in estimated outlier payments.

Observing that changes in DRGs and comorbidities did not appear to be driving the increased estimated outlier payments in FY 2020, we wanted to understand what was causing the higher estimated costs relative to estimated IPF Federal per diem payments that we observed in FY 2020. Following our longstanding methodology, we estimate the costs per case based on the covered charges on each IPF claim and the IPF's most recent CCR. Therefore, in order to better understand estimated costs, we looked at covered charges in FY 2019 and FY 2020. For this analysis, we used a different source for claims which enabled us to calculate covered charge by categories corresponding to the MedPAR ancillary departments. We analyzed FY 2019 and FY 2020 IPF claims data from the Common Working File (CWF).

In general, laboratory charges make up roughly one third of the covered charges per IPF claim. Comparing FY 2019 to FY 2020, we observed that covered lab charges per claim in our CWF dataset increased approximately 6.8 percent. Looking on a monthly basis, we observed fluctuation in covered lab charges per claim and per day during the COVID-19 PHE. We looked specifically at the period January 2020 (the month in which the COVID-19 PHE was declared) to September 2020 (the end of FY 2020), and observed peaks and valleys in covered lab charges that we believe may be related to the response to the COVID-19 PHE. Covered lab charges per day increased approximately 6.3 percent (2.4 percent per claim) from January 2020 to March 2020, decreased approximately 7.1 percent (1.1 percent per claim) from March 2020 to April 2020, and then increased approximately 6.2 percent (0.9 percent per claim) from April 2020 to September 2020. Overall, covered lab charges per day increased approximately 4.9 percent (2.2 percent per claim) from January 2020 to September 2020. In other words, most of the 6.8 percent increase in covered lab

charges from FY 2019 to FY 2020 occurred during the period January 2020 to September 2020, with the highest levels of lab charges occurring during February/March and June through September. Based on the data available, we are not able to determine the root cause of these increases in covered lab charges during the COVID-19 PHE, however we acknowledge that these increased charges may be related to services in response to the COVID-19 PHE, such as COVID-19 testing. We are requesting comments on this analysis. Specifically, we are requesting comments from stakeholders about likely explanations for the observed fluctuations and overall increases in covered lab charges per claim and per day. We are also requesting comments regarding likely explanations for the increases in estimated cost per stay relative to estimated IPF Federal per diem payment amounts per stay.

As discussed in this section, estimated outlier payments increased and estimated total PPS payments decreased, when comparing FY 2020 to FY 2019. Based on our analysis, we believe it is likely that the response to the COVID-19 PHE in FY 2020 has contributed to both of these trends. As a result, in contrast to our usual methodology, we are not confident that FY 2020 claims are the best available data for setting the FY 2022 proposed outlier fixed dollar loss threshold. Furthermore, the distributional effects of the updates presented in column 4 of Table 17 (the budget-neutral update to the IPF wage index, the LRS, and the proposed updated COLA factors) are very similar when using the FY 2019 or FY 2020 claims data. Therefore, we believe the FY 2019 claims would be the best available data for estimating payments in this FY 2022 proposed rulemaking, and we are proposing to use the FY 2019 claims to calculate the outlier fixed dollar loss threshold and wage index budget neutrality factor.

IPF payments are therefore estimated to increase by 2.3 percent in urban areas and 2.4 percent in rural areas based on this proposal. Overall, IPFs are estimated to experience a net increase in payments as a result of the updates in this proposed rule. The largest payment increase is estimated at 2.9 percent for IPFs in the South Atlantic region.

4. Effect on Beneficiaries

Under the FY 2022 IPF PPS, IPFs will continue to receive payment based on the average resources consumed by patients for each day. Our longstanding payment methodology reflects the differences in patient resource use and costs among IPFs, as required under

section 124 of the BBRA. We expect that updating IPF PPS rates as proposed in this rule will improve or maintain beneficiary access to high quality care by ensuring that payment rates reflect the best available data on the resources involved in inpatient psychiatric care and the costs of these resources. We continue to expect that paying prospectively for IPF services under the FY 2022 IPF PPS will enhance the efficiency of the Medicare program.

As discussed in sections IV.E.2, IV.E.3, and V.A.2.d of this proposed rule, we expect that additional program measures will improve follow-up for patients with both mental health and substance use disorders and ensure health-care personnel COVID-19 vaccinations. We also estimate a \$20,911,738 reduction in information collection burden as a result of our measure removal proposals. Therefore, we expect that the proposed updates to the IPFQR program will improve quality for beneficiaries.

5. Effects of Updates to the IPFQR Program

As discussed in section V. of this proposed rule and in accordance with section 1886(s)(4)(A)(i) of the Act, we will apply a 2 percentage point reduction in the FY 2022 market basket update for IPFs that have failed to comply with the IPFQR Program requirements for FY 2022, including reporting on the required measures. In section V. of this proposed rule, we discuss how the 2 percentage point reduction will be applied. For FY 2021, of the 1,634 IPFs eligible for the IPFQR Program, 43 IPFs (2.6 percent) did not receive the full market basket update because of the IPFQR Program; 31 of these IPFs chose not to participate and 12 did not meet the requirements of the program. We anticipate that even fewer IPFs would receive the reduction for FY 2022 as IPFs become more familiar with the requirements. Thus, we estimate that the IPFQR Program will have a negligible impact on overall IPF payments for FY 2022.

Based on the IPFQR Program proposals made in this proposed rule, we estimate a total decrease in burden of 785,477 hours across all IPFs, resulting in a total decrease in information collection burden of \$20,911,738 across all IPFs. As discussed in section VI. of this proposed rule, we will attribute the cost savings associated with the proposals to the year in which these savings begin; for the purposes of all the proposals in this proposed rule, that year is FY 2023. Further information on these estimates

can be found in section VI. of this proposed rule.

We intend to closely monitor the effects of the IPFQR Program on IPFs and help facilitate successful reporting outcomes through ongoing stakeholder education, national trainings, and a technical help desk.

6. 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 be directly impacted and will review this proposed rule, we assume that the total number of unique commenters on the most recent IPF proposed rule from FY 2021 (85 FR 20625) 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 IPF proposed rule in detail, and it is also possible that some reviewers chose not to comment on that proposed rule. For these reasons, we thought that the number of commenters would be a fair estimate of the number of reviewers who are directly impacted by this proposed rule. We solicited comments on this assumption.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule; therefore, for the

purposes of our estimate, we assume that each reviewer reads approximately 50 percent of this proposed rule.

Using the May, 2019 mean (average) wage information from the BLS for medical and health service managers (Code 11-9111), we estimate that the cost of reviewing this proposed rule is \$110.74 per hour, including overhead and fringe benefits (<https://www.bls.gov/oes/current/oes119111.htm>). Assuming an average reading speed of 250 words per minute, we estimate that it would take approximately 93.5 minutes (1.56 hours) for the staff to review half of this proposed rule, which is approximately 23,365 words. For each IPF that reviews the proposed rule, the estimated cost is (1.56 × \$110.74) or \$172.75. Therefore, we estimate that the total cost of reviewing this proposed rule is \$79,810.50 (\$172.75 × 462 reviewers).

D. Alternatives Considered

The statute does not specify an update strategy for the IPF PPS and is broadly written to give the Secretary discretion in establishing an update methodology. We continue to believe it is appropriate to routinely update the IPF PPS so that it reflects the best available data about differences in patient resource use and costs among IPFs as required by the statute. Therefore, we are proposing to update the IPF PPS using the methodology published in the November 2004 IPF PPS final rule; applying the 2016-based IPF PPS market basket update for FY 2022 of 2.3 percent, reduced by the statutorily required multifactor productivity

adjustment of 0.2 percentage point along with the wage index budget neutrality adjustment to update the payment rates; and proposing a FY 2022 IPF wage index which uses the FY 2022 pre-floor, pre-reclassified IPPS hospital wage index as its basis.

As discussed in section VI.C.3 of this proposed rule, we also considered using FY 2020 claims data to determine the proposed FY 2022 outlier fixed dollar loss threshold, wage index budget neutrality factor, per diem base rate, and ECT rate. For the reasons discussed in that section, we are proposing to use FY 2019 claims data.

E. Accounting Statement

As required by OMB Circular A-4 (available at www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf), in Table 18, we have prepared an accounting statement showing the classification of the expenditures associated with the updates to the IPF wage index and payment rates in this proposed rule. Table 18 provides our best estimate of the increase in Medicare payments under the IPF PPS as a result of the changes presented in this proposed rule and based on the data for 1,526 IPFs with data available in the PSF and with claims in our FY 2019 MedPAR claims dataset. Table 18 also includes our best estimate of the cost savings for the 1,634 IPFs eligible for the IPFQR Program. Lastly, Table 18 also includes our best estimate of the costs of reviewing and understanding this proposed rule.

TABLE 18—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS, SAVINGS, AND TRANSFERS

Category	Primary estimate (\$million/year)	Low estimate	High estimate	Units		
				Year dollars	Discount rate (%)	Period covered
Regulatory Review Costs	0.08	2020	* 2021–2022
Annualized Monetized Costs Savings	–20.91	–15.68	–26.14	2020	7	* 2023–2031
	–17.79	–13.34	–22.24	2020	3	2023–2031
Annualized Monetized Transfers from Federal Government to IPF Medicare Providers	90	2020	2021–2022

F. Regulatory Flexibility Act

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 IPFs and most other providers and suppliers are small entities, either by nonprofit status or having revenues of \$8 million to \$41.5 million or less in any 1 year.

Individuals and states are not included in the definition of a small entity.

Because we lack data on individual hospital receipts, we cannot determine the number of small proprietary IPFs or the proportion of IPFs’ revenue derived from Medicare payments. Therefore, we assume that all IPFs are considered small entities.

The Department of Health and Human Services 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 overall

revenue impact of this proposed rule on all IPFs is to increase estimated Medicare payments by approximately 2.3 percent. As a result, since the estimated impact of this proposed rule is a net increase in revenue across almost all categories of IPFs, the Secretary has determined that this proposed rule will have a positive revenue impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a

significant impact on the operations of a substantial number of small rural hospitals. This 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 discussed in section V.C.1 of this proposed rule, the rates and policies set forth in this proposed rule will not have an adverse impact on the rural hospitals based on the data of the 240 rural excluded psychiatric units and 60 rural psychiatric hospitals in our database of 1,526 IPFs for which data were available. Therefore, the Secretary has determined that this proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

G. Unfunded Mandate Reform Act (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 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. This proposed rule would not impose a mandate that will result in the expenditure by state, local, and Tribal Governments, in the aggregate, or by the private sector, of more than \$158 million in any one year.

H. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. This proposed rule does not impose substantial direct costs on state or local governments or preempt state law.

List of Subjects in 42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

■ 1. The authority citation for part 412 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 2. Section 412.402 is amended by adding definitions for “Closure of an IPF”, “Closure of an IPF’s residency training program”, and “Displaced resident” in alphabetical order to read as follows:

§ 412.402 Definitions.

* * * * *

Closure of an IPF means closure of a hospital as defined in § 413.79(h)(1)(i) by an IPF meeting the requirements of § 412.404(b) for the purposes of accounting for indirect teaching costs.

Closure of an IPF’s residency training program means closure of a hospital residency training program as defined in § 413.79(h)(1)(ii) by an IPF meeting the requirements of § 412.404(b) for the purposes of accounting for indirect teaching costs.

* * * * *

Displaced resident means a displaced resident as defined in § 413.79(h)(1)(iii) for the purposes of accounting for indirect teaching costs.

* * * * *

■ 3. Section 412.424 is amended by revising paragraph (d)(1)(iii)(F) to read as follows:

§ 412.424 Methodology for calculating the Federal per diem payment amount.

* * * * *

(d) * * *

(1) * * *

(iii) * * *

(F) *Closure of an IPF.* (1) For cost reporting periods beginning on or after July 1, 2011, an IPF may receive a temporary adjustment to its FTE cap to reflect displaced residents added because of another IPF’s closure if the IPF meets the following criteria:

(i) The IPF is training additional displaced residents from an IPF that closed on or after July 1, 2011.

(ii) No later than 60 days after the IPF begins to train the displaced residents, the IPF submits a request to its Medicare contractor for a temporary adjustment to its cap, documents that the IPF is eligible for this temporary adjustment by identifying the displaced residents who have come from the closed IPF and have caused the IPF to exceed its cap, and specifies the length of time the adjustment is needed.

(2) *Closure of an IPF’s residency training program.* If an IPF that closes its residency training program on or

after July 1, 2011, agrees to temporarily reduce its FTE cap according to the criteria specified in paragraph (d)(1)(iii)(F)(2)(ii) of this section, another IPF(s) may receive a temporary adjustment to its FTE cap to reflect displaced residents added because of the closure of the residency training program if the criteria specified in paragraph (d)(1)(iii)(F)(2)(i) of this section are met.

(i) *Receiving IPF(s).* For cost reporting periods beginning on or after July 1, 2011, an IPF may receive a temporary adjustment to its FTE cap to reflect displaced residents added because of the closure of another IPF’s residency training program if the IPF is training additional displaced residents from the residency training program of an IPF that closed a program; and if no later than 60 days after the IPF begins to train the displaced residents, the IPF submits to its Medicare Contractor a request for a temporary adjustment to its FTE cap, documents that it is eligible for this temporary adjustment by identifying the displaced residents who have come from another IPF’s closed program and have caused the IPF to exceed its cap, specifies the length of time the adjustment is needed, and submits to its Medicare contractor a copy of the FTE reduction statement by the hospital that closed its program, as specified in paragraph (d)(1)(iii)(F)(2)(ii) of this section.

(ii) *IPF that closed its program.* An IPF that agrees to train displaced residents who have been displaced by the closure of another IPF’s program may receive a temporary FTE cap adjustment only if the hospital with the closed program temporarily reduces its FTE cap based on the FTE of displaced residents in each program year training in the program at the time of the program’s closure. This yearly reduction in the FTE cap will be determined based on the number of those displaced residents who would have been training in the program during that year had the program not closed. No later than 60 days after the displaced residents who were in the closed program begin training at another hospital, the hospital with the closed program must submit to its Medicare contractor a statement signed and dated by its representative that specifies that it agrees to the temporary reduction in its FTE cap to allow the IPF training the displaced residents to obtain a temporary adjustment to its cap; identifies the displaced residents who were in training at the time of the program’s closure; identifies the IPFs to which the displaced residents are transferring once the program closes; and specifies the

reduction for the applicable program years.

* * * * *

■ 4. Section 412.434 is amended by revising paragraph (b)(3) to read as follows:

§ 412.434 Reconsideration and appeals procedures of Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program decisions.

* * * * *

(b) * * *

(3) Contact information for the inpatient psychiatric facility's chief executive officer and QualityNet security official, including each individual's name, email address, telephone number, and physical mailing address;

* * * * *

Dated: March 29, 2021.

Elizabeth Richter,
Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: April 6, 2021.

Xavier Becerra,
Secretary, Department of Health and Human Services.

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