



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 412

[CMS-1750-F]

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: Final rule.

SUMMARY: This final rule updates 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 acute care hospital or critical access hospital. This rule also updates and clarifies the IPF teaching policy with respect to IPF hospital closures and displaced residents and finalizes a technical change to one of the 2016-based IPF market basket price proxies. In addition, this final rule finalizes proposals on quality measures and reporting requirements under the Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program. We note that this final rule does not finalize two proposals to remove quality measures. The changes finalized in this rule for the IPFQR Program are effective for IPF discharges occurring during the Fiscal Year (FY) beginning October 1, 2021 through September 30, 2022 (FY 2022).

DATES: These regulations are effective on October 1, 2021.

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:

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

Addendum A to this final 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 final rule shows the complete listing of ICD-10 Clinical Modification (CM) and Procedure Coding System (PCS) codes, 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 final rule updates 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 FY 2022 beginning October 1, 2021 through September 30, 2022. This rule also updates and clarifies the IPF teaching policy with respect to IPF hospital closures and displaced residents and finalizes a technical change to one of the 2016-based IPF

market basket price proxies. In addition, the final rule finalizes proposals to adopt 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 finalizing our proposal 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 (2.7 percent) for economy-wide productivity (0.7 percentage point) as required by section 1886(s)(2)(A)(i) of the Social Security Act (the Act), resulting in a final IPF payment rate update of 2.0 percent for FY 2022.
- Make technical rate setting changes: The IPF PPS payment rates will be adjusted annually for inflation, as well as statutory and other policy factors. This final rule updates:

++ The IPF PPS Federal per diem base rate from \$815.22 to \$832.94.

++ The IPF PPS Federal per diem base rate for providers who failed to report quality data to \$816.61.

++ The Electroconvulsive therapy (ECT) payment per treatment from \$350.97 to \$358.60.

++ The ECT payment per treatment for providers who failed to report quality data to \$351.57.

++ The labor-related share from 77.3 percent to 77.2 percent.

++ The wage index budget-neutrality factor from 0.9989 to 1.0017.

++ The fixed dollar loss threshold amount from \$14,630 to \$14,470 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 final rule, we are:

- Adopting voluntary patient-level data reporting for chart-abstracted measures for data submitted for the FY 2023 payment determination and mandatory patient-level data reporting for chart-abstracted measures for the FY 2024 payment determination and subsequent years;

- Revising our regulations at 42 CFR 412.434(b)(3) by replacing the term “QualityNet system administrator” with “QualityNet security official”;

- Adopting the Coronavirus disease 2019 (COVID-19) Vaccination Coverage Among Health Care Personnel (HCP) measure for the FY 2023 payment determination and subsequent years;

- Adopting the Follow-up After Psychiatric Hospitalization (FAPH) measure for the FY 2024 payment determination and subsequent years; and

- Removing the following two measures for FY 2024 payment determination and subsequent years:

- ++ 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.

- Not finalizing our proposals to remove the following two 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; and

- ++ Tobacco Use Treatment Provided or Offered and Tobacco Use Treatment (TOB-2/2a) measure.

C. Summary of Impacts

Provision Description	Total Transfers & Cost Reductions
FY 2022 IPF PPS payment update	The overall economic impact of this final rule is an estimated \$80 million in increased payments to IPFs during FY 2022.
FY 2023 IPFQR Program update.	The overall economic impact of the IPFQR Program provisions of this final rule is an estimated \$512,065 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 of an acute care hospital or of a Critical Access Hospital (CAH), which is excluded from payment under the Inpatient Prospective Payment System (IPPS) or CAH payment system, respectively. These excluded psychiatric units will 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.

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 can 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 Final Rule and Responses to Comments

A. Final 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. Final FY 2022 IPF Market Basket Update

For FY 2022 (that is, beginning October 1, 2021 and ending September 30, 2022), we proposed to update the IPF PPS payments by a market basket increase factor with a productivity adjustment as required by section 1886(s)(2)(A)(i) of the Act. In the FY 2022 IPF proposed rule (86 FR 19483), we proposed to use the same methodology described in the FY 2021 IPF PPS

final rule (85 FR 47045 through 47046), with one proposed modification to the 2016-based IPF market basket.

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

In the FY 2022 IPF PPS proposed rule, we stated that 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 believed that the iBoxx AAA Corporate Bond Yield index is technically appropriate to use in the 2016-based IPF market basket.

Based on IGI's fourth quarter 2020 forecast with historical data through the third quarter of 2020, the proposed 2016-based IPF market basket increase factor for FY 2022 was projected to be 2.3 percent. We also proposed that if more recent data became available after the publication of the proposed rule and before the publication of this final rule (for example, a more recent estimate of the market basket update or MFP), we would use such data, if appropriate, to determine the FY 2022 market basket update in this final rule.

Section 1886(s)(2)(A)(i) of the Act requires that, after establishing the increase factor for a FY, the Secretary shall reduce such increase factor for FY 2012 and each subsequent FY, by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Section

1886(b)(3)(B)(xi)(II) of the Act sets forth the definition of this productivity adjustment. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business MFP (as projected by the Secretary for the 10-year period ending with the applicable FY, year, cost reporting period, or other annual period) (the “productivity adjustment”). The U.S. Department of Labor’s Bureau of Labor Statistics (BLS) publishes the official measure of private nonfarm business MFP. Please see <http://www.bls.gov/mfp> for the BLS historical published MFP data. A complete description of the MFP projection methodology is available on the CMS website at <https://www.cms.gov/Research-Statistics-Dataand-Systems/Statistics-Trends-andReports/MedicareProgramRatesStats/MarketBasketResearch.html>. We note that effective with FY 2022 and forward, CMS is changing the name of this adjustment to refer to it as the productivity adjustment rather than the MFP adjustment. We note that the adjustment relies on the same underlying data and methodology. This new terminology is more consistent with the statutory language described in section 1886(s)(2)(A)(i) of the Act.

Using IGI’s fourth quarter 2020 forecast, the productivity adjustment for FY 2022 was projected to be 0.2 percent. We proposed to then reduce the proposed 2.3 percent IPF market basket update by the estimated productivity adjustment for FY 2022 of 0.2 percentage point. Therefore, the proposed FY 2022 IPF update was equal to 2.1 percent (2.3 percent market basket update reduced by the 0.2 percentage point productivity adjustment). Furthermore, we proposed that if more recent data became available after the publication of the proposed rule and before the publication of this final rule (for example, a more recent estimate of the market basket or MFP), we would use such data, if appropriate, to determine the FY 2022 market basket update and productivity adjustment in this final rule.

Based on the more recent data available for this FY 2022 IPF final rule (that is, IGI’s second quarter 2021 forecast of the 2016-based IPF market basket with historical data through the first quarter of 2021), we estimate that the IPF FY 2022 market basket update is 2.7 percent.

The current estimate of the productivity adjustment for FY 2022 is 0.7 percentage point.

Therefore, the current estimate of the FY 2022 IPF increase factor is equal to 2.0 percent (2.7 percent market basket update reduced by 0.7 percentage point productivity adjustment).

We invited public comment on our proposals for the FY 2022 market basket update and productivity adjustment. The following is a summary of the public comments received on the proposed FY 2022 market basket update and productivity adjustment and our responses:

Comment: One commenter supported the update to the IPF payment rates of 2.1 percent.

Response: We thank the commenter for their support.

Comment: One commenter stated that given the growing behavioral health and substance abuse crisis made worse by the COVID-19 Public Health Emergency (PHE), that CMS should provide additional payment for IPFs in the future.

Response: We understand the commenter's concern. We acknowledge that the COVID-19 PHE has amplified the growing need for behavioral health services in this country and remain committed to trying to find ways to mitigate its impact on IPFs. Our goal is to ensure that the IPF payment rates accurately reflect the best available data. For example, as discussed in section VI.C.3 of this final rule, in comparing and analyzing FY 2019 and FY 2020 claims, we determined that the COVID-19 PHE appears to have significantly impacted the FY 2020 IPF claims such that the FY 2019 claims are the best available data to set the outlier fixed dollar loss threshold for FY 2022. Therefore, we deviated from our longstanding practice of using the most recent available year of claims, that is, FY 2020 claims, for estimating IPF PPS payments in FY 2022. We will continue to analyze more recent available IPF claims data to better understand both the short- and long-term effects of the COVID-19 PHE on the IPF PPS.

Final Decision: After consideration of the comments we received, we are finalizing a FY 2022 IPF update equal to 2.0 percent based on the more recent data available.

3. Final 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 proposed 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 proposed to calculate the labor-related share for FY 2022 as the sum of the FY 2022 relative importance of Wages and Salaries; Employee Benefits; Professional Fees: Labor-related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-related Services; and a portion of the Capital-Related relative importance from the 2016-based IPF market basket. For more details regarding the methodology for determining specific cost categories for inclusion in the 2016-based IPF labor-related share, see the FY 2020 IPF PPS final rule (84 FR 38445 through 38447).

The relative importance reflects the different rates of price change for these cost categories between the base year (FY 2016) and FY 2022. Based on IGI's fourth quarter 2020 forecast of the 2016-based IPF market basket, the sum of the FY 2022 relative importance for Wages and Salaries; Employee Benefits; Professional Fees: Labor-related; Administrative and Facilities Support Services; Installation Maintenance & Repair Services; and All Other: Labor related Services was 74.0 percent. We proposed that the portion of Capital-Related costs that are influenced by the local labor market is 46 percent. Since the relative importance for Capital-Related costs was 6.7 percent of the 2016-based IPF market basket for FY 2022, we proposed to take 46 percent of 6.7 percent to determine the labor-related share of Capital-Related costs for FY 2022 of 3.1 percent. Therefore, we proposed a total labor-related share for FY 2022 of 77.1 percent (the sum of 74.0 percent for the labor-related share of operating costs and 3.1 percent for

the labor-related share of Capital-Related costs). We also proposed that if more recent data became available after publication of the proposed rule and before the publication of this final rule (for example, a more recent estimate of the labor-related share), we would use such data, if appropriate, to determine the FY 2022 IPF labor-related share in the final rule.

Based on IGI’s second quarter 2021 forecast of the 2016-based IPF market basket, the sum of the FY 2022 relative importance for Wages and Salaries; Employee Benefits; Professional Fees: Labor-related; Administrative and Facilities Support Services; Installation Maintenance & Repair Services; and All Other: Labor-related Services is 74.1 percent. Since the relative importance for Capital-Related costs is 6.7 percent of the 2016-based IPF market basket for FY 2022, we take 46 percent of 6.7 percent to determine the labor-related share of Capital-Related costs for FY 2022 of 3.1 percent. Therefore, the current estimate of the total labor-related share for FY 2022 is equal to 77.2 percent (the sum of 74.1 percent for the labor-related share of operating costs and 3.1 percent for the labor-related share of Capital-Related costs). Table 1 shows the final FY 2022 labor-related share and the final FY 2021 labor-related share using the 2016-based IPF market basket relative importance.

TABLE 1: FY 2022 IPF Labor-Related Share and FY 2021 IPF Labor-Related Share

	Relative importance, labor-related share, FY 2021¹	Relative importance, labor-related share, FY 2022²
Wages and Salaries	52.9	52.8
Employee Benefits	13.6	13.6
Professional Fees: Labor-related	4.3	4.3
Administrative and Facilities Support Services	0.6	0.6
Installation, Maintenance and Repair	1.3	1.3
All Other Labor-related Services	1.5	1.5
Capital-related (.46)	3.1	3.1
Total	77.3	77.2

1. Based on the 2nd quarter 2020 IHS Global Inc. forecast of the 2016-based IPF market basket.

2. Based on the 2nd quarter 2021 IHS Global Inc. forecast of the 2016-based IPF market basket.

We invited public comments on the proposed labor-related share for FY 2022.

Comment: Several commenters supported the decrease in the labor-related share from 77.3 percent in FY 2021 to 77.1 percent in FY 2022 noting that it will help any facility that has a wage index less than 1.0. The commenters stated that, across this country there is a growing disparity between high-wage and low-wage states. Recognizing this disparity and slightly lowering the labor-related share provides some aid to hospitals in many rural and underserved communities.

Response: We thank the commenter for their support. We agree with the commenters that the labor-related share should reflect the proportion of costs that are attributable to labor and vary geographically to account for differences in labor-related costs across geographic areas. More recent data became available; therefore, based on IGI's second quarter 2021 forecast with historical data through the first quarter 2021 the FY 2022 labor-related share for the final rule is 77.2 percent as shown in Table 1.

After consideration of comments received, we are finalizing the use of the sum of the FY 2022 relative importance for the labor-related cost categories based on the most recent forecast (IGI's second quarter 2021 forecast) of the 2016-based IPF market basket labor-related share cost weights, as proposed.

B. Final 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 final update to the ICD-10-PCS code set for FY 2022. Addendum B to this final 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. Final 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 final FY 2022 Federal per diem base rate, we applied the payment rate update of 2.0 percent—that is, the 2016-based IPF market basket increase for FY 2022 of 2.7 percent less the productivity adjustment of 0.7 percentage point—and the wage index budget-neutrality factor of 1.0017 (as discussed in section III.D.1 of this final rule) to the FY 2021 Federal per diem base rate of \$815.22, yielding a final Federal per diem base rate of \$832.94 for FY 2022. Similarly, we applied the 2.0 percent payment rate update and the 1.0017 wage index budget-neutrality factor to the FY 2021 ECT payment per treatment of \$350.97, yielding a final ECT payment per treatment of \$358.60 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 0.0 percent payment rate update—that is, the IPF market basket increase for FY 2022 of 2.7 percent less the productivity adjustment of 0.7 percentage point for an update of 2.0 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 1.0017 to the FY 2021 Federal per diem base rate of \$815.22, yielding a Federal per diem base rate of \$816.61 for FY 2022.

- For IPFs that fail to meet requirements under the IPFQR Program, we applied the 0.0 percent annual payment rate update and the 1.0017 wage index budget-neutrality factor to the FY 2021 ECT payment per treatment of \$350.97, yielding an ECT payment per treatment of \$351.57 for FY 2022.

C. Final 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 are finalizing our proposal to 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. Final 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 did not propose any changes to the IPF MS-DRG adjustment factors. Therefore, we are finalizing our proposal to maintain the existing 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 finalizing our proposal 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 will still receive the Federal per diem base rate and all other applicable adjustments, but the payment will not include an MS-DRG adjustment.

The diagnoses for each IPF MS-DRG will be updated as of October 1, 2021, using the final IPPS FY 2022 ICD-10-CM/PCS code sets. The FY 2022 IPPS/LTCH PPS final rule includes tables of the changes to the ICD-10-CM/PCS code sets, which underlie the FY 2022 IPF MS-DRGs. Both the FY 2022 IPPS final rule and the tables of final changes to the ICD-10-CM/PCS code sets, which underlie the FY 2022 MS-DRGs, are available on the CMS 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 will follow the instructions in the ICD–10–CM Tabular List. 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 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 codes in the IPF Code First table. For FY 2021, there were 18 ICD-10-CM codes deleted from the final IPF Code First table. For FY 2022 there are 18 codes finalized for deletion from the ICD-10-CM codes in the IPF Code First table. The final 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. Final 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 will 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 finalizing our proposal 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 final FY 2022 update to the ICD-10-CM/PCS code set. The final 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. These updates are detailed in Addenda B of this final 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 finalized 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.

Comment: A commenter requested that CMS add 13 ICD-10-CM codes for infectious diseases to the list of codes that qualify for the IPF PPS comorbidity adjustment.

Response: As noted previously, 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. Also, the comorbidity adjustments were derived through a regression analysis, which also includes other IPF PPS adjustments (for example, the age adjustment). Our established policy is to annually update the ICD-10-CM/PCS codes, which are associated with the existing IPF PPS comorbidity categories. Adding or removing codes to the existing comorbidity categories that are not part of the annual coding update would occur as part of a larger IPF PPS refinement. We did not propose to refine the IPF PPS in the FY 2022 IPF PPS proposed rule, and therefore, are not changing the policy in this final rule. However, we will consider the comment to potentially inform future refinements.

c. Final 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

finalizing our proposal 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. Final 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 length of stay (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 finalizing our proposal 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. Final 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 considering 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 was 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 will result in the most up-to-date wage data being the basis for the IPF wage index. It will 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 will 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 proposed to continue to use the concurrent pre-floor, pre-reclassified IPPS hospital wage index as the basis for the IPF wage index.

Comment: Several commenters expressed concerns with our proposal to continue using the concurrent pre-floor, pre-reclassified IPPS hospital wage index as the basis for the IPF wage index. Three commenters recommended CMS extend the transition for the reductions in payment for certain IPFs resulting from the wage index changes adopted in the FY 2021 IPF PPS final rule. Another commenter also recommended that CMS apply a non-budget neutral 5 percent cap on decreases to a hospital's wage index value to help mitigate wide annual swings that are beyond a hospital's ability to control.

Response: We did not propose to modify the transition policy that was finalized in the FY 2021 IPF PPS final rule; therefore, we are not changing the previously adopted policy in this final rule. As we discussed in the FY 2021 IPF PPS final rule (85 FR 47058 through 47059), the transition policy caps the estimated reduction in an IPF's wage index to 5 percent in FY 2021,

with no cap applied in FY 2022. We stated our belief that implementing updated wage index values along with the revised OMB delineations will result in wage index values being more representative of the actual costs of labor in a given area. As evidenced by the detailed economic analysis (85 FR 47065 through 47068), we estimated that implementing these wage index changes would have distributional effects, both positive and negative, among IPF providers. We continue to believe that applying the 5-percent cap transition policy in year one provided an adequate safeguard against any significant payment reductions, has allowed for sufficient time to make operational changes for future FYs, and provided a reasonable balance between mitigating some short-term instability in IPF payments and improving the accuracy of the payment adjustment for differences in area wage levels.

We note that certain changes to wage index policy may significantly affect Medicare payments. These changes may arise from revisions to the OMB delineations of statistical areas resulting from the decennial census data, periodic updates to the OMB delineations in the years between the decennial censuses, or other wage index policy changes. While we consider how best to address these potential scenarios in a consistent and thoughtful manner, we reiterate that our policy principles with regard to the wage index include generally using the most current data and information available and providing that data and information, as well as any approaches to addressing any significant effects on Medicare payments resulting from these potential scenarios, in notice and comment rulemaking.

Comment: Two commenters recommended that CMS incorporate a frontier state floor into the IPF wage index. Another commenter requested that CMS implement policies to address the disparity in payments between rural and urban IPFs, similar to policies that have been adopted for IPPS hospitals.

Response: We appreciate commenters' suggestions regarding opportunities to improve the accuracy of the IPF wage index. We did not propose the specific policies that commenters have suggested, but we will take them into consideration to potentially inform future rulemaking.

Final Decision: For FY 2022, we are finalizing the proposal to continue to use the concurrent pre-floor, pre-reclassified IPPS hospital wage index as the basis for the IPF wage index. Since we did not propose any changes to the 2-year transition that was finalized in the FY 2021 IPF PPS final rule, there will be no cap applied to the reduction in the wage index for the second year (that is, FY 2022).

We will 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 will change from 77.3 percent in FY 2021 to 77.2 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 and, when necessary and appropriate, has proposed and finalized transition policies for these changes.

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).

Subsequently, CMS adopted the changes that were published in past OMB bulletins in the FY 2016 IPF PPS final rule (80 FR 46682 through 46689), the FY 2018 IPF PPS rate update (82 FR 36778 through 36779), the FY 2020 IPF PPS final rule (84 FR 38453 through 38454), and the FY 2021 IPF PPS final rule (85 FR 47051 through 47059). We direct readers to each of these rules for more information about the changes that were adopted and any associated transition policies.

In part due to 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 will 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 did not propose to adopt OMB Bulletin 20-01 in the FY 2022 IPF PPS proposed rule.

(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. Final 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 proposed 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).

Comment: We received one comment in favor of the proposed extension of the 17 percent payment adjustment for rural IPFs. The commenter acknowledged CMS' efforts to avoid disparities in payments to facilities in rural and underserved communities.

Response: We appreciate this comment of support. Since the inception of the IPF PPS, we have applied a 17 percent adjustment for IPFs located in rural areas. As stated in the previous paragraph, this adjustment was derived from the results of our regression analysis and was incorporated into the payment system in order to ensure the accuracy of payments to rural IPFs. CMS continues to look for ways to ensure accuracy of payments to rural IPFs.

Final Decision: For FY 2022, we are finalizing our proposal 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).

d. Final 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 finalizing our proposal 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 final FY 2022 IPF wage index values (available on the CMS website) and final 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 1.0017.

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. Final 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 $(1 + (\text{the number of FTE residents training in the IPF} / \text{the IPF's ADC}))$. The teaching variable is then raised to the 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 final rule, we discuss finalized 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 final rule, we are finalizing our proposal to continue to retain the coefficient value of 0.5150 for the teaching adjustment to the Federal per diem base rate.

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

For FY 2022, we proposed to change the IPF policy regarding displaced residents from IPF closures and closures of IPF teaching programs. Specifically, we proposed 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 that 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 proposed 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.

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

Although not explicitly stated in regulatory 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 proposed 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 proposed 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 proposed that the ideal day will 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 will 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 will address the needs of the first group of residents as previously described: Residents who 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 proposed 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 displaced residents. Thus, we proposed 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 or that it is closing an IPF residency program(s). Specifically, we are adopting 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 proposed 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 will 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 that have caused the receiving IPF to exceed its cap, and the receiving IPF must specify the length of time the adjustment is needed. Moreover, we want to propose clarifications on how the information will be delivered in this letter. Consistent with IPPS teaching policy, we proposed that the letter from the receiving IPF will 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 proposed 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 also clarified, as 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, 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 will be voluntary and made at the sole discretion of the originating IPF.

However, if the originating IPF decides to do so, then it will be the originating IPF's responsibility to determine how much of an available cap slot will go with a particular resident (if any). We also note, 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.

Comment: We received 3 comments on our proposed updates to IPF teaching policy. All commenters appreciate the alignment of IPF teaching policy with IPPS. They believe it is important to protect medical education. Therefore, decreasing confusion and streamlining the process gives residents and program directors more time to find a new program or rotation site, which can only help the transfer process.

Response: We thank these commenters for their support.

Final Decision: For FY 2022, we are finalizing the closure policy as proposed. Section 124 of the BBRA gives the Secretary broad discretion to determine the appropriate adjustment factors for the IPF PPS. We are finalizing our proposal to implement the policy regarding IPF resident caps and closures to remain consistent with the way that the IPSS 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 finalizing our proposal that in the future, we will deviate from IPSS 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.

In addition, we are finalizing our proposal 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. 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 also finalizing our proposal 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 are finalizing our proposal that the ideal day will 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 will 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 will address the needs of the first group of residents as previously described: Residents who 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 are finalizing 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 finalizing our proposal 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 or that it is closing an IPF residency program(s).

Specifically, we are adopting 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 finalizing our proposal 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 will 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)(I)(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 that have caused the receiving IPF to exceed its cap, and the receiving IPF must specify the length of time the adjustment is needed. Moreover, we are finalizing the clarifications on how the information will be delivered in this letter. Consistent with IPPS teaching policy, the letter from the receiving IPF will 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 also finalizing our proposal 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 finalizing the clarification that 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, 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 will be voluntary and made at the sole discretion of the originating IPF. However, if the originating IPF decides to do so, then it will be the originating IPF's responsibility to determine how much of an available cap slot will 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. Final 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 will 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 finalizing our proposal 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 finalizing our proposal 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 finalizing our proposal 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) 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 finalizing our proposal 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 finalizing our proposal 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 final 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 finalizing our proposal 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 finalizing our proposal 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 Table 2. For comparison purposes, we also are showing the COLA factors effective for FY 2018 through FY 2021.

TABLE 2: 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
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 final IPF PPS COLA factors for FY 2022 are also shown in Addendum A to this final rule, and is available at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html>.

4. Final 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 finalizing our proposal 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 Final 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. Final Update to the Outlier Fixed Dollar Loss Threshold Amount

In accordance with the update methodology described in § 412.428(d), we are finalizing our proposal 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 final rulemaking, the most recent available data are the FY 2020 claims. However, during FY 2020, the U.S. healthcare system undertook an unprecedented response to the 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 the FY 2022 IPF PPS proposed rule (86 FR 19524 through 195266), 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 appeared to be the best

available data at this time. We refer the reader to section VI.C.3 of the FY 2022 IPF PPS proposed rule (86 FR 19524 through 195266 FR) for a detailed discussion of that analysis.

Comment: We received 2 comments on our analysis of the FY 2019 and FY 2020 claims in determining the best available data for estimating IPF PPS payments in FY 2021 and FY 2022. Both comments were supportive of our proposal to use the FY 2019 claims for this purpose. One of these commenters expressed appreciation for the proposed reduction in the outlier fixed dollar loss threshold. Another commenter agreed with our assessment that FY 2020 claims were heavily impacted by the intensity of the COVID-19 pandemic.

Response: We appreciate these commenters' support. Based on the revised impact analysis discussed in section VI.C.3 of this final rule, we continue to believe that the FY 2019 claims are the best available data for estimating FY 2021 and FY 2022 payments.

Final Decision: We are finalizing as proposed to use the June 2020 update of the FY 2019 IPF claims for updating the outlier fixed dollar loss threshold.

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 finalizing our proposal 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 1.9 percent in FY 2021. Therefore, we are finalizing our proposal to update the outlier threshold amount to \$14,470 to maintain estimated outlier payments at 2 percent of total estimated aggregate IPF payments for FY 2022. This final update is a decrease from the FY 2021 threshold of \$14,630. In contrast, using the FY 2020 claims to estimate payments, the final outlier fixed dollar loss threshold for FY 2022 would

be \$22,720, which would have been an increase from the FY 2021 threshold of \$14,630. We refer the reader to section VI.C.3 of this final rule for a detailed discussion of the estimated impacts of the final update to the outlier fixed dollar loss threshold.

We note that our use of the FY 2019 claims to set the final outlier fixed dollar loss threshold for FY 2022 deviates from what has been our longstanding practice of using the most recent available year of claims, which is FY 2020 data. However, we are finalizing this policy in a way that remains otherwise consistent with the established outlier update methodology. As discussed in this section and in section VI.C.3 of this final rule, we are finalizing our proposal 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 finalizing our proposal to deviate from our longstanding practice of using the most recent available year of claims only because, and to the extent that, the COVID-19 PHE appears to have significantly impacted the FY 2020 IPF claims. As discussed in section VI.C.3 of this final rule, we have analyzed more recent available IPF claims data and continue to believe that using FY 2019 IPF claims is appropriate for the FY 2022 update. We intend to continue to analyze further data in order to better understand both the short-term and long-term effects of the COVID-19 PHE on IPFs.

3. Final 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 finalizing our proposal 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 2.0261 for rural IPFs, and 1.6879 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 finalizing our proposal 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.

B. Covered Entities

In the FY 2013 IPPS/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 IPPS/LTCH PPS final rule (77 FR 53645).

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 IPF PPS RY means 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)

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 5 of this final rule and the following final rules:

- The FY 2013 IPPS/LTCH PPS final rule (77 FR 53646 through 53652);
- The FY 2014 IPPS/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 IPPS/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 IPPS/LTCH PPS final rule (77 FR 53653 through 53660);
- The FY 2014 IPPS/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 IPPS/LTCH PPS final rule (81 FR 57248 through 57249);
- The FY 2018 IPPS/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 requested 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 RFI that was included in the proposed rule 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.

The RFI contained four parts:

- *Background*: This section provided information describing our commitment to health equity, and existing initiatives with an emphasis on reducing health disparities.
- *Current CMS Disparity Methods*: This section described the methods, measures, and indicators of social risk currently used with the CMS Disparity Methods.
- *Future potential stratification of quality measure results*: This section described 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 specified 12 requests for feedback on these topics. We reviewed 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}

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

5, 6, 7, 8, 9 Such disparities in 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

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, Burkhart, Q, Klein, DJ, Gildner, J, and Haviland, AM. Racial, Ethnic, and Gender Disparities in Health Care in Medicare Advantage. Baltimore, MD: CMS Office of Minority Health. 2020.

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>

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 final 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.

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>

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) in their efforts to engage with and assist providers that care for vulnerable populations; Federal, state, local, and tribal organizations; providers; researchers; policymakers; beneficiaries and their families; and other stakeholders in activities to achieve health equity²⁷. 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 providing transparency about health disparities, supporting providers with evidence-informed solutions to achieve health equity, and reporting to providers 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

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>

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

- 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 (NASEM)³⁵ and the Office of the Assistant Secretary for Planning

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

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>.

and Evaluation (ASPE)³⁶ which have examined the influence of social risk factors on several of our quality programs. In this RFI, we addressed only the seventh 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 discussed 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

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

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

factors. This method also 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, in the 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 readmissions 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 sought 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 previously in this section, 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 noted 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

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-medicares-value-based-purchasing-programs>

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

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 in section IV.D.2 of this final rule. 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 in section IV.D of this final rule, 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

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

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

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>

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 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 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

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, Joynt 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>

Resources for Standardized Demographic and Language Data Collection⁵¹ and supported collection of specialized International Classification of Disease, 10th Revision, 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

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>

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 in section IV.D.2, 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

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

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

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 with self-reported race and ethnicity of 0.96 through 0.99 for API, Black, Hispanic, and White beneficiaries 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.⁶⁰ 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.

⁵⁷ 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

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 MBISG 2.1 validation results performed under contract #GS-10F-0012Y/HHSM-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>

⁶⁰ 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

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 expressed interest in learning more about, and solicited 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.⁶¹ 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.⁶² This could potentially include expansion to additional social risk factors, such as disability status, where accuracy of administrative data is currently limited.

⁶¹ 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>

⁶² 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>

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 solicited 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)⁶³ 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).⁶⁴ 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 final 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

⁶³ https://minorityhealth.hhs.gov/assets/pdf/checked/1/Fact_Sheet_Section_4302.pdf

⁶⁴ https://www.healthit.gov/sites/default/files/2020-08/2015EdCures_Update_CCG_USCDI.pdf

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*⁶⁵.

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 determinants of health (initially dual eligibility and indirectly estimated race and ethnicity); and

⁶⁵ Agniel D, Martino SC, Burkhart Q, et al. Incentivizing Excellent Care to At-Risk Groups with a Health Equity Summary Score. *J Gen Intern Med*. Published online November 11, 2019 Nov 11. doi: 10.1007/s11606-019-05473-x

- 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 solicited public comments on the possibility of stratifying IPFQR Program measures by dual eligibility and race and ethnicity. We also solicited public comments on mechanisms of incorporating co-occurring disability status into such stratification as well. We sought 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 also solicited 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 solicited 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 also noted our intention for additional RFIs or rulemaking on this topic in the future.

Specifically, we solicited 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 they are 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 considerations or any combination of these 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.

We received comments on these topics.

Comments: Many commenters expressed support for the collection of data to support stratifying or otherwise measuring disparities in care related to dual-eligibility, race and ethnicity, and disability. Some commenters specifically supported the confidential reporting of

stratified results to facilities. Several commenters urged CMS to expand data collection and measure stratification to include factors such as language preference, veteran status, health literacy, gender identity, and sexual orientation to provide a more comprehensive assessment of health equity. One commenter urged CMS to collect data on race and ethnicity specifically for patients suffering from psychiatric disorders, while another noted that for the IPF patient population risk factors, such as substance abuse, may be of more importance. One commenter also provided examples of how their health system has successfully collected and begun to analyze patient-level demographic data. Another commenter referred to an existing effort by the National Committee for Quality Assurance to improve the collection of race and ethnicity data as a possible model for improving data collection. This commenter also supported the use of indirect estimation of race and ethnicity for Medicare beneficiaries, noting some concern about the lack of granularity, especially with respect to Native American and Asian populations. One commenter urged CMS to explore how to best identify social determinants of health using current claims data.

While many commenters expressed support for stratification of claims-based measures, many commenters expressed concern that the existing chart-abstracted measures would face limitations when stratified and thus felt the burden of collecting stratification data for these measures significantly outweighed any potential benefit of doing so. Specifically, commenters noted that stratifying the IPF patient population is more vulnerable to statistical concerns during the stratification process than other patient populations (for example, numbers of patients in one or more strata may be insufficient for reliable sampling and calculations) due to low patient volume in some facilities. One commenter suggested that for this and other reasons CMS should develop disparities reporting specifically for the IPF program rather than adopt an approach developed for a different program. A few commenters also questioned the value of stratification of these measures given the current high levels of performance by many IPFs.

One commenter noted that stratified claims-based measures would exclude all privately

insured care and thus be less useful. Several commenters stated that interoperability issues such as a lack of EHRs, particularly for IPFs that are smaller or not part of a large hospital or health system, further add to the burden of stratifying chart-abstracted measures and may contribute to bias in the data.

Several commenters also noted that stratification may be challenging due to differences in the patient population served by IPFs compared to other Medicare programs such as acute and long-term care hospitals, for example, age, proportion and reason for dual-eligibility (income versus disability), and substance abuse disorder prevalence. However, several commenters noted many of these same characteristics, as well as the mental and behavioral health needs of patients cared for by IPFs, are evidence of the need to improve data collection and measurement in IPFs. A commenter also recommended further analysis on the predictive power of social risk factors on mental and behavioral health patient outcomes compared to that of the diagnosis requiring treatment. Several commenters recommended CMS further address issues related to the potential stratification of data such as: patient privacy and the collection and sharing of social risk factors from patient records or through indirect estimation, differing requirements for collection of race and ethnicity data, transparency regarding indirect estimation methods, and differing Medicaid eligibility requirements by state. One commenter related these concerns to public reporting, suggesting support for confidential reporting until these issues are addressed.

We appreciate all of the comments and interest in this topic. We believe that this input is very valuable in the continuing development of the CMS health equity quality measurement efforts. We will continue to take all concerns, comments, and suggestions into account for future development and expansion of our health equity quality measurement efforts.

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.

We received comments on these topics.

Comments: We received mixed feedback regarding demographic data collection. Many commenters supported the need for and use of such data, noting that structured, interoperable electronic health data are the gold standard. They also noted that many barriers exist to adopting electronic health information technology systems necessary for capture of these data, particularly in freestanding psychiatric facilities. A commenter stated that the commenter’s organization cannot support demographic data collection due to the workload burden it would place on both the IPF and patients and their families. This commenter also noted that the likelihood of patients and families comfortably answering multiple sensitive demographic questions is low, especially upon admission. Another commenter expressed concerns with the current capabilities of the industry to collect these data, specifying a lack of standardization in screening and data collection and need for staff training. Multiple commenters expressed concern about the patient and family’s perception of the organization if given a data collection questionnaire upon admission, noting that they may think the organization is more focused on data collection rather than care.

Other commenters noted the importance of closing the health equity gap through measurement of demographic characteristics. A commenter suggested that agencies leverage the role of nurses in identifying sociodemographic factors and barriers to health equity. Another commenter supported this method, noting that although this may add another step to data collection processes, it would be valuable in addressing health equity gaps. To reduce possible

workload burden on organizations that are new to this process, a commenter recommended a staggered approach to data collection, suggesting CMS require providers and facilities to collect data on age and sex by the end of 2022, race and ethnicity by the end of 2023, etc., with the goal of at least 80 percent data completeness with 80 percent accuracy. In addition, commenters suggested reducing burden by adopting standardized screening tools to collect this information, such as ICD-Z-codes, which in practice would allow patients to be referred to resources and initiatives when appropriate. Several commenters encouraged collection of comprehensive social determinants of health and demographic information in addition to race and ethnicity, such as disability, sexual orientation, and primary language. Several commenters provided feedback on the potential use of an indirect estimation algorithm when race and ethnicity are missing/incorrect, and emphasized the sensitivity of demographic information and recommended that CMS use caution when using estimates from the algorithm, including assessing for potential bias, reporting the results of indirect estimation alongside direct self-report at the organizational level for comparison, and establishing a timeline to transition to entirely directly collected data. Commenters also advised that CMS be transparent with beneficiaries and explain why data are being collected and the plans to use these data. A commenter noted that information technology infrastructure should be established in advance to ensure that this information is being used and exchanged appropriately.

We appreciate all of the comments and interest in this topic. We believe that this input is very valuable in the continuing development of the CMS health equity quality measurement efforts. We will continue to take all concerns, comments, and suggestions into account for future development and expansion of our health equity quality measurement efforts.

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.

We received comments on these topics.

Comments: Commenters generally supported ongoing thoughtful investigation into best practices for measuring health equity.

Many commenters expressed concerns about the potential Facility Equity Score. Commenters argued that the current approach used to generate the composite score may not lead to aggregate results, which would not be actionable for many facilities. Commenters also raised concerns about risk adjustment, limitations in stratification variables, and the appropriateness of the current measure set. A commenter noted that although they support thoughtful efforts to categorize performance, the HESS has been established only as a “proof of concept” and will require considerable time and resources to produce a valid and actionable measure. The same commenter also noted that HESS scoring was only feasible for less than one-half of Medicare Advantage (MA) plans and as such, may not be practical for many smaller facilities, or facilities whose enrolled populations differ in social risk factor distribution patterns compared to typical MA plans.

Commenters generally did not support use of the Facility Equity Score in public reporting or payment incentive programs, suggesting that it is imperative to first understand any unintended consequences prior to implementation. More specifically, several commenters gave the example of facilities failing to raise the quality of care for at-risk patients while appearing to achieve greater equity due to lower quality of care for patients that are not at risk. A commenter stated the belief that CMS should begin their initiative to improve health equity by using

structural health equity measures. Commenters also raised concerns about use of dual-eligibility as a social risk factor due to variations in state-level eligibility for Medicaid, making national comparisons, or benchmarking of facility scores unreliable. Additionally, commenters who expressed data reliability concerns recommended that CMS focus its resources on improving standardized data collection and reporting procedures for sociodemographic data before moving forward with a Facility Equity Score.

We appreciate all of the comments and interest in this topic. We believe that this input is very valuable in the continuing development of the CMS health equity quality measurement efforts. We will continue to take all concerns, comments, and suggestions into account for future development and expansion of our health equity quality measurement efforts.

We also received comments on the general topic of health equity in the IPFQR Program.

Comments: Many commenters expressed overall support of CMS' goals to advance health equity. There were some comments regarding the need to further extend and specify the definition of equity provided in the proposed rule. Commenters also noted that equity initiatives should be based on existing disparities and population health goals, be mindful of the needs of the communities served, and work to bridge hospitals with post-acute and community-based providers. Several commenters encouraged CMS to be mindful about whether collection of additional quality measures and standardized patient assessment elements might increase provider burden. Several commenters noted support for consideration of a measure of organizational commitment to health equity, outlining how infrastructure supports delivery of equitable care. A commenter noted the importance of focusing programming on inequities in vaccine-preventable illness. Another commenter noted that CMS may expand their view of equity beyond quality reporting to payment and coverage policies.

We appreciate all of the comments and interest in this topic. We believe that this input is very valuable in the continuing development of the CMS health equity quality measurement efforts. We will continue to take all concerns, comments, and suggestions into account for future

development and expansion of our health equity quality measurement 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 for the IPFQR Program.

2. COVID-19 Vaccination Coverage Among Health Care Personnel (HCP)⁶⁶ Measure for the FY 2023 Payment Determination and Subsequent Years

a. Background

On January 31, 2020, the Secretary declared a 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).⁶⁷ COVID-19 is a contagious respiratory illness⁶⁸ 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-19.⁶⁹

As of April 2, 2021, the U.S. had reported over 30 million cases of COVID-19 and over 550,000 COVID-19 deaths.⁷⁰ Hospitals and health systems saw significant surges of COVID-19 patients as community infection levels increased.⁷¹ From December 2, 2020 through January 30, 2021, more than 100,000 Americans were in the hospital with COVID-19 at the same time.⁷²

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

⁶⁶ This measure was previously titled, “SARS-CoV-2 Vaccination Coverage among Healthcare Personnel.”

⁶⁷ 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>.

⁶⁸ 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>.

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). CDC COVID Data Tracker. Accessed on April 3, 2021 at: https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days.

⁷¹ 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>

⁷² US Currently Hospitalized | The COVID Tracking Project <https://covidtracking.com/data/charts/us-currently-hospitalized>.

contact with one another.⁷³ 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.⁷⁴ 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-19.⁷⁵ 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),⁷⁶ and that in certain circumstances, infection can occur through airborne transmission.⁷⁷

Subsequent to the publication of the proposed rule, the CDC confirmed that the three main ways that COVID-19 is spread are: (1) Breathing in air when close to an infected person who is exhaling small droplets and particles that contain the virus; (2) Having these small droplets and particles that contain virus land on the eyes, nose, or mouth, especially through splashes and sprays like a cough or sneeze; and (3) Touching eyes, nose, or mouth with hands that have the virus on them.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

⁷³ 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>.

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 July 15, 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>.

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

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,

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-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>. (as reissued on May 10, 2021)

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> (as reissued on July 7, 2021); U.S. Food and Drug Administration. (2021). Janssen COVID-19 Vaccine EUA Letter of Authorization. Available at <https://www.fda.gov/media/146303/download> (as reissued on June 10, 2021).

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> (as reissued on May 10, 201) and U.S. Food and Drug Administration. (2020). Moderna COVID-19 Vaccine EUA Letter of Authorization. Available at <https://www.fda.gov/media/144636/download> (as reissued on July 7, 2021); U.S. Food and Drug Administration. (2021). Janssen COVID-19 Vaccine EUA Letter of Authorization. Available at <https://www.fda.gov/media/146303/download> (as reissued on June 10, 2021).

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/>

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.E.b.i of this final rule.⁹² By July 15, 2021 the CDC reported that over 336,000,000 doses had been administered, and approximately 160,000,000 people had received a complete vaccination course.⁹³ 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 2021.⁹⁴ Subsequent to the publication of the IPF PPS proposed rule, on June 3, 2021, the White House confirmed that there was sufficient

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:’ US 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%2Dgrowing,of%20the%20healthcare%20work%20for ce.>

⁹² CDC. COVID Data Tracker. COVID-19 Vaccinations in the United States. Accessed on 4/4/21 at: <https://covid.cdc.gov/covid-data-tracker/#vaccinations>

⁹³ CDC. COVID Data Tracker. COVID-19 Vaccinations in the United States. Accessed on 7/6/2021 at: <https://covid.cdc.gov/covid-data-tracker/#vaccinations>

⁹⁴ 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/>

vaccine supply for all Americans.⁹⁵

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 proposed 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 reporting period, see section V.E.2.c of this final rule. The measure would assess the proportion of an IPF's health care workforce that has been vaccinated against COVID-19.

Although at the time of the proposed rule, data to show the effectiveness of COVID-19 vaccines to prevent asymptomatic infection or transmission of SARS-CoV-2 were limited, we stated our belief that 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.⁹⁶ Data from influenza vaccination demonstrates that provider uptake of the vaccine is associated with that provider recommending vaccination to patients,⁹⁷ 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 would be helpful to many patients, including those who are at high-risk for developing serious complications from COVID-19, as they choose facilities from which to seek treatment. Under CMS' Meaningful Measures Framework, the COVID-19 measure addresses the quality priority of "Promote Effective Prevention and Treatment of Chronic Disease" through the Meaningful Measure Area of

⁹⁵ Press Briefing by White House COVID-19 Response Team and Public Health Officials | The White House

⁹⁶ 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>

⁹⁷ 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

“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.⁹⁸

The numerator is the cumulative number of HCP eligible to work in the IPF for at least 1 day 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.⁹⁹ 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 are 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,”¹⁰⁰ 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

⁹⁸ Centers for Disease Control and Prevention. Contraindications and precautions.

<https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Contraindications>

⁹⁹ 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

¹⁰⁰ <https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94212>

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.¹⁰¹ The MAP also stated that collecting information on COVID-19 vaccination coverage among HCP and providing feedback to facilities would allow facilities to benchmark coverage rates and improve coverage in their IPF, and that reducing rates of COVID-19 in HCP may reduce transmission among patients and reduce instances of staff shortages due to illness.¹⁰²

In its preliminary recommendations, the MAP Hospital Workgroup did not support this measure for rulemaking, subject to potential for mitigation.¹⁰³ To mitigate its concerns, the MAP believed that the measure needed well-documented evidence, finalized specifications, testing, and NQF endorsement prior to implementation.¹⁰⁴ 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.¹⁰⁵ The MAP specifically stated, “the incomplete specifications require immediate mitigation and further development should continue.”¹⁰⁶ The spreadsheet of final recommendations no longer cited concerns regarding evidence, testing, or NQF endorsement.¹⁰⁷ In response to the MAP final recommendation request that CMS bring the

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. MAP Preliminary Recommendations 2020-2021. Accessed on January 24, 2021 at: http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx

¹⁰⁴ Measure Applications Partnership. MAP Preliminary Recommendations 2020-2021. Accessed on January 24, 2021 at: http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx

¹⁰⁵ 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

¹⁰⁶ Measure Applications Partnership. 2020-2021 MAP Final Recommendations. Accessed on February 23, 2021 at: http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx

¹⁰⁷ *Ibid.*

measure back to the MAP once the specifications were 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 measure 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 was in process at that time. These preliminary findings showed 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 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.¹⁰⁸ 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.¹⁰⁹

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,

¹⁰⁸ 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>.

¹⁰⁹ Measure Applications Partnership. 2020-2021 MAP Final Recommendations. Accessed on February 23, 2021 at: http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx

including IPFs. We continue to engage with the MAP to mitigate concerns and appreciate 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 endorsement consideration. The CDC, in collaboration with CMS, are planning to submit the measure for consideration in the NQF Fall 2021 measure cycle.

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, in the FY 2022 IPF PPS proposed rule, we proposed 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 (86 FR 19504). Thereafter, we proposed quarterly¹¹⁰ reporting periods.

¹¹⁰ We note that the proposed rule incorrectly read "annual reporting periods" however the section of the proposed rule on data submission (IV.J.2.a) correctly described the data submission process and timelines.

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 final rule.

We proposed that IPFs would report the measure through the CDC National Healthcare Safety Network (NHSN) web-based surveillance system.¹¹¹ 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 IPF 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 IV.J.4. of this final rule.

We invited 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.

Comment: Some commenters supported the proposed COVID-19 Vaccination Coverage Among Healthcare Personnel measure. One commenter observed that data on vaccination coverage are important for patients and for individuals seeking employment at IPFs. Several commenters noted the importance of vaccines to reduce transmission, and one commenter

¹¹¹ 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.

specifically observed that vaccination is particularly important in settings such as IPFs because non-pharmaceutical interventions are challenging in such institutional settings. Another commenter expressed the belief that the measure is methodologically sound.

Response: We thank these commenters for their support.

Comment: Many commenters expressed concern that using NHSN for reporting is too burdensome and disproportionately affects smaller and freestanding IPFs. Some of these commenters further expressed that requiring reporting through NHSN is inconsistent with the removal of Influenza Vaccine Coverage among HCP measure because the rationale for removing the Influenza Vaccine Coverage among HCP measure was the high reporting burden associated with NHSN reporting.

Response: We believe that there are many significant benefits to collecting and reporting data on COVID-19 vaccination coverage among HCP that outweigh its burden. As discussed in our proposal to adopt this measure, HCP vaccination can potentially reduce illness that leads to work absence and limit disruptions to care (86 FR 19502). The CDC has emphasized that health care settings can be high-risk places for COVID-19 exposure and transmission.¹¹² In these 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.¹¹³

Subsequent to the publication of the IPF PPS proposed rule, the CDC updated its Science Brief on COVID-19 Vaccines and Vaccination and observed that the growing body of evidence indicates that people who are fully vaccinated with an mRNA vaccine are less likely to have asymptomatic infection or to transmit SARS-CoV-2 to others. The CDC further noted that the studies are continuing on the benefits of the Johnson & Johnson/Janssen vaccine.¹¹⁴ Therefore

¹¹² 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.

¹¹³ 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>

¹¹⁴ <https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html>

we believe that vaccination coverage among HCP will reduce the risk of contracting COVID-19 for patients in IPFs, and that IPFs reporting this information can help patients identify IPFs where they may have lower risk of COVID-19 exposure. 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 IPFs from which to seek treatment.

While we agree with the commenters that there is some burden associated with reporting this measure (see Section (V)(A)(2)(c) of this final rule), we believe the benefits of data collection and reporting on COVID-19 vaccination coverage among HCP are sufficient to outweigh this burden. In addition, commenters are correct in noting that when we removed the Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) measure from the IPFQR Program in the FY 2019 IPF PPS final rule, we observed that reporting measure data through the NHSN is relatively more burdensome for IPFs than for acute care hospitals and that this may be especially true for independent or freestanding IPFs (83 FR 38593 through 38595). However, in our analysis of facilities that did not receive full payment updates for FY 2018 and FY 2019 and the reasons these facilities did not receive full payment updates we observed that 98.24 percent and 99.05 percent of IPFs respectively, including small, independent, and freestanding IPFs, successfully reported data for the Influenza Vaccination Coverage Among Health Care Personnel (NQF # 0431) measure prior to its removal from the IPFQR Program. For the reasons outlined above, the COVID-19 pandemic and associated PHE has had a much more significant effect on most aspects of society, including the ability of the healthcare system to operate smoothly, than influenza, making the benefits of the COVID-19 Vaccination Among HCP measure greater than those of the Influenza Vaccination Coverage Among Health Care Personnel (NQF # 0431) measure.

Comment: Other commenters expressed concern that facilities face duplicative reporting requirements given that other agencies are requiring reporting through systems other than NHSN, such as the HHS TeleTracking site. A few of these commenters recommended that CMS

use the TeleTracking site for data reporting and consumer information as opposed to adopting a quality measure. Other commenters recommended that CMS sunset TeleTracking and use NHSN for reporting COVID-19 vaccination coverage data. One commenter recommended that CMS collaborate with CDC to ensure minimal reporting burden.

Response: We recognize that this measure may lead to duplicative reporting requirements if facilities voluntarily report COVID-19 HCP vaccination information to data reporting systems other than NHSN, and we are collaborating with other HHS agencies, including the CDC, to ensure minimal reporting burden and to eliminate duplicative requirements to the extent feasible.

Comment: Some commenters expressed concern about the measure specifications leading to increased reporting burden. Several of these commenters expressed that the proposed quarterly reporting of three weeks of data (one week per month) is excessively burdensome. Other commenters expressed concern that the measure specifications are not aligned with the Influenza Vaccination Coverage Among Healthcare Personnel measure (NQF #0431), specifically noting that the COVID Vaccination Coverage Among HCP measure requires data elements (such as contraindications) that are not required for Influenza Vaccination Coverage Among Healthcare Personnel measure (NQF #0431). One commenter observed that including all staff (not just clinical staff or staff directly employed by the IPF) makes the measure unduly burdensome. Another commenter observed that tracking location is challenging in large organizations with staff that work across locations.

Response: We recognize commenters' concern regarding reporting burden associated with the specifications of this measure. We believe that, given the public health importance of vaccination in addressing the COVID-19 PHE, the benefits of requiring reporting outweigh the burden. We believe that reporting these data on a frequent interval would increase their value by allowing the CDC to better track these important public health data while also being a valuable quality measure that supports consumer choice and IPF improvement initiatives. Because the

CDC requests data reported on a monthly basis for one week per month, we believe this is an appropriate reporting frequency for our quality measure to ensure that IPFs do not have duplicative reporting requirements to meet the CDC's need for public health data and CMS' quality measure reporting requirements. We further note that while we have sought to align this measure with the Influenza Vaccination Coverage Among HCP measure (NQF #0431), each measure addresses different public health initiatives and therefore complete alignment may not be possible. For example, because influenza vaccinations are provided during the influenza season (that is, October 1 through March 31) these measures have different reporting periods.

Further, we note that while the Influenza Vaccination Coverage Among HCP measure (NQF #0431) does not have a denominator exclusion for HCP with contraindications to the influenza vaccine, there is a numerator category for these HCP. Specifically, the numerator description is as follows: "HCP in the denominator population who during the time from October 1 (or when the vaccine became available) through March 31 of the following year: ... (b) were determined to have a medical contraindication/condition of severe allergic reaction to eggs or to other component(s) of the vaccine, or a history of Guillain-Barre Syndrome within 6 weeks after a previous influenza vaccination..."¹¹⁵ We believe that this numerator element requires the IPF to track HCP's contraindications to the influenza vaccination. Therefore, we disagree with the commenter's statement that the COVID-19 Vaccination Coverage Among HCP measure is more burdensome than the Influenza Vaccination Coverage Among HCP measure due to requiring IPFs to track HCP's contraindications to the vaccine.

Finally, we note that CDC's guidance for entering data requires submission of HCP count at the IPF level¹¹⁶ and the measure requires reporting consistent with that guidance. We proposed the reporting schedule of monthly reporting of data from only one week a month to provide COVID-19 vaccination coverage data on a more timely basis than annual influenza

¹¹⁵ http://www.qualityforum.org/Projects/n-r/Population_Health_Prevention/0431_InfluenzaImmunizationHCPersonnelForm_CDC.aspx

¹¹⁶ COVID-19 Vaccination Non-LTC Healthcare Personnel TOI (cdc.gov)

vaccination coverage (NQF #0431) while also reducing burden on facilities of weekly reporting which has been the reporting cycle for many COVID-19-related metrics during the pandemic. As described in response to previous commenters, we believe that the public health benefits to having these data available are high, and that they therefore outweigh the burden of reporting for systems with multiple facilities or locations. In summary, we recognize that there may be some elements of the measure specifications that increase burden for some IPFs, however given the impact that the COVID-19 PHE has had on society and the healthcare system, we believe that the benefits outweigh this reporting burden.

Comment: Some commenters expressed concern that having some vaccinations require two doses creates undue reporting burden for IPFs. One commenter recommended modelling this measure on the measure under consideration for patient vaccination coverage within the Merit-Based Incentive Payment System (MIPS) program which would require reporting based on receipt of one dose, as opposed to requiring reporting on receipt of a full course of the vaccine. Some commenters expressed concern that because it can take up to 28 days for an individual to be fully vaccinated, requiring reporting for HCP who have worked only one day of the reporting period is burdensome or that this disparately affects facilities without access to the one-dose vaccine.

Response: We believe that it is appropriate to require data on HCP who have received complete COVID-19 vaccination courses, because an IPF has more long-term and regular contact with the HCP who work there than an ambulatory care provider, such as those being evaluated under the MIPS Program, has with their patient population. This gives the IPF more ability to track and encourage HCP to receive their complete vaccination course.

We recognize that since a complete vaccination course could take up to 28 days, some IPFs may initially appear to have lower performance than others (based on having access to two dose vaccinations as opposed to one dose vaccination). However, we believe that with the reporting frequency these providers should show rapid improvement as their staff become fully vaccinated.

We note that given the highly infectious nature of the COVID-19 virus, we believe it is important to encourage all personnel within the IPF, regardless of patient contact, role, or employment type, to receive the COVID-19 vaccination to prevent outbreaks within the IPF which may affect resource availability and have a negative impact on patient access to care.

Comment: Some commenters recommended deferring measurement of vaccine coverage among HCP until there is at least one vaccine that has received full FDA approval (as opposed to an EUA). A few commenters expressed concern that the long-term effects of the vaccines are unknown and that some HCP concerned about the risk of serious adverse events; one commenter further expressed concerns regarding the rapid development and EUA timelines. A few commenters expressed concerns regarding HCP being unwilling to receive a vaccine which has not received full FDA approval.

Response: We support widespread vaccination coverage, and note that in issuing the EUAs for these vaccines FDA has established that the known and potential benefits of these vaccines outweigh the known and potential risks.¹¹⁷ Furthermore, as of July 15, 2021, more than 336,000,000 doses have been administered in the United States.¹¹⁸ Although COVID-19 vaccines are authorized for emergency use to prevent COVID-19 and serious health outcomes associated with COVID-19, including hospitalization and death¹¹⁹, we understand that some HCP may be concerned about receiving the COVID-19 vaccine prior to the vaccine receiving full FDA approval. We also understand that some HCP may be concerned about long-term effects. We note that the COVID-19 Vaccination Coverage Among HCP measure does not require HCP to receive the vaccination, nor does this measure reward or penalize IPFs for the rate of HCP who have received a COVID-19 vaccine. The COVID-19 Vaccination Coverage

¹¹⁷ <https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained>

¹¹⁸ CDC COVID Data Tracker

¹¹⁹ <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine>

<https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine>, <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/janssen-covid-19-vaccine>

Among HCP measure requires IPFs to collect and report COVID-19 vaccination data that would support public health tracking and provide beneficiaries and their caregivers information to support informed decision making. Therefore, we believe that it is appropriate to collect and report these data as soon as possible.

Comment: One commenter observed that there are interventions through which an IPF can promote vaccination coverage, such as by removing barriers to access (through means such as extended vaccine clinic hours). This commenter recommended encouraging these interventions as opposed to promoting vaccination coverage among HCP by adopting the COVID-19 Vaccination Coverage Among HCP measure.

Response: We agree with the commenter that there are interventions through which an IPF can increase vaccination coverage by reducing barriers to access. However, we believe that it is appropriate to propose this measure for the IPFQR Program to encourage such interventions by collecting data on vaccination coverage among HCP. We believe that vaccination is an important health intervention that can protect the health of vulnerable patients and the availability of the healthcare system (that is, limiting the number of HCP absent from work due to illness to ensure that patients have access to care).

Comment: Some commenters expressed the belief that it is inappropriate to use IPF payment policies to drive vaccination coverage among HCP. Some commenters expressed concern that this measure could lead facilities to mandate vaccines for staff, with potential unintended consequences (specifically, staff quitting or legal risk for facilities for staff experiencing adverse events). One commenter expressed the belief that the tie to public reporting and potentially IPF payment is an indirect vaccine mandate.

Several commenters recommended CMS not consider this measure for pay-for-reporting because state laws regarding mandates vary and therefore could lead to inconsistent performance through no fault of facilities. One commenter expressed the belief that this measure was developed for public health tracking and is not appropriate for quality assessment.

Response: We note that this measure does not require vaccination coverage among HCP at IPFs; it requires IPFs to report of COVID-19 vaccination rates. Therefore, we believe it is incorrect to characterize this measure as a “vaccine mandate.” Furthermore, we note that the historical national average of providers who had received the influenza vaccination, as reported on the then *Hospital Compare* website was 85 percent, 80 percent, and 82 percent respectively for the FY 2017, FY 2018, and FY 2019 payment determinations prior to removal of the Influenza Vaccination Coverage among Healthcare Personnel measure from the IPFQR Program. We do not believe that this represents performance that would be consistent with a widespread “vaccine mandate” and therefore we do not believe that a vaccination coverage among HCP measure, including the COVID-19 Vaccination Coverage among HCP measure, inherently leads to “vaccine mandates.” However, we believe that data regarding COVID-19 vaccination coverage among HCP are important to empower patients to make health care decisions that are best for them.

Comment: Some commenters expressed concern that the measure does not fully account for potential reasons that HCP may not receive COVID-19 vaccinations. One commenter recommended expanding the exclusions to the measure’s calculation, specifically citing religious objections as an exclusion category. Another commenter observed that there is uncertainty about how effective vaccines are for certain populations, such as those with underlying conditions.

Response: We recognize that there are many reasons, including religious objections or concerns regarding an individual provider’s specific health status, which may lead individual HCP to decline vaccination. The CDC’s NHSN tool allows facilities to report on the number of HCP who were offered a vaccination but declined for reasons including religious or philosophical objections.¹²⁰ We agree that there is uncertainty about effectiveness among certain patient populations, including those with underlying conditions. The CDC has found that there is evidence of reduced antibody response to or reduced immunogenicity of COVID-19 mRNA

¹²⁰ <https://www.cdc.gov/nhsn/forms/instr/57.220-toi-508.pdf>

vaccine among some immunosuppressed people.¹²¹ However, we note that COVID-19 vaccines may be administered to most people with underlying medical conditions.¹²² Therefore, we believe that individual HCP who may have underlying conditions that could affect vaccine efficacy should make the decision of whether to receive the COVID-19 vaccination in discussion with their individual care provider. We believe that vaccination coverage rates are meaningful data for beneficiaries to use in choosing an IPF which can also be used for public health tracking.

Comment: One commenter expressed the concern that this may have an adverse impact on HCP as it is unclear whether in the future individual HCP will be required to pay for the vaccination themselves.

Response: We understand the commenter's concerns that individual HCP may potentially have to pay for the COVID-19 vaccine in the future. In alignment with our pledge to put patients first in all our programs, we believe that it is important to empower patients to work with their doctors and make health care decisions that are best for them.¹²³ This includes the belief that HCP should be empowered to work with their own healthcare providers to make the health care decisions that are best for them, based on the totality of their circumstances, including potential costs to receive the vaccine and their increased risks of contracting COVID-19 based on occupational exposure.

Comment: Many commenters expressed concern that this measure should not be adopted until there is clarity around the impact of future boosters. These commenters also noted that booster availability could have an impact on vaccination coverage among HCP. One commenter specifically expressed concern regarding past supply chain disruptions and observed that similar issues may affect booster availability in the future.

Response: The COVID-19 Vaccination Coverage among HCP measure is a measure of a completed vaccination course (as defined in section IV.E.2.b.(1) of the FY 2022 IPF PPS

¹²¹ <https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html>

¹²² <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/underlying-conditions.html>

¹²³ Home - Centers for Medicare & Medicaid Services | CMS

proposed rule (86 FR 19502 through 19503) and does not address booster shots. Currently, the need for COVID-19 booster doses has not been established, and no additional doses are currently recommended for HCP. However, we believe that the numerator is sufficiently broad to include potential future boosters as part of a “complete vaccination course” and therefore the measure is sufficiently specified to address boosters. We acknowledge the potential for supply chain disruptions or other factors that affect vaccine availability, but we believe that the urgency of adopting the measure to address the current COVID-19 PHE outweighs these potential concerns.

Comment: Some commenters expressed that collecting the data to report this measure is challenging. These commenters observed that because, unlike influenza vaccinations, HCP have received COVID vaccinations from settings outside their places of employment, employers may still be attaining vaccination records from employees. One commenter observed that the data for HCP is housed in separate systems from those typically used for quality reporting.

Response: We recognize that some IPFs may still be obtaining vaccination records from their employees and other personnel that work within their facilities. However, most healthcare settings, including IPFs, have been reporting COVID-19 data to Federal or state agencies for some time and therefore have established the appropriate workflows or other means to obtain these records from employees or other personnel that work within the IPF. Therefore, we believe that IPFs must have the means to obtain the data, either directly from HCP or from other systems in which these data are housed, and that it is appropriate to require IPFs to report these data.

Comment: Another commenter expressed concern that the shortened performance period for the first year may lead to incomplete data. One commenter recommended allowing voluntary reporting without publicly reporting data for the first performance year to account for potential data gaps.

Response: Given that results would be calculated quarterly for this measure, facilities should show rapid progress as they obtain more complete data on vaccination coverage for their

HCP. While we understand the desire for a year of voluntary reporting to account for potential data gaps, we believe that the importance of providing patients and their caregivers with data on COVID-19 Vaccination Coverage among HCP at individual IPFs in a timely manner outweighs this concern and should be accomplished as soon as practical.

Comment: A few commenters expressed concern that due to the delay between data collection (which takes place during a quarter) and public reporting (which follows the reporting of the data collected during the quarter, the deadline for which is 4.5 months after the end of the quarter) the data would not be useful by the time they are publicly reported either because they are too old or because the trajectory of the pandemic has changed. One commenter opposed public reporting until data has been reported for several years.

Response: We believe that it is important to make these data available as soon as possible. We agree with commenters that observe that there is a delay between data collection and public reporting for this measure, and note that such a delay exists for all measures in the IPFQR Program. However, we believe that the data will provide meaningful information to consumers in making healthcare decisions because the data will be able to reflect differences between IPFs in COVID-19 vaccination coverage among HCP even if the data do not reflect the current vaccination rates and we believe it will benefit consumers to have these data available as early as possible. We proposed the shortened reporting period for the first performance period to make the COVID-19 Vaccination among HCP measure data available as quickly as possible.

Comment: One commenter observed that the data would not provide consumers a complete picture of infection control procedures because vaccines are only one tactic to prevent and control infections. Another commenter observed that public reporting may lead to comparisons between facilities. An additional commenter recommended a validation process to ensure that consumers can rely on the data.

Response: While we recognize that the data may not fully represent all activities to prevent and control infections, we believe that the data would be useful to consumers in choosing

IPFs, including making comparisons between facilities. We note that we do not currently have a validation process for any measures in the IPFQR Program and refer readers to section IV.J.3 of this final rule where we discuss considerations for a validation program for the IPFQR Program.

Comment: Some commenters recommended deferring the measure until it has been fully tested and NQF endorsed. One commenter observed that the MAP reviewed the measure concept, not the full measure, and therefore it is premature to include it in the IPFQR Program without further review. Another commenter observed that such rapid measure adoption may set a precedent for future rapid measure adoption.

Response: We believe that given the current COVID-19 PHE, it is important to adopt this measure as quickly as possible to allow tracking and reporting of COVID-19 Vaccination Coverage Among HCP in IPFs. This tracking would provide consumers with important information. We refer readers to FY 2022 IPF PPS proposed rule where we discuss our consideration of NQF endorsed measures on the topic of COVID-19 vaccination coverage among healthcare personnel for additional information (86 FR 19503 through 19504). We note that the MAP had the opportunity to review and provide feedback on the full measure in the March 15th meeting. The CDC, in collaboration with CMS, is planning to submit the measure for consideration in the NQF Fall 2021 measure cycle. Finally, we evaluate all measures on a case-by-case basis and therefore the pace at which we propose to adopt one measure is dependent on the measure and the purpose for adopting it.

Comment: One commenter requested clarification for the reporting frequency.

Response: We recognize that the proposed required frequency for reporting, may have been unclear because we referred to “annual reporting” periods two times in the proposed rule. Specifically, we referenced annual reporting periods in the first paragraph of section IV.E.2.c (86 FR 19504) and in our burden estimate for the measure (86 FR 19519). Our description of data submission under IV.J.2.a in which we stated that facilities would be required to report the vaccination data to the NHSN for at least one week each month and that if they reported more

than one week, the most recent week's data would be used (86 FR 19513) is correct. In that section, we further noted that the CDC would calculate a single quarterly result for summarizing the data reported monthly. In summary, the measure would require monthly reporting of at least one week's data per month. This would be calculated into quarterly results. We note that IPFs are required to report to NHSN sufficient data (that is, vaccination data for at least one week in each month per quarter) to calculate four quarterly results per year, except for the first performance period which depends on only one quarter of data (the vaccination data for at least one week in each month in Q1 of FY 2022). While IPFs can report data to the NHSN at any time, they must report by 4.5 months following the preceding quarter for the purposes of measure calculation. For the first performance period for this measure (that is Q1 of FY 2022), 4.5 months following the end of the quarter is May 15, 2022.

Comment: One commenter requested clarification on which provider types are considered healthcare personnel.

Response: The provider types that are considered healthcare personnel, along with the specifications for this measure, are available at <https://www.cdc.gov/nhsn/nqf/index.html>. The categories of HCP included in this measure are ancillary services employees; nurse employees; aide, assistant, and technician employees; therapist employees; physician and licensed independent practitioner employees; and other HCP. For more detail about each of these categories we refer readers to the Table of Instructions for Completion of the Weekly Healthcare Personnel COVID-19 Cumulative Vaccination Summary Form for Non-Long-Term Care Facilities available at <https://www.cdc.gov/nhsn/forms/instr/57.220-toi-508.pdf>.

Comment: One commenter observed that the definition of "location" for measure calculation is unclear.

Response: CDC's guidance for entering data requires submission of HCP count at the IPF level, not at the location level within the IPF.¹²⁴

¹²⁴ COVID-19 Vaccination Non-LTC Healthcare Personnel TOI (cdc.gov)

After consideration of the public comments, we are finalizing the COVID-19 Vaccination Coverage Among Healthcare Personnel measure as proposed for the FY 2023 payment determination and subsequent years.

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

a. Background

We proposed 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 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 proposed to adopt the FAPH measure and replace the FUH measure and refer readers to section IV.F.2.d of the FY 2022 IPF PPS proposed rule for our proposal to remove the FUH measure contingent on adoption of the FAPH measure (86 FR 19510). 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 as principal diagnoses (including patients with any combination of SUD, dementia, or behavioral health disorders), 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

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.^{132, 133} Among patients with serious mental illness, 90 percent have comorbid clinical conditions such as hypertension, cardiovascular disease, hyperlipidemia, or diabetes.¹³⁴ 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.¹³⁵ 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.

¹²⁵ 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>

¹²⁶ 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>

¹²⁷ 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>

¹²⁸ 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>

¹²⁹ 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>

¹³⁰ 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>

¹³¹ 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>

¹³² Germack, H. D., et al. (2019, January). Association of comorbid serious mental illness diagnosis with 30-day medical and surgical readmissions. *JAMA Psychiatry*.

¹³³ 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>

¹³⁴ 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>

¹³⁵ 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/jhmhp.2018.08.05>

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.”¹³⁶ 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.^{137, 138} 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.^{139, 140, 141} 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, 2017.¹⁴² Medicare FFS data from July 1, 2016, to June 30, 2017, show the national 7-day

¹³⁶ 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.

¹³⁷ 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.

¹³⁸ 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.

¹³⁹ 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.

¹⁴⁰ 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.

¹⁴¹ 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.

¹⁴² <https://data.cms.gov/provider-data/archived-data/hospitals>”

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 method¹⁴³), 53,841 additional discharges would have a 7-day follow-up visit, and 47,552 would have a 30-day follow-up visit.¹⁴⁴

During the development process, we used the CMS Quality Measures Public Comment Page to ask for public comments on the measure.¹⁴⁵ We accepted public comments from January 25, 2019, to 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.¹⁴⁶

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 an IPF's control. However, as described previously in this section, we believe that there are interventions (such as pre-discharge transition interviews, appointment reminder letters or

¹⁴³ <https://nhqrnet.ahrq.gov/inhqrdr/resources/methods#Benchmarks>

¹⁴⁴ Quality AfHRA. 2017 National Healthcare Quality and Disparities Report. Rockville, MD: Services USDoHaH; 2018.

¹⁴⁵ https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/IPF_-Follow-Up-After-Psychiatric-Hospitalization_Public-Comment-Summary.pdf

¹⁴⁶ Mathematica. FAPH public comment summary. April 2019.

reminder phone calls, meetings with outpatient 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 an IPF 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 an IPF 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 IPF-level rates of follow-up after psychiatric hospitalization. We evaluated measure reliability based on a signal-to-noise analysis,¹⁴⁷ in which a score of 0.0 implies that all variation is 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

¹⁴⁷ For additional information on reliability tests see http://www.qualityforum.org/Measuring_Performance/Improving_NQF_Process/Measure_Testing_Task_Force_Final_Report.aspx

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.¹⁴⁸

(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

¹⁴⁸ 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

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 proposed 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 final 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 would include discharges between July 1, 2021 and June 30, 2022.¹⁴⁹

We invited 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.

We received the following comments on our proposal.

Comment: Many commenters supported the adoption of the FAPH measure. Some commenters expressed that the expanded cohort would improve the measure's value. Some commenters expressed that expanding the eligible provider types for the follow-up visit would improve care because of the shortage of psychiatrists. A few commenters observed that care transitions are important, and that outpatient follow-up serves to improve the value of the inpatient services provided. One commenter expressed that adoption of this measure is timely due to the increased behavioral health needs associated with the COVID-19 pandemic. One commenter recommended using this measure at the health system level to better identify care coordination, access, and referral network adequacy.

Response: We thank these commenters for their support. We agree that the expanded definitions would improve the measure's applicability and capture more follow-up visits. Regarding the commenter's recommendation on using this measure at the health system level, we believe the commenter is recommending adopting this measure to evaluate performance of regional or local health systems (such as those affiliated with large hospital networks). We note that the IPFQR Program applies to Medicare participating freestanding psychiatric hospitals and psychiatric units and we believe that health systems that have IPFs that participate in the IPFQR Program would find this measure useful as they assess access and referral network adequacy

¹⁴⁹ 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.

within their systems.

Comment: Some commenters observed that some follow-ups, especially for substance use disorders, may not be identifiable in claims. A few commenters specifically noted that some providers who often provide follow-ups are not covered by Medicare (for example, therapists) or that some follow-ups may be covered by other insurers. These commenters observed that this may lead the measure to undercount follow-ups provided. A few of these commenters did not support measure adoption because of this undercount. However, one commenter that expressed this concern supported measure adoption because the commenter believes that burden reduction associated with claims reporting outweighs the potential undercounting.

Response: We acknowledge that, like the Follow-Up After Hospitalization for Mental Illness (FUH, NQF #0576) measure that we proposed to replace with the FAPH measure, the FAPH measure would not be able to capture follow-up visits provided by professionals outside of Medicare, or if the patient uses another payer or self-pay to cover the patient's follow-up care, which could lead to an undercount. However, we believe that the data captured by the measure would be sufficient to inform consumers and to provide data for quality improvement initiatives. Further, we agree with the commenter that the burden reduction associated with using claims-based measures outweighs the potential undercounting.

Comment: Some commenters expressed concern that this measure may be difficult for some IPFs to perform well on due to factors outside of the IPF's control. One commenter observed that many rural hospitals lack community resources and therefore cannot refer patients to outpatient psychiatrists. Another commenter observed that some patients may be unwilling to see an outpatient psychiatrist. Other commenters observed that this measure captures patient behavior, not provider actions. Some of these commenters observed that lack of transportation, access barriers, homelessness or other patient characteristics outside of the IPF's control may affect performance. Some of these commenters expressed preference for a process measure that tracks whether IPFs performed interventions to improve follow-up rates before or during

discharge.

Response: We recognize that there is regional variation in access to outpatient resources and that patients have varying comfort levels with different provider types. However, we believe that this updated measure helps to address some of the commenters' concerns. Specifically, we note that this measure expands the definition of follow-up to include a wider range of outpatient providers, including family or general practice physicians, internal medicine physicians, nurse practitioners, and physician assistants. We agree with commenters that there are factors that influence follow-up that are outside of an IPF's control (including patient behavior, lack of transportation, access barriers, homelessness, among others).

As described in the FY 2022 IPF PPS proposed rule (86 FR 19504 through 19505), there are interventions that allow facilities to improve their follow-up adherence. We believe it is incumbent upon facilities to identify potential barriers to follow-up adherence and apply appropriate interventions to improve adherence. We believe that this measure is preferable to a process measure because it provides insight into the success of interventions by identifying follow-up rates. As discussed in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50894 through 50895) and the FY 2022 IPF PPS proposed rule in our proposal to adopt the FAPH measure (86 FR 19504 through 19507) we do not expect 100 percent of patients discharged from IPFs to receive follow-up care within 7 or 30 days of discharge because of factors both within and outside of the control of facilities such as availability of providers in the referral network.

Comment: Some commenters opposed the FAPH measure because it is not NQF endorsed and because it was not fully supported by the MAP. A few commenters observed that the measure may undergo changes to achieve NQF endorsement which would create burden if the measure were in the program when these changes occurred. Some commenters recommended delaying implementation until NQF's concerns are fully addressed. One commenter observed that the similar NQF-endorsed FUH measure is available and therefore CMS has not properly considered available consensus endorsed measures.

Response: We appreciate the commenters' concerns about the FAPH measure's lack of NQF endorsement. As we stated in the proposed rule, after having given due consideration to similar measures, FUH measure (NQF #0576) and Continuity of Care after Inpatient or Residential Treatment for SUD (NQF #3453), we believe that the FAPH measure is an improvement over the FUH measure currently in the IPFQR Program (86 FR 19507). The FAPH measure expands the number of discharges in the denominator by adding patients with SUD or dementia, populations that also benefit from timely follow-up care. We propose updates to the IPFQR program measure set on an annual basis through the rulemaking process. During the measure evaluation process, we carefully consider the potential burden to clinicians, health systems, and patients of any updates that are under consideration.

The primary concerns of some NQF Behavioral Health and Substance Use Standing Committee members with the FAPH measure were exclusions for patients who died during the 30-day follow-up period or who were transferred. While we respect the NQF's concerns, we note that these same exclusions align with the exclusions in the Follow-Up After Hospitalization for Mental Illness (FUH, NQF #0576) measure which is already NQF endorsed, and which we adopted under the IPFQR Program in the FY 2014 IPPS/LTCH PPS final rule. This measure has a very similar denominator (78 FR 50893 through 50895). The clinical expert work group and technical expert panel convened by our contractor supported these exclusions as being appropriate for both measures.

After having given due consideration to similar measures, FUH measure (NQF #0576) and Continuity of Care after Inpatient or Residential Treatment for SUD (NQF #3453), we believe that the FAPH measure is an improvement over the FUH measure which is currently in the IPFQR Program, because it includes patients with SUD or dementia, populations that also benefit from timely follow-up care (86 FR 19504 through 19506).

Comment: Some commenters recommended further research or testing. Some commenters recommended that CMS continue to consider evidence supporting the expanded

patient cohort.

Response: We thank commenters for these recommendations and will continue to evaluate them as part of our measure monitoring and evaluation process. We believe that the evidence cited in our proposal, including the evidence supporting the APA grade of [I] applied to the 2010 guidelines for the treatment of SUD patients that 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”¹⁵⁰ is sufficient evidence to support measuring follow up after hospitalization for SUD. We note that because discharge from an IPF is a time of transition to less intensive levels of care these guidelines apply to discharge from an IPF and support the expanded patient cohort.

Comment: One commenter requested CMS specifically consider the impact of the physician self-referral law (commonly referred to as “the Stark Law”) on an IPF’s ability to ensure necessary SUD follow-up care. Some commenters recommended that CMS evaluate additional risk adjustment for social risk factors. One commenter further expressed that this measure may not be a successful strategy for reducing readmissions. Another commenter recommended that CMS investigate whether FAPH is an appropriate replacement for the Alcohol & Other Drug Use Disorder Treatment Provided or Offered at Discharge and Alcohol & Other Drug Use Disorder Treatment at Discharge (SUB-3/3a) measure.

Response: Section 1877 of the Act, also known as the physician self-referral law: (1) prohibits a physician from making referrals for certain designated health services payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship, unless an exception applies; and (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payer) for those referred services.

¹⁵⁰ 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.

A financial relationship is an ownership or investment interest in the entity or a compensation arrangement with the entity.¹⁵¹ We believe that the comment regarding the physician self-referral law relates to compensation arrangements between IPFs (which qualify as hospitals, and “entities”, for purposes of the physician self-referral law) and physicians who provide post-discharge SUD follow-up care that may implicate the physician self-referral law. To the extent an IPF enters into a compensation arrangement with a physician who provides SUD follow-up care to patients discharged from the hospital, we note that there are exceptions to the physician self-referral law applicable to such compensation arrangements, including recently finalized exceptions for value-based arrangements.

We will consider this measure for potential risk adjustment or stratification as we seek to close the equity gap as described in section IV.D of this final rule. We note that a reduction in readmissions is this measure’s objective, though improved follow-up adherence may serve to reduce readmissions because of improved continuity of care. Finally, we will evaluate whether the FAPH measure is an appropriate replacement for Alcohol & Other Drug Use Disorder Treatment Provided or Offered at Discharge and Alcohol & Other Drug Use Disorder Treatment at Discharge (SUB-3/3a).

Comment: Some commenters requested clarification regarding visits that would be considered post-discharge follow-up. Some commenters requested clarification regarding whether telehealth visits, specifically audio-only telehealth visits, would be considered follow-up for purposes of the measure. A few commenters requested clarification regarding whether visits implemented through collaborative agreements with mental health providers would be considered follow-ups. These commenters further observed that including these visits would incentivize community partnerships. One commenter requested clarification regarding whether a visit to any HCP (including physicians, clinics, etc.) would be considered follow-up for purposes of the measure. This commenter further requested clarification regarding whether specific

¹⁵¹ <https://www.cms.gov/medicare/fraud-and-abuse/physicianselfreferral>

diagnosis codes would be required to be present on the follow-up claim.

Response: Regarding the request for clarification about the eligibility of telehealth visits for FAPH measure, both in-person and telehealth outpatient visits are acceptable, including audio-only visits. The FAPH numerator defines qualifying outpatient visits as outpatient visits, intensive outpatient encounters or partial hospitalizations that occur within 7 or 30 days of discharge and are defined by the Current Procedural Terminology (CPT), Healthcare Common Procedure Coding System (HCPCS), and Uniform Billing (UB) Revenue codes, with or without the GT telehealth modifier. The CPT codes 99441, 99442, and 99443, which represent telephone E/M visits, are included in the list of codes to identify eligible outpatient visits. With respect to the request for clarification regarding collaborative agreements, the measure is agnostic to relationships between mental health providers, other providers, and health systems. The codes used to identify outpatient visits for the FAPH measure are not limited to mental health providers. The outpatient visit may be any outpatient visit, intensive outpatient encounter or partial hospitalization that occurs within 7 or 30 days of discharge as defined in section IV.E.3.b.(1). This visit must be paired with a qualifying ICD-10-CM diagnosis of mental illness or substance use disorder used to define the denominator.

Comment: One commenter observed that historical trending would no longer be available due to the transition from FUH to FAPH.

Response: We agree with the commenter that replacing FUH with FAPH would mean that historical trending would no longer be available. However, we believe that the benefits associated with the expanded patient population and the expanded provider types for follow-up appointments outweigh the loss of trend data.

After consideration of the public comments, we are finalizing the FAPH measure as proposed for 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 did not propose 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 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 the FY 2022 IPF PPS proposed rule we described that 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 believed were appropriate to propose removing from the IPFQR Program for the FY 2024 payment determination and subsequent years (86 FR 19507). Our discussion of these measures follows.

2. Measures Proposed for Removal in the FY 2022 IPF PPS Proposed Rule

a. Retention of the Alcohol Use Brief Intervention Provided or Offered and Alcohol Use Brief Intervention (SUB-2/2a) measure Beginning with FY 2024 Payment Determination

We proposed to remove the Alcohol Use Brief Intervention Provided or Offered (SUB-2) and subset measure Alcohol Use Brief Intervention (SUB2a) collectively referred to as the 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 IPF performance was not consistent. Therefore, the measure provided a means of distinguishing IPF 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 assesses whether the IPF provided or offered a brief intervention for alcohol use). However, for the FY 2019 and FY 2020 payment determinations, the rate of improvement has leveled off to consistently high performance, as indicated in Table 3. 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.

As stated in the proposed rule, 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 3: – 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

In the proposed rule, we noted that 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 IPF 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 proposed 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 welcomed public comments on our proposal to remove the SUB-2/2a measure from the IPFQR Program.

We received the following comments on our proposal.

Comment: Many commenters supported our proposal to remove the Alcohol Use Brief

Intervention Provided or Offered and Alcohol Use Brief Intervention (SUB-2/2a) measure.

Some commenters agreed with our rationale that the costs of this measure outweigh the benefit of its continued use in the IPFQR Program. A few commenters recommended that CMS remove the measure immediately, rather than beginning with FY 2024 payment determination as proposed, to further reduce burden. One commenter agreed that providers will continue these interventions after the measure has been removed. Another commenter also supported removal because the measure is no longer NQF endorsed and was not specified for this setting.

Response: We thank the commenters for their support. While we continue to believe that the performance on the SUB-2/2a measure in recent years indicates that IPFs routinely offer alcohol use brief interventions, we recognize that we will not be able to monitor whether IPFs continue these interventions if we remove this measure. We considered proposing to remove the measure sooner, but because data are currently being collected to report during CY 2022 to inform the FY 2023 payment determination, we proposed removing the measure following that payment determination, that is, for the FY 2024 payment determination.

The commenter is correct that the measure is no longer NQF endorsed and is not specified for the IPF setting. However, we continue to believe that this measure is appropriate for the IPF setting. We reiterate that we proposed to remove this measure because of the belief that the costs of the measure outweigh its continued benefits in the IPFQR Program, not because it is no longer NQF endorsed nor because it was not specified for this setting.

Comment: One commenter supported removal of the SUB-2/2a measure, but recommended development of more meaningful measures than SUB-2/2a and the Alcohol & Other Drug Use Disorder Treatment Provided or Offered at Discharge and Alcohol & Other Drug Use Treatment at Discharge (SUB-3/3a) measure to address screening and intervention for substance use. Another commenter recommended that CMS consult with consumers to ascertain the benefits of measures in the IPFQR Program prior to proposing to remove any such measures, this commenter specifically recommended that CMS not finalize removal of the SUB-2/2a

measure until fully considering input from consumers.

Response: We appreciate this commenter's input and are continually seeking to improve our measure set by developing more meaningful and less burdensome measures. As we evaluate areas appropriate for measure development, we will consider additional measures or measure concepts that more meaningfully address alcohol use disorder treatment for the IPF patient population.

In response to the request that we consult with consumers to ascertain the benefits of the measure, we note that we evaluate input from all stakeholders, including consumers, patients, caregivers, and patient advocacy groups that we receive in response to our proposals to adopt or remove measures from the IPFQR Program. As part of this process, we have reviewed input from consumers regarding the benefits of the measure and considered this input in our analysis.

Comment: Some commenters expressed concern about removing the measure. A few of these commenters stated that not all facilities perform well on the measure and, therefore, there is still room for improvement. One commenter stated that the COVID-19 pandemic has led to increased alcohol use and expressed the belief that removing the measure now is poorly timed.

Response: We note that we proposed to remove the measure because of the belief that the benefits of retaining it have lessened to the point that its costs outweigh those benefits, not because the measure is topped out. We agree with commenters that not all facilities perform uniformly well on the Alcohol Use Disorder Brief Intervention Provided or Offered and Alcohol Use Disorder Brief Intervention Provided (SUB-2/2a) measure.

We also agree that alcohol use has increased during the COVID-19 pandemic.^{152, 153,154} In our literature review regarding this comment, we also identified evidence that individuals with

¹⁵² Pollard et al., Changes in Adult Alcohol Use and Consequences During the COVID-19 Pandemic in the US, *JAMA Network Open*, 2020;3(9):e2022942. doi:10.1001/jamanetworkopen.2020.22942

¹⁵³ Alcohol Consumption Rises Sharply During Pandemic Shutdown; Heavy Drinking by Women Rises 41%, RAND, <https://www.rand.org/news/press/2020/09/29.html>

¹⁵⁴ Nemani et al., Association of Psychiatric Disorders With Mortality Among Patients With COVID-19, *JAMA Psychiatry* .386-380:(4)78;2021 .doi:10.1001/jamapsychiatry.2020.4442; COVID-19 and people at increased risk, CDC, <https://www.cdc.gov/drugoverdose/resources/covid-drugs-QA.html>; U. Saengow et. al.,

mental health and substance use conditions may be at an increased risk of COVID-19 complications and appropriate substance use disorder treatment may help mitigate these complications.^{155, 156} To ensure that providers would continue to address alcohol use disorders among this patient population, we have maintained the Alcohol & Other Drug Use Disorder Treatment Provided or Offered at Discharge and Alcohol & Other Drug Use Treatment at Discharge (SUB-3/3a) measure. However, we note that a prominent model to ensure those with alcohol use disorder are identified and referred to treatment include both brief interventions and referrals.¹⁵⁷ Given the increased need for alcohol use brief interventions due to the pandemic, the current performance levels¹⁵⁸ (for FY 2018 payment determination, the mean performance nationally was approximately 80 percent of patients who screened positive for alcohol use disorder were offered or provided a brief intervention), and the importance of providing alcohol use brief interventions to improve the efficacy of alcohol use treatment at discharge, we believe that the benefits of retaining the Alcohol Use Brief Intervention Provided or Offered and Alcohol Use Brief Intervention (SUB-2/2a) measure are greater than we initially estimated in our proposal to remove this measure and that the measure should not be removed from the program at this time.

Comment: One commenter observed that this measure may be useful for future stratification based on race and ethnicity.

Response: We agree with the commenter that this measure may be useful for future stratification based on race and ethnicity. While we do not believe it would be appropriate to retain this measure specifically for the purpose of potential future stratification, we agree that

¹⁵⁵ Wang et. al., COVID-19 risk and outcomes in patients with substance use disorders: analyses from electronic health records in the United States, *Molecular Psychiatry* volume 26, pages 30–39 (2021), <https://www.nature.com/articles/s41380-020-00880-7>

¹⁵⁶ Vai et. al., Mental disorders and risk of COVID-19-related mortality, hospitalisation, and intensive care unit admission: a systematic review and meta-analysis, *Lancet Psychiatry*, [https://www.thelancet.com/pdfs/journals/lanpsy/PIIS2215-0366\(21\)00232-7.pdf](https://www.thelancet.com/pdfs/journals/lanpsy/PIIS2215-0366(21)00232-7.pdf)

¹⁵⁷ <https://www.samhsa.gov/sbirt>; <https://www.samhsa.gov/sbirt/coding-reimbursement>

¹⁵⁸ For FY 2018 payment determination, the mean performance nationally was approximately 80 percent of patients who screened positive for alcohol use disorder were offered or provided a brief intervention.

this potential is another benefit of the measure that we had not considered in our previous analysis of the benefits versus the costs of retaining the measure.

Comment: One commenter observed that there are benefits to retaining this measure because IPFs and health systems use performance data on this measure as part of quality improvement initiatives to reduce alcohol use and that removal may affect these programs.

Response: We thank the commenter for this input. We note that IPFs are responsible for abstracting the data for this measure, so we believe that IPFs who use these data for their own quality improvement initiatives have access to these data regardless of whether the measure is in the IPFQR Program. However, we recognize that such IPFs and health systems would not have access to publicly reported data regarding other IPFs and that these data may be useful for baselining. Therefore, we agree that such IPF level and systemic programs to reduce alcohol use is a benefit to retaining the measure that we had not evaluated in our proposal to remove this measure.

Comment: One commenter observed that this measure is less burdensome than the newly proposed COVID-19 vaccination measure and therefore the commenter believes that removing this measure because the costs, especially the information collection burden, outweigh benefits is inconsistent.

Response: We evaluate measures on a case-by-case basis looking at the overall benefits of the measure versus the overall costs of the measure. Therefore, measures are not evaluated based on whether they are more or less burdensome than other measures. However, we now believe that the benefits of retaining this measure are greater than we had considered in our proposal to remove the measure from the IPFQR Program measure set.

After consideration of the public comments, we now believe that the benefits of retaining this measure, which include the potential for IPFs to continue improving performance on this measure, the importance of substance use interventions due to increased substance use during the COVID-19 pandemic, and this measure's potential influence on other quality improvement

activities related to substance use are greater than we had considered in our proposal to remove the measure from the IPFQR Program measure set. Accordingly, we are not finalizing our proposal to remove the Alcohol Use Brief Intervention Provided or Offered and Alcohol Use Brief Intervention (SUB-2/2a) measure beginning with the FY 2024 payment determination. That is, we are retaining the Alcohol Use Disorder Brief Intervention Provided or Offered and Alcohol Use Disorder Brief Intervention Provided (SUB-2/2a) measure in the IPFQR Program measure set.

After consideration of the public comments, we are not finalizing our proposal to remove the Alcohol Use Brief Intervention Provided or Offered and Alcohol Use Brief Intervention (SUB-2/2a) measure beginning with the FY 2024 payment determination. That is, we are retaining the Alcohol Use Disorder Brief Intervention Provided or Offered and Alcohol Use Disorder Brief Intervention Provided (SUB-2/2a) measure in the IPFQR Program measure set.

b. Retention of the Tobacco Use Treatment Provided or Offered and Tobacco Treatment (TOB-2/2a) measure Beginning with FY 2024 Payment Determination.¹⁵⁹

We proposed to remove the Tobacco Use Treatment Provided or Offered (TOB-2) and Treatment (TOB-2a), collectively referred to as the 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 Treatment Provided or Offered and Tobacco Use Treatment (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).

¹⁵⁹ We note that the proposed rule incorrectly referred to this measure as the Tobacco Use Brief Intervention Provided or Offered and Tobacco Use Brief Intervention (TOB-2/2a) measure, we have corrected it here and throughout this final rule.

When we introduced the TOB-2/2a measure to the IPFQR Program, the benefits of this measure were high, because IPF performance was not consistent and therefore the measure provided a means of distinguishing IPF 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 4. 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 stated in the proposed rule that 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 4: Performance Analysis for Tobacco Use Treatment 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 IPF 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 proposed to remove the Tobacco Use Treatment Provided or Offered and Tobacco Use Treatment (TOB-2/2a) measure from the IPFQR Program beginning with the FY 2024 payment determination. We welcomed public comments on our proposal to remove the TOB-2/2a measure from the IPFQR Program.

We received the following comments on our proposal.

Comment: Many commenters supported our proposal to remove the Tobacco Use Treatment Provided or Offered and Tobacco Use Treatment (TOB-2/2a) measure. Some of these commenters agreed with our rationale that the costs of this measure outweigh the benefits of its continued use in the IPFQR Program. Several commenters recommended removing the measure immediately, rather than beginning with FY 2024 payment determination as proposed, to further reduce burden. One commenter agreed that providers will continue offering this intervention even if it is not being measured. Another commenter further expressed that removal is appropriate because the measure is no longer NQF endorsed and is not specified for this setting.

Response: We thank the commenters for their support. We considered proposing to remove the measure sooner, but because data are currently being collected to report during CY 2022 to inform the FY 2023 payment determination, we proposed to remove the measure

following that payment determination, that is, for the FY 2024 payment determination. While we continue to believe that the performance on the TOB-2/2a measure in recent years indicates that IPFs routinely offer tobacco use cessation interventions during the inpatient stay, we recognize that we will not be able to monitor whether IPFs continue these interventions if we remove this measure. The commenter is correct that the measure is no longer NQF endorsed and is not specified for the IPF setting. We reiterate that we proposed to remove this measure because of the belief that the costs of the measure outweigh its continued benefits in the IPFQR Program not because it is no longer NQF endorsed nor because it was not specified for this setting and we continue to believe that this measure is appropriate for the IPF setting.

Comment: One commenter expressed the belief that progress in electronic reporting systems leads to lower burden for reporting this measure. This commenter expressed the belief that this reduced burden should factor into the consideration of whether costs outweigh benefits and recommended that CMS retain this measure.

Response: We thank the commenter for this feedback. However, we note that because this is a chart-abstracted measure, we do not believe access to electronic reporting systems will significantly impact the burden of collecting and reporting this measure for most IPFs.

Comment: One commenter supported removal of the Tobacco Use Treatment Provided or Offered and Tobacco Use Treatment Provided (TOB-2/2a) measure, but recommended development of more meaningful measures than TOB-2/2a and Tobacco Use Treatment Provided or Offered at Discharge and Tobacco Use Treatment Provided at Discharge (TOB-3/3a) to address screening and intervention for tobacco use. One commenter recommended that CMS seek consumer input on the benefit of measures before proposing to remove them.

Response: We appreciate this commenter's input and are continually seeking to improve our measure set by developing more meaningful and less burdensome measures. As we evaluate areas appropriate for measure development, we will consider additional measures or measure concepts that more meaningfully address tobacco use treatment for the IPF patient population.

In response to the request that we consult with consumers to ascertain the benefits of the measure, we note that we evaluate input from all stakeholders, including consumers, patients, caregivers, and patient advocacy groups that we receive in response to our proposals to adopt or remove measures from the IPFQR Program. As part of this process, we have reviewed input from consumers regarding the benefits of the measure and considered this input in our analysis.

Comment: Some commenters expressed concern about removing the TOB-2/2a measure from the IPFQR Program measure set. Some of these commenters expressed that there continues to be significant room for improvement in providing interventions. One commenter specifically observed that the measure is not topped out. A few commenters observed that the proposed removal is poorly timed due to the increase in tobacco use during the COVID-19 pandemic. Another commenter cited evidence supporting the benefit of brief interventions as part of a comprehensive program to address topped out.

We agree with commenters that not all facilities perform uniformly well on the Tobacco Use Treatment Provided or Offered and Tobacco Use Treatment Provided (TOB-2/2a) measure. We also agree with the commenter's observation that tobacco use has increased during the COVID-19 pandemic.¹⁶⁰ In our literature review, we also identified evidence that individuals who use tobacco may be at an increased risk of COVID-19 complications and tobacco use treatment may help mitigate these complications.¹⁶¹ To ensure that providers would continue to address tobacco use among this patient population, we maintained the Tobacco Use Treatment Provided or Offered at Discharge and Tobacco Use Treatment Provided at Discharge (TOB-3/3a). However, we agree with the commenter who expressed that these interventions are most effective as part of a comprehensive tobacco treatment program. Given the increased need for tobacco use interventions due to the COVID-19 pandemic, that this measure is not topped out

¹⁶⁰ Giovenco et. al., Multi-level drivers of tobacco use and purchasing behaviors during COVID-19 "lockdown": A qualitative study in the United States, *International Journal of Drug Policy*, Volume 94, August 2021, 103175

¹⁶¹ <https://www.who.int/news/item/11-05-2020-who-statement-tobacco-use-and-covid-19>

and there is room for improvement across facilities,¹⁶² and the importance of providing tobacco use treatment during the inpatient stay to improve the efficacy of tobacco use treatment at discharge, we believe that the benefits of retaining the Tobacco Use Treatment Provided or Offered and Tobacco Use Treatment Provided (TOB-2/2a) measure are greater than we estimated in our proposal to remove this measure and that the measure should not be removed from the program at this time.

Comment: Many commenters opposed removal of the measure because of the clinical importance of treating tobacco use in the IPF patient population. Many of these commenters observed that tobacco use is undertreated. Some of these commenters referenced CDC data stating that only 48.9 percent of mental health treatment facilities reported screening patients for tobacco use. Some commenters pointed to this statistic and expressed concern that without measures related to tobacco use treatment this care may no longer be provided in IPFs. These commenters observed that tobacco use is nearly three times more prevalent in people with serious psychological distress than in those without. Some of these commenters observed that this discrepancy contributes to a shorter life expectancy for patients with mental illness who smoke. These commenters expressed the belief that the potential to increase patient life expectancy and quality of life outweighs the costs of reporting the measure. A few of these commenters observed there are high costs associated with treating tobacco associated illness and that these costs could be significantly reduced by increased screening, intervention, and treatment.

Some commenters stated that the 2020 Surgeon General's report specifically stated that tobacco dependence treatment is applicable to the behavioral health setting. One commenter observed that brief interventions are part of the "Treating Tobacco Use and Dependence Clinical Practice Guidelines." One commenter stated that behavioral health patients often have limited

¹⁶² For the FY 2018 payment determination, the mean performance nationally was approximately 79 percent of patients who screened positive for tobacco use were provided or offered treatment while inpatients.

interaction with the healthcare system and therefore the commenter believes that it is important to use these interactions to drive health behaviors.

Response: We agree with commenters that providing or offering tobacco use brief intervention within the IPF setting is a valuable intervention because of the prevalence of this comorbidity within this patient population and because of the ability of this intervention to facilitate quitting tobacco use. We further agree that brief interventions are part of clinical guidelines and are appropriate to provide to patients receiving care for behavioral health conditions. We note that the tobacco screening statistics cited by commenters refer to all behavioral health and substance use treatment facilities, whereas the IPFQR Program only requires reporting on treatment provided by IPFs that receive Medicare payment under the IPF PPS, therefore the statistics cited by commenters do not directly reflect care provided by IPFs.¹⁶³ However, we acknowledge that the low performance on tobacco use screening in the behavioral health setting does indicate that tobacco screening and treatment performance may lapse in the IPF setting without measures to address this topic, and that the inpatient setting may be a uniquely opportune setting for providing tobacco cessation interventions to some patients due to limited access to or utilization of the healthcare system. We also agree with commenters that providing tobacco use brief interventions has the potential to increase patient life expectancy and quality of life while reducing healthcare costs associated with treating tobacco associated illness. Given the importance of tobacco use interventions in extending life expectancy and improving quality of life, the concern regarding potential reduction in performance if measures are removed (as demonstrated by CDC data that show that the provision of brief intervention for tobacco use cessation is not the current standard of care across behavioral health settings as only 48.9 percent of mental health treatment facilities report screening patients for tobacco use), and the room for improvement in the current performance levels, we believe that the benefits of retaining the Tobacco Use Treatment Provided or Offered and Tobacco Use Treatment Provided (TOB-2/2a)

¹⁶³ <https://www.cdc.gov/mmwr/volumes/67/wr/mm6718a3.htm>

measure are greater than we estimated in our proposal to remove this measure and that the measure should not be removed from the program at this time.

Comment: One commenter observed that there are health equity concerns regarding tobacco use and recommended that CMS retain this measure for future stratification based on race and ethnicity.

Response: We agree with the commenter that this measure may be useful for future stratification based on race and ethnicity. While we do not believe it would be appropriate to retain this measure specifically for the purpose of potential future stratification, we agree that this potential is another benefit of the measure that we had not considered in our previous analysis of the benefits versus the costs of retaining the measure.

Comment: One commenter observed that there are benefits to retaining this measure because IPFs and health systems use performance data on this measure as part of quality improvement initiatives to reduce tobacco use and that measure removal may affect those programs.

Response: We thank the commenter for this feedback. We note that IPFs are responsible for abstracting the data for this measure, so we believe that IPFs who use these data for their own quality improvement initiatives have access to these data regardless of whether the measure is in the IPFQR Program. However, we recognize that such IPFs and health systems would not have access to publicly reported data regarding other IPFs and that these data may be useful for baselining. Therefore, we agree that such IPF level and systemic programs to reduce tobacco use is a benefit to retaining the measure that we had not evaluated in our proposal to remove this measure.

Comment: Many commenters expressed the belief that without this measure IPFs would not continue to provide tobacco use brief interventions. Some commenters expressed concern that removing this measure would reduce providers' incentive to offer brief interventions. These commenters further observed that it would be difficult to determine whether IPFs continue to

offer this intervention as the ability to track that depends on the continued collection of this measure. Some commenters further expressed concern that CMS policies drive the behavior of other payers and without this measure the healthcare system may lose focus on tobacco treatment for patients with behavioral health disorders.

Response: We understand commenters' concern regarding the potential for IPFs and other payers to no longer focus on tobacco treatment without the Tobacco Use Treatment Provided or Offered and Tobacco Use Treatment (TOB-2/2a) quality measure in the IPFQR Program and we agree that ensuring continuing focus on tobacco use treatment in this setting is a benefit of retaining this measure in the IPFQR program. Additionally, we agree that tracking whether IPFs continue to offer this intervention is a benefit of retaining the measure in the IPFQR program measure set.

Comment: One commenter observed that the Tobacco Use Treatment Provided or Offered and Tobacco Use Treatment (TOB-2/2a) measure is not as burdensome as the newly proposed COVID-19 vaccination measure and therefore the commenter believes that removing this measure because the costs, especially the information collection burden, outweigh benefits is inconsistent.

Response: We evaluate measures on a case-by-case basis looking at the overall benefits of the measure versus the overall costs of the measure. Therefore, measures are not evaluated based on whether they are more or less burdensome than other measures. However, we now believe that the benefits of retaining this measure are greater than we had considered in our proposal to remove the measure from the IPFQR Program measure set.

After consideration of the public comments, we now believe that the benefits of retaining this measure, which include the potential for IPFs to continue improving performance on this measure, the importance of tobacco use interventions due to increased tobacco use during the COVID-19 pandemic, and this measure's potential influence on other quality improvement activities related to tobacco use, are greater than we had considered in our proposal to remove

the measure from the IPFQR Program measure set. Accordingly, we are not finalizing our proposal to remove the Tobacco Use Treatment Provided or Offered and Tobacco Use Treatment (TOB-2/2a) measure beginning with the FY 2024 payment determination. That is, we are retaining the Tobacco Use Treatment Provided or Offered and Tobacco Use Treatment (TOB-2/2a) measure in the IPFQR Program measure set.

c. Removal of the Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) measure Beginning with FY 2024 Payment Determination

We proposed 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 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 therefore did not propose 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 or other administrative 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, transfer to another health care facility or to another community provider, or combination of patient events 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 as defined in the CoP) 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 noted 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 further note that the CoPs referenced in the proposed rule are not an exhaustive list of data transfer requirements.

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 the capacity to generate information for electronic patient event notifications, 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 proposed 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 welcomed public comments on our proposal 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.

We received the following comments on our proposal.

Comment: Many commenters supported the removal of the Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) measure. One commenter recommended immediate removal to further reduce burden. Another commenter expressed that this measure was not developed for IPFs and has been difficult to report because the specifications are not appropriate for the setting. Another commenter further noted that the measure is no longer NQF endorsed.

Response: We thank the commenters for their support. We considered removing the measure sooner, but because data are currently being collected to report during CY 2022 to inform the FY 2023 payment determination, we decided to propose removing the measure following that payment determination, therefore we proposed removal for the FY 2024 payment determination. The commenter is correct that the measure is no longer NQF endorsed and is not specified for the IPF setting; however we continue to believe that this measure is appropriate for the setting. We reiterate that removal of the measure is because we believe that the costs of the measure outweigh its continued benefits in the IPFQR Program.

Comment: Some commenters observed that the updated CoPs will not apply to many IPFs, especially freestanding IPFs that are not part of larger healthcare facilities, because IPFs were excluded from Meaningful Use incentives and therefore often do not have electronic data systems capable of meeting the standards in the updated CoPs.

Response: We acknowledge that there are a large number of IPFs that do not possess

EHR systems with the technical capacity to generate information for electronic patient event notifications of a patient's admission, discharge, or transfer to another health care facility or to another community provider, or combination of patient events at the time of a patient's discharge or transfer. However, for those IPFs that can meet these requirements, we believe that retaining the Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) measure could be burdensome depending on how facilities implement new requirements. Therefore, while for some IPFs the benefits may outweigh the costs, overall, for the IPFQR Program we believe the costs now outweigh the benefits. We reiterate that for IPFs that do not possess EHR systems with the capacity to generate information for patient event notifications as defined in the CoP regulations set forth at 42 CFR 482.24(d), such facilities should continue to transmit data using their existing infrastructure and timelines.

Comment: A few commenters recommended that CMS retain the Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) measure. Some of these commenters believe that the measure's benefits are more significant than the burden. One commenter recommended that CMS seek consumer input on benefits prior to proposing measures for removal.

Response: We reiterate that we do not believe that the benefits of transmitting the transition record within 24 hours of discharge are reduced, or are lower than the costs of reporting; we believe that given the updates to the CoPs which overlap with this measure the benefits of retaining the Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) measure are no longer sufficient to justify retention. We used the notice and comment rulemaking process to solicit input on measure benefits from all stakeholders, including consumers.

After consideration of the public comments, we are finalizing our proposal to remove the Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self

Care or Any Other Site of Care) measure beginning with the FY 2024 payment determination.

d. Removal of the Follow-Up After Hospitalization for Mental Illness (FUH, NQF #0576)

Beginning with FY 2024 Payment Determination

In the FY 2022 IPF PPS proposed rule we stated that if we finalize adoption of the Follow-Up After Psychiatric Hospitalization measure described in section IV.E.3, we believed that our current measure removal Factor 3 would apply to the existing Follow-Up After Hospitalization for Mental Illness (FUH, NQF #0576) measure (86 FR 19510). 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 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 proposed to remove the FUH measure under measure removal Factor 3 only if we finalized our proposal to adopt of the FAPH measure. We noted that if we did not adopt the FAPH measure, we would retain the FUH measure because we believe this measure addresses an important clinical topic. We welcomed public comments on our proposal to remove FUH if we were to adopt FAPH.

We received the following comments on our proposal.

Comment: Many commenters supported removal of this measure. Some commenters specifically noted that FAPH is more broadly applicable and therefore preferable.

Response: We thank these commenters for their support.

Comment: One commenter does not support either the FUH measure or the FAPH

measure due to the belief that measures of follow-up after hospitalization are not appropriate for the IPFQR Program and recommended removing the FUH measure but not adopting the FAPH measure.

Response: For the reasons set forth in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50894 through 50895) and the FY 2022 IPF PPS proposed rule in our proposal to adopt the FAPH measure (86 FR 19504 through 19507), we believe that a measure of follow-after hospitalization is an important concept for the inpatient psychiatric setting. Therefore, we do not believe it would be appropriate to remove the FUH measure without adopting the FAPH measure.

Comment: One commenter observed that the FUH measure is an NQF-endorsed measure, while the NQF declined to endorse the FAPH measure. This commenter recommended retaining the FUH measure because it is endorsed.

Response: The commenter is correct that the FUH measure is NQF endorsed and that the NQF declined to endorse the FAPH measure. However, as discussed in the FY 2022 IPF PPS proposed rule, the FUH measure does not apply to as broad a patient population, nor does it allow for follow-up care to be provided by as many provider types (86 FR 19507). Further, for the reasons we discussed in the FY 2022 IPF PPS proposed rule, we believe the exception under section 1886(s)(4)(D)(ii) of the Act applies (86 FR 19507). Because the FAPH measure is a more broadly applicable measure we believe it is appropriate for adoption into the IPFQR Program.

After consideration of the public comments, we are finalizing our proposal to remove Follow-Up After Hospitalization for Mental Illness (FUH, NQF #0576) measure beginning with the FY 2024 payment determination.

G. Summary of IPFQR Program Measures

1. IPFQR Program 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 final rule, we are adopting one measure for the FY 2023 payment determination and subsequent years. The 15 measures which will be in the program are shown in Table 5.

TABLE 5: IPFQR Program Measure Set for the FY 2023 Payment Determination and Subsequent Years with Finalized Measure Adoption

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
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. IPFQR Program 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 final rule, we are adopting one measure for the FY 2023 payment determination and subsequent years. Additionally, we are finalizing our proposal to remove one measure and replace one measure for the FY 2024 payment determination and subsequent years. We are not finalizing our proposals to remove two measures for the FY 2024 payment

determination and subsequent years. The 14 measures which will be in the program for FY 2024 payment determination and subsequent years are shown in Table 6.

TABLE 6: IPFQR Program Measure Set for the FY 2024 Payment Determination and Subsequent Years

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-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
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.¹⁶⁴ 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 sought public comment on each of these topics and other future measure considerations which stakeholders believe are important.

We received the following public comment on measure considerations which stakeholders believe are important.

Comments: Many commenters suggested measure areas that they believe are important for IPFs. These areas were: (1) suicide evaluation and reduction; (2) patient experience; (3) patient improvement; (4) clinical processes that impact significant numbers of patients in important clinical domains; (5) patient and workforce safety; (6) caregiver engagement; (7) safety culture; (8) workforce engagement, (9) immunization status; (10) measures that more rigorously capture data on tobacco and substance use interventions; and (11) discharge planning measures. Some commenters recommended developing improved discharge planning measures. One commenter recommended that CMS ensure that the role of nurse practitioners is included in measures. One commenter recommend that CMS engage with patients and their caregivers to identify topics they find important. Another commenter recommended that CMS seek industry input on measure considerations.

Response: We thank these commenters for this input. We will consider these recommendations as we seek to develop a more comprehensive measure set for the IPFQR Program.

1. Patient Experience of Care Data Collection Instrument

¹⁶⁴ <https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization>

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, in the FY 2022 IPF PPS proposed rule (86 FR 19511 through 19512) we sought 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).

We received the following comments in response to our request.

Comment: Many commenters expressed support for development of a uniform patient experience of care measure because this is a gap in the IPFQR measure set. Many commenters expressed that there is currently no patient experience of care measure in the IPFQR Program and expressed the belief that such a survey could improve provider accountability, show respect

for patients, and drive quality improvement. Some commenters observed that patients should be given the opportunity to share their experiences regardless of diagnosis. One commenter observed that evaluations of patient experience of care can be a driver of health equity.

Many commenters shared personal or family experiences in IPFs and indicated that being able to share such experiences in a formal survey would allow patients and caregivers to have a voice, provide valuable feedback, feel respected, provide information for quality improvements, and inform other potential patients. One commenter observed that allowing proxies would be valuable. Some commenters observed that not collecting patient experience of care data leads to the perception that patients' opinions are not valid and expressed the concern that this message may further objectify and traumatize a vulnerable patient population in a stressful and potentially stigmatizing situation (that is, psychiatric hospitalization). Other commenters expressed that not collecting such data normalizes poor treatment of psychiatric patients. Some commenters observed that patients with psychiatric illness are not less likely to be competent to express their experience of care than patients with other acute care needs.

Many commenters recommended that CMS identify a minimum set of items to include in surveys, as opposed to requiring a specific survey. These commenters observed that the net promoter score (NPS) used by the National Health Service in the UK may be a good model to consider. Some commenters observed that many facilities have designed their own surveys tailored to their patient populations (for example, pediatric patients, involuntarily admitted, etc.) and that it would be preferable for these facilities to add questions to meet a minimum set rather than to replace their surveys.

Many commenters expressed that they do not support HCAHPS for the IPF setting. These commenters expressed that 1) the HCAHPS was developed for patients with non-psych primary diagnoses and not for behavioral health diagnoses therefore the questions on HCAHPS do not address patients' top concerns regarding IPF care; 2) the survey protocols which allow for administration of the survey up to 6 weeks post-discharge may negatively impact completion

rates due to the transient nature of the patient population; 3) the protocols do not have a web-interface for survey administration nor e-mail or text survey invites; and 4) HCAHPS does not account for involuntary admissions. Some commenters also expressed concern that HCAHPS is not validated, nor has it been through psychometric testing in this setting. Some commenters observed the HCAHPS survey is due for a redesign and observed that CMS could potentially address concerns with the HCAHPS survey as part of the intended redesign. Other commenters recommended that CMS develop a survey unique to this setting that addresses aspects of care specific to the setting (such as group therapy, treatment by therapists, involuntary admission, medication treatment, consistency of treatment). One commenter recommended that CMS collaborate with AHRQ in survey design and development. Some commenters recommended that CMS ensure proper risk adjustment because patient characteristic can affect patient experience.

Some commenters observed that the questions on HCAHPS apply to IPF patients and recommended that CMS test HCAHPS for this setting. A few of these commenters observed that using the same measure across settings would improve behavioral health parity, facility comparison, and reduce burden for facilities that are distinct part units in acute care hospitals that use HCAHPS. A few commenters expressed concern that excluding psychiatric patients from HCAHPS is discrimination based on a disability which, because of the benefits derived from patient experience surveys, denies patients with psychiatric diagnoses equal treatment. Other commenters observed that minimizing burden is not a factor in establishing patient experience of care measures in other settings and that therefore it should not be a consideration in this setting. Some commenters observed that CMS has requested and received input on this subject for several years and requested a specific plan of action.

A few commenters recommended that CMS collaborate with IPFs to determine how to assess patients' experience of care, several commenters recommended that CMS establish a technical expert panel (TEP) with IPF members

One commenter recommended that CMS reintroduce the attestation measure until a solution for assessing patient experience of care is identified.

Response: We thank these commenters for their input. We agree that Patient Experience of Care is a gap in the current IPFQR Program measure set and we agree with commenters that adoption of such a measure would be a meaningful step towards ensuring that patients have a voice regarding the care they receive. We appreciate the input from patients and their caregivers explaining how meaningful such a measure would be for these stakeholders. We intend to use the feedback provided here and in past requests to identify the most appropriate path forward towards adopting such a measure as soon as possible.

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 sought 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.

We received the following comments in response to our request.

Comment: Many commenters supported the concept of a functional outcomes measure

and recommended preceding development of such a measure with an attestation measure which asks IPFs whether they use an assessment, and if so which one.

Some commenters expressed concern regarding outcome measures in this setting. One commenter specifically observed that short lengths of stay often lead to minimal progress on outcomes. One commenter mentioned the lack of endorsed, public domain outcome measures for this setting.

A few commenters recommended that CMS convene a technical expert panel (TEP) on patient reported outcomes for this setting.

One commenter uses PHQ-9 to assess outcomes. Another commenter uses BASIS-32 or CABA-Y depending on the patient population.

Response: We thank the commenters for their input and will consider this feedback as we continue to evaluate a functional outcomes measure for this setting.

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 sought 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.

We received the following comments in response to our request.

Comment: Several commenters supported transitioning the IPFQR Program to electronic reporting.

Many commenters observed that IPFs have not received Federal incentives to support EHR adoption and expressed the belief that electronic data reporting without such funding is premature.

Some commenters observed that the Transition Record measure is a complicated measure for e-specification. Some of these commenters noted that this measure requires a large number of data elements, some of which are not available in structured fields. One commenter recommended considering Metabolic Screening or Influenza Immunization for electronic specification as these measures have fewer data elements and those elements are available in structured fields. Another commenter observed that e-specification of existing chart measures often does not provide comparable results.

Response: We thank commenters for this input. We acknowledge that IPFs were not eligible to receive prior Federal incentives to support EHR adoption and will consider this and other input as we seek to transition the IPFQR Program to electronic data reporting.

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. We did not propose 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 final rule, we are finalizing our proposal to use the term “QualityNet

security official” instead of “QualityNet system administrator,” finalizing our proposal 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 Web site” (77 FR 53654).

a. Updated References 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 the FY 2022 IPF PPS proposed rule, we proposed 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 (86 FR 19512). The term “security official” would refer to “the individual(s)” who have responsibilities for security and account management requirements for a IPF’s QualityNet account. To clarify, this update in terminology will not change the individual's responsibilities or add burden.

We invited public comment on our proposal to replace the term “QualityNet system administrator” with “QualityNet security official.”

We did not receive any public comments on this proposal.

We are finalizing our proposal to replace the term “Quality Net system administrator” with “QualityNet security official” as proposed.

Additionally, we proposed 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 user¹⁶⁵ 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 adopting 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 IPFQR Program requirements, including data submission and administrative requirements, while recommending, but not requiring, that hospitals maintain an active QualityNet security official account.

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

We received the following comments in response to our proposal.

Comment: Many commenters supported removal of the requirement to have an active QualityNet Security Official for the complete year to meet IPFQR Program requirements and therefore be eligible to receive a full payment update.

Response: We thank these commenters for their support. We note that IPFs that do not meet all IPFQR Program requirements must receive a 2 percent reduction to their annual payment update.

After review of the public comments received, we are finalizing our proposal to no longer require facilities to maintain an active QualityNet security official account to qualify for payment as proposed.

b. Updated Reference to QualityNet Administrator in Code of Federal Regulations

We proposed to revise our regulation at § 412.434(b)(3) by replacing “QualityNet system

¹⁶⁵ 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.”

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 update in terminology would not change the individual's responsibilities or add burden. The revised paragraph (b)(3) reads: “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 invited public comment on our proposal to replace the term “QualityNet system administrator” with “QualityNet security official” at § 412.434(b)(3).

We did not receive any public comments in response to our proposal.

We are finalizing our proposal to no longer require facilities to replace the term “QualityNet system administrator” with “QualityNet security official” at § 412.434(b)(3) as proposed.

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 final rule, we are finalizing our proposal 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 finalizing our proposal 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 finalizing for FY 2023 payment determination and subsequent years

(the COVID-19 Vaccination Coverage Among HCP 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 would be calculated and publicly reported, so that the public would know what percentage of the HCP have been vaccinated in each IPF.

For the COVID-19 HCP Vaccination measure, we proposed 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. CMS will publicly report the CDC's quarterly summary of COVID-19 vaccination coverage for IPFs.

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

We did not receive any comments in response to our proposal.

We are finalizing our proposal to require facilities to report the COVID-19 HCP vaccination measure as proposed.

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 did not propose any changes to our data submission policies associated with the proposal to adopt this measure.

c. 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-3¹⁶⁶, 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 proposed 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 proposed to require patient-level reporting of the both the numerator and the denominator. Table 7 lists the proposed FY 2023 IPFQR measure set categorized by whether we would require patient-level data submission through the QualityNet secure portal.

TABLE 7: 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

¹⁶⁶ We note that in the FY 2022 IPF PPS proposed rule this incorrectly read HBIPS-2 (86 FR 19514). We have corrected it to HBIPS-3 here.

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 IPF would 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 would increase provider costs or burden associated with measure submission.

Because we believe that patient-level data would improve the data accuracy without increasing provider burden, we proposed 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 7: 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 proposed 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 proposed to allow voluntary patient-level reporting prior to requiring such data submission for one year prior to the FY 2024 payment determination. 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 also proposed 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 welcomed 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.

We received the following comments in response to our proposal.

Comment: Many commenters supported the adoption of patient-level reporting. Many of these commenters supported initiating the process with one year of voluntary participation. One commenter observed that having patient level data would help accurately identify trends and improve outcomes and with demographic data could help identify health disparities. One commenter specifically supported the numerator only patient-level reporting for HBIPS-2 and HBIPS-3. One commenter observed that HBIPS-2 was listed twice in the proposed rule (86 FR

19514).

Response: We thank these commenters for their support.

Comment: Some commenters recommended that CMS use a more gradual transition to patient-level reporting. One commenter specifically recommended two cycles of voluntary reporting to ensure that the data submission system works properly. Others recommended that CMS provide additional guidance and education, including XML specifications or other reporting templates prior to the voluntary reporting period. One commenter recommended aligning guidance across programs. One commenter observed that the start date for collecting data for the mandatory reporting period is before the data submission timeframe for the voluntary reporting period.

Response: We recognize that IPFs will need additional guidance and education in preparation for patient-level reporting. We will provide templates, guidance, and education and outreach sessions prior to beginning patient level reporting. We note that, to the extent feasible, we will align guidance across programs. We do not believe that it is necessary to have a longer voluntary reporting period because many IPFs also have experience with these tools already and we have extensive experience with patient-level reporting, both using electronic data reporting systems, and using tools such as the CMS Abstraction & Reporting Tool (CART) in our other quality reporting programs and intend to provide templates, guidance and education and outreach to IPFs.

Comment: Some commenters recommended that CMS not require patient level reporting for measures proposed for removal.

Response: We note that the measure being removed from the IPFQR Program (Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or any Other Site of Care)) is being removed for FY 2024 payment determination and subsequent years. The first year of mandatory patient-level reporting is FY 2024 payment determination. Therefore, this measure will no longer be in the program when patient-level reporting is required.

We further note that we are not finalizing our proposals to remove Alcohol Use Brief Intervention Provided or Offered and Alcohol Use Brief Intervention (SUB-2/2a) and Tobacco Use Treatment Provided or Offered and Tobacco Use Treatment (TOB-2/2a); and therefore these patient-level data reporting will be required for these measures beginning with the FY 2024 payment determination.

Comment: Some commenters oppose patient level reporting because of a lack of technology. Some commenters observed that CMS should assist with development of EHRs in the same way they did for acute care hospitals. One commenter observed that patient-level reporting would be burdensome without EHR technology.

Response: We disagree with commenters that EHR technology is necessary for patient level reporting and note that acute care hospitals reported patient-level data for the Hospital IQR Program prior to the introduction of the HITECH act and associated meaningful use incentives. We further note that because IPFs must abstract the same data from patient records regardless of whether they are reporting at the patient-level or in aggregate, we do not believe that submitting patient-level data is more burdensome than aggregate data reporting for providers whether or not they have EHR technology.

Comment: One commenter requested clarification on the start date for voluntary patient-level data submission for FY 2023. This commenter specifically requested clarification on whether that would be for discharges beginning for FY 2023 or CY 2023.

Response: The voluntary patient-level data submission period is for FY 2023 payment determination. This applies to the data submitted during CY 2022 (which affects FY 2023 payment determination). Data submitted during CY 2022 covers discharges that occur during CY 2021.

After review of the public comments we received, we are finalizing our proposal 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 as proposed.

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). In the FY 2022 IPF PPS proposed rule, we noted 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 (86 FR 19515). 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 sought 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.

We received the following comments in response to our request.

Comment: Many commenters supported the concept of data validation but recommended that CMS ensure a stable and successful patient-level reporting process prior to developing a data validation plan.

One commenter recommended using two measures and 200 hospitals to pilot data validation.

Some commenters did not support eventual adoption of validation for the IPFQR program because of the belief that data validation would be burdensome. One commenter observed data validation is only necessary in pay-for-performance programs.

Response: We thank these commenters for this input and will take it into consideration if

we develop a data validation program for the IPFQR Program.

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. We did not propose 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. In the FY 2022 IPF PPS proposed rule, we noted that neither the measure we proposed to remove (FUH – NQF #0576) nor the measure we proposed 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 (86 FR 19515). Furthermore, the denominator of the COVID-19 Healthcare Personnel Vaccination measure we are adopting in this final rule is all healthcare personnel, and therefore, this measure is not eligible for sampling. We did not propose any changes to these 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. We did not propose 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. We did not propose 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. We did not propose 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. We did not propose 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.

In the FY 2022 IPF PPS proposed rule (86 FR 19480) we solicited public comment on each of the section 3506(c)(2)(A)-required issues for the following information collection requirements (ICRs). As indicated in section V.2.c.(1) of this final rule, we received some comments that generally discuss the burden of reporting through NHSN, but not comments

specific to our information collection estimates. We have not made any changes from what was proposed.

A. Final ICRs for the (IPFQR) Program

The following final 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). In May 2019, the U.S. Bureau of Labor Statistics (BLS) revised their \$18.83/hr wage figure to \$20.50/hr (May 2019).¹⁶⁷ In response, we proposed to adjust our cost estimates using the updated median wage rate figure of \$20.50/hr., an increase of \$1.67/hr. We are finalizing our proposal to use the \$20.50/hr wage in this FY 2022 final rule.

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.¹⁶⁸ 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 8 presents these assumptions.

TABLE 8: Wage assumptions for the IPFQR Program

Occupation Title	Occupation	Median Hourly	Fringe Benefits	Adjusted Hourly
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¹⁶⁷ <https://www.bls.gov/oes/current/oes292098.htm> (Accessed on June 28, 2021)

¹⁶⁸ http://www.whitehouse.gov/omb/circulars_a076_a76_incl_tech_correction

	Code	Wage (\$/hr)	and Overhead (\$/hr)	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 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 finalized policies 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 9, 10, and 11 provide an overview of our currently approved burden. These tables use our previous estimate of \$37.66/hr (\$18.83/hr base salary plus \$18.83/hr fringe benefits and overhead) hourly labor cost. For more information on our currently approved burden estimates, please see Supporting Statement A on the Office of Information and Regulatory Affairs (OIRA) website.¹⁶⁹

¹⁶⁹ https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201908-0938-011

TABLE 9: 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
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)	609	0.25	152.25	1,679	255,627.75	9,626,941

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 (\$)
		Facility to Home/Self Care or Any Other Site of Care)						
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 10: 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 11: 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)	3,358	126,462
Notice of Participation, Data Accuracy	N/A	N/A	N/A	N/A

Requirement	Respondents	Responses	Time (hours)	Cost (\$)
Acknowledgment, and Vendor Authorization Form*				
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. Final 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 finalizing our proposal 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 12, 13, and 14, 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 final rule, on our previously estimated burden.

TABLE 12: Measure Collection and Reporting Burden Based on Updated Wage Rate, Facility Count, and Case Count

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	609*	0.25	152.25	1,634	248,776.5	10,199,836.50

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 (\$)
		Treatment Provided or Offered at Discharge and Alcohol and Other Drug Use Disorder Treatment at Discharge						
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	0	0	0	0	0	0

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 (\$)
		psychiatric hospitalization in an IPF*						
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 IPF 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 13: Non-Measure Data Collection and Reporting Burden Based on Updated Wage Rate, Facility Count, and Case Count

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 14: Total Burden Based on Updated Wage Rate, Facility Count, and Case Count

Requirement	Respondents	Responses	Time (hours)	Cost (\$)
Measure Data Collection and Reporting (See Table 12)	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 (See Table 13)	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 Final Rule

(1) Updates Due to Final Measure Adoptions

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

- COVID-19 Vaccination Among HCP 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 adopting the COVID-19 Vaccination among HCP measure beginning with an initial reporting period from October 1 to December 31, 2021 affecting the FY 2023 payment determination followed by quarterly reporting beginning with the FY 2024 payment determination and subsequent years. IPFs will submit data through the CDC's NHSN. The NHSN is a secure, Internet-based system that is maintained by the CDC and provided free. The CDC does not estimate burden for COVID-19 vaccination reporting since the department has been granted a waiver under Section 321 of the National Childhood Vaccine Injury Act of 1986 (NCVIA).¹⁷⁰

Although the burden associated with the COVID-19 HCP Vaccination measure is not accounted for due to the NCVIA waiver, the burden is set forth here and will be accounted for by the CDC under OMB control number 0920-1317.

Consistent with the CDC's experience of collecting data using the NHSN, we estimate that it will 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 time and wages. We believe it

¹⁷⁰ 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.

would take an Administrative Assistant¹⁷¹ between 45 minutes (0.75 hr) and 1 hour and 15 minutes (1.25 hr) to enter the 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 responses at 1 response per month) and 3.75 hours (1.25 hours * 3 responses at 1 response per month) per IPF. For all 1,634 IPFs, the total time would range from 3,676.5 hours (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 * \$36.62/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 x \$36.62/hr) and \$549.30 annually (15 hours x \$36.62/hr). The estimated cost across all 1,634 IPFs would be between \$134,641.60 (\$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 \$897,556.20 (\$549.30/IPF * 1,634 IPFs) annually thereafter. Since the burden falls under the authority of the CDC, we have not added such burden to Table 16.

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

¹⁷¹ <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.

communities throughout the PHE and beyond outweigh the costs of reporting. In our proposed rule, we welcomed comments on the time to collect data and enter it into the NHSN. While we did receive some comments addressing the burden of NHSN reporting, which we address in section IV.E.2 of this rule, we did not receive any public comments on the estimated time to collect and submit such data.

We further note that as described in section IV.E.3 of this preamble, we will calculate the FAPH measure using Medicare Part A and Part B claims that IPFs and other providers (specifically outpatient providers who provide the follow-up care) 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 warrant any changes under that control number.

(2) Updates Due to Final Measure Removals

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

- 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).

We note that we are not finalizing our proposals to remove the following two measures:

- SUB-2 – Alcohol Use Brief Intervention Provided or Offered and the subset measure SUB-2a Alcohol Use Brief Intervention Provided; and

- TOB-2 – Tobacco Use Treatment Provided or Offered and the subset measure TOB-2a Tobacco Use Treatment.

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. One of the measures we are removing (the Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self

Care or Any Other Site of Care) measure) falls under our previously finalized “global sample” (80 FR 46717 through 46718) and, therefore, would require abstraction of 609 records. We estimate that removing this measure would result in a decrease in burden of 152.25 hours per facility (609 cases per facility * 0.25 hours per case), or 248,776.5 hours (152.25 hours/facility x 1,634 facilities) across all IPFs. Therefore, the decrease in costs for each measure is approximately \$6,242.25 per IPF (\$41.00/hr * 152.25 hours), or \$10,199,836.50 across all IPFs (\$6,242.25/facility * 1,634 facilities).

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 15 describes our estimated reduction in burden associated with removing these two measures.

TABLE 15: Burden Updates Due to Final 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 (\$)
0576	FUH	Follow-Up After Hospitalization for Mental Illness*	0	0	0	1,634	0	0
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)	(10,199,836.5050)
TOTAL			(609)	Varies	152.25	1,634	(248,776.5)	(10,199,836.5050)

* 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.

** We note that the previously approved number of IPFs is 1,679; however we adjusted that in Table 12 based on updated data.

***At \$41.00/hr

(3) Updates Due to Final Administrative Policies

(a) Updates Associated with Final Updated Reference to QualityNet System Administrator

In section IV.J.1.a of this preamble, we are finalizing our proposal to use the term

“QualityNet security official” instead of “QualityNet system administrator.” Because this final update will 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 Adoption of Patient-Level Reporting for Certain Chart Abstracted Measures

In section IV.J.2.c of this preamble, we are adopting patient-level data submission for the 11 chart -abstracted measures currently in the IPFQR Program measure set (for more details on these measures we refer readers to Table 7). 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 16 summarizes the estimated burden associated with the IPFQR Program.

TABLE 16: Total Estimated IPFQR Program Measure Set Burden Estimates

Measure/ Response Description	Estimated Responses per Facility	Time per Response (hours)	Annual Time per Facility (hours)	Total Annual Responses (Responses per Facility * 1,634 facilities)	Total Annual Time (hours)	Total Annual Cost (\$)
Hours of Physical Restraint Use (See Table 12)	1,346	0.25	336.50	2,199,364	549,841	22,543,481
Hours of Seclusion Use (See Table 12)	1,346	0.25	336.50	2,199,364	549,841	22,543,481
Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification (See Table 12)	609*	0.25	152.25	995,106	248,776.5	10,199,836.50
Alcohol Use Brief Intervention Provided or Offered (SUB-2 and SUB-2a) (See Table 12)	609*	0.25	152.25	995,106	248,776.5	10,199,836.50
Alcohol and Other Drug Use Disorder Treatment Provided or Offered at Discharge and	609*	0.25	152.25	995,106	248,776.5	10,199,836.50

Measure/ Response Description	Estimated Responses per Facility	Time per Response (hours)	Annual Time per Facility (hours)	Total Annual Responses (Responses per Facility * 1,634 facilities)	Total Annual Time (hours)	Total Annual Cost (\$)
Alcohol and Other Drug Use Disorder Treatment at Discharge (SUB-3 and SUB-3a) (See Table 12)						
Tobacco Use Treatment Provided or Offered and Tobacco Use Treatment (TOB-2 and TOB-2a) (See Table 12)	609*	0.25	152.25	995,106	248,776.5	10,199,836.50
Tobacco Use Treatment Provided or Offered at Discharge and Tobacco Use Treatment at Discharge (TOB-3 and TOB-3a) (See Table 12)	609*	0.25	152.25	995,106	248,776.5	10,199,836.50
Influenza Immunization (See Table 12)	609*	0.25	152.25	995,106	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) (See Table 12)	609*	0.25	152.25	995,106	248,776.5	10,199,836.50
Screening for Metabolic Disorders (See Table 12)	609*	0.25	152.25	995,106	248,776.5	10,199,836.50
Thirty-day all-cause unplanned readmission following psychiatric hospitalization in an IPF (See Table 12)	0**	0	0	0	0	0
Medication Continuation Following Inpatient Psychiatric Discharge (See Table 12)	0**	0	0	0	0	0
COVID-19 Vaccination Rate Among Healthcare Personnel (See Table 12)	0***	0	0	0	0	0
Follow-Up After Psychiatric Hospitalization (See Table 12)	0**	0	0	0	0	0
SUBTOTAL	7,564	N/A	1,891	12,359,576	3,089,894	126,685,654
Non-Measure Data Collection and Reporting (See Table 13)	4	0.5	2.0	6,536	3,268	133,988
TOTAL	7,568	N/A	1,893	12,366,112	3,093,162	126,819,642

* 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 final rule (including all updates to wage rate, case counts, facility numbers, and the measures and administrative policies) is a reduction

of 287,924 hours and \$512,065 from our currently approved burden of 3,381,086 hours and \$127,331,707. We refer readers to Table 17 for details.

TABLE 17: Summary of Final Requirements and Annual Burden Estimates Under OMB Control Number 0938-1171 (CMS-10432)

Program Changes	No. Respondents	Total Responses	Time per Response (hr)	Total Time (hr)	Labor Cost (\$/hr)	Total Cost (\$)
Active Burden	1,679	13,517,629	Varies	3,381,086	37.66	127,331,707
Total Burden Under CMS-1750-F (See Table 16)	1,634	12,366,112	Varies	3,093,162	41.00	126,819,642
DIFFERENCE	(45)	(1,151,517)	Varies	(287,924)	Varies	(512,065)

VI. Regulatory Impact Analysis

A. Statement of Need

This rule finalizes 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 finalizing our proposal to apply the 2016-based IPF market basket increase of 2.7 percent, less the productivity adjustment of 0.7 percentage point as required by 1886(s)(2)(A)(i) of the Act for a final total FY 2022 payment rate update of 2.0 percent. In this final rule, we are finalizing our proposal 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 final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), 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), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)). Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public

health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a rule: (1) having an annual effect on the economy of \$100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with significant regulatory action/s or with economically significant effects (\$100 million or more in any 1 year).

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 \$80 million. This reflects an \$75 million increase from the update to the payment rates (+\$100 million from the 2nd quarter 2021 IGI forecast of the 2016-based IPF market basket of 2.7 percent, and -\$25 million for the productivity adjustment of 0.7 percentage point), as well as a \$5 million increase as a result of the update to the outlier threshold amount. Outlier payments are estimated to change from 1.9 percent in FY 2021 to 2.0 percent of total estimated IPF payments in FY 2022.

Based on our estimates, OMB’s Office of Information and Regulatory Affairs has determined that this rulemaking is “economically significant,” and hence also a major rule under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act).

C. Detailed Economic Analysis

In this section, we discuss the historical background of the IPF PPS and the impact of this final 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 final 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 final rule will be due to the market basket update for FY 2022 of 2.7 percent (see section III.A.4 of this final rule) less the productivity adjustment of 0.7 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 \$80 million in payments to IPF providers. This reflects an estimated \$75 million increase from the update to the payment rates and a \$5 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 final rule).

2. Impact on Providers

To show the impact on providers of the changes to the IPF PPS discussed in this final 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 reduced 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 final rulemaking, that would be the FY 2020 claims. However, as discussed in section III.F.2 of this final 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.

As discussed in the FY 2022 IPF PPS proposed rule (86 FR 19524 through 19526), 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 was driving the divergent results in our proposed rule impacts between FY 2019 claims and FY 2020 claims. Based on our analysis, we stated that we believe it is likely that the response to the COVID-19 PHE in FY 2020 has contributed to increases in estimated outlier payments and to decreases in estimated total PPS payments in the FY 2020 claims. Therefore, we proposed, in contrast to our usual methodology, to use the FY 2019 claims to calculate the outlier fixed dollar loss threshold and wage index budget neutrality factor.

We requested comments from stakeholders about likely explanations for the declines in total PPS payments, covered IPF days, and covered IPF stays in FY 2020. Additionally, we requested comments from stakeholders about likely explanations for the observed fluctuations and overall increases in covered lab charges per claim and per day, which we identified through our analysis. Lastly, we requested comments regarding likely explanations for the increases in estimated cost per stay relative to estimated IPF Federal per diem payment amounts per stay.

Comment: We received 1 comment regarding our analysis of FY 2020 claims and 3 comments in support of our proposal to use FY 2019 claims for calculating the outlier fixed dollar loss threshold and wage index budget neutrality factor for FY 2022. One commenter appreciated CMS' recognition of the impact of the COVID-19 PHE on providers. Another commenter agreed with our analysis about the effect of the COVID-19 PHE on the FY 2020 claims, stating their belief that FY 2020 cases were heavily impacted by the intensity of the COVID-19 pandemic, which continues to subside.

Response: We appreciate the support from these commenters. As we discuss later in this section of this final rule, based on the results of our final impact analysis, we continue to believe that the FY 2019 claims are the best available data for estimating payments in this FY 2022 final rulemaking, due to the likely impact of the COVID-19 PHE on IPF utilization in FY 2020. We will continue to analyze data in order to understand its short-term and long-term effects on IPF utilization.

Final Decision: In light of the comments received and after analyzing more recently updated FY 2020 claims, we are finalizing our proposal to use the FY 2019 claims to calculate the outlier fixed dollar loss threshold and wage index budget neutrality factor.

To illustrate the impacts of the FY 2022 changes in this final 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, March 2021 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 final update to the outlier fixed dollar loss threshold amount.
- The final FY 2022 IPF wage index, the final FY 2022 labor-related share, and the final updated COLA factors.
- The final market basket update for FY 2022 of 2.7 percent less the productivity adjustment of 0.7 percentage point in accordance with section 1886(s)(2)(A)(i) of the Act for a payment rate update of 2.0 percent.

Our final column comparison in Table 18 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 final rule. For each column, Table 18 presents a side-by-side comparison of the results using FY 2019 and FY 2020 IPF PPS claims.

TABLE 18: FY 2022 IPF PPS Final Payment Impacts
[Percent Change in columns 3 through 5]

Facility by Type	Number of Facilities		Outlier		FY 2022 Wage Index, 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	1,519	1,534	0.1	-1.1	0.0	0.0	2.1	0.9
Total Urban	1,220	1,235	0.1	-1.1	0.0	0.0	2.1	0.8

Urban unit	739	737	0.2	-1.8	-0.1	-0.1	2.2	0.1
Urban hospital	481	498	0.0	-0.3	0.0	0.0	2.1	1.7
Total Rural	299	299	0.1	-0.7	0.2	0.2	2.2	1.5
Rural unit	239	238	0.1	-0.8	0.1	0.1	2.2	1.3
Rural hospital	60	61	0.1	-0.4	0.4	0.4	2.4	2.0
By Type of Ownership:								
Freestanding IPFs								
Urban Psychiatric Hospitals								
Government	116	123	0.2	-1.7	-0.2	-0.2	2.0	0.1
Non-Profit	95	97	0.1	-0.5	-0.2	-0.1	1.9	1.4
For-Profit	270	278	0.0	-0.1	0.1	0.1	2.1	2.0
Rural Psychiatric Hospitals								
Government	31	32	0.1	-0.8	0.5	0.6	2.6	1.8
Non-Profit	12	12	0.2	-1.2	-0.1	0.0	2.1	0.7
For-Profit	17	17	0.0	0.0	0.4	0.4	2.4	2.4
IPF Units								
Urban								
Government	108	107	0.3	-3.4	0.1	0.1	2.5	-1.4
Non-Profit	479	478	0.2	-1.7	-0.1	-0.1	2.1	0.2
For-Profit	152	152	0.1	-0.7	-0.1	-0.1	2.0	1.2
Rural								
Government	58	57	0.1	-0.4	0.4	0.3	2.4	1.9
Non-Profit	132	131	0.1	-1.0	0.1	0.1	2.2	1.0
For-Profit	49	50	0.1	-0.6	-0.2	-0.2	1.9	1.2
By Teaching Status:								
Non-teaching	1,321	1,336	0.1	-0.8	0.0	0.0	2.1	1.1
Less than 10% interns and residents to beds	109	109	0.2	-1.9	0.1	0.1	2.3	0.2
10% to 30% interns and residents to beds	67	67	0.3	-2.4	-0.1	-0.1	2.2	-0.5
More than 30% interns and residents to beds	22	22	0.4	-3.2	-0.2	-0.1	2.2	-1.3
By Region:								
New England	106	106	0.2	-1.2	-0.4	-0.4	1.8	0.3
Mid-Atlantic	214	216	0.2	-2.0	-0.2	-0.2	2.0	-0.2
South Atlantic	240	243	0.1	-0.7	0.6	0.6	2.7	1.9
East North Central	243	244	0.1	-0.7	-0.2	-0.2	1.9	1.0
East South Central	152	155	0.1	-0.7	-0.5	-0.5	1.6	0.7
West North Central	108	109	0.2	-1.4	0.1	0.1	2.3	0.7
West South Central	224	227	0.1	-0.5	-0.2	-0.3	1.8	1.3
Mountain	103	103	0.1	-0.7	0.3	0.3	2.4	1.6
Pacific	129	131	0.2	-1.4	0.4	0.4	2.6	1.0
By Bed Size:								
Psychiatric Hospitals								
Beds: 0-24	83	88	0.1	-0.5	0.1	0.0	2.1	1.5
Beds: 25-49	79	83	0.1	-0.2	-0.3	-0.3	1.8	1.5
Beds: 50-75	84	88	0.0	-0.1	0.1	0.2	2.1	2.2
Beds: 76 +	295	300	0.1	-0.4	0.1	0.1	2.2	1.7
Psychiatric Units								

Beds: 0-24	536	531	0.2	-1.2	0.0	0.0	2.2	0.7
Beds: 25-49	258	259	0.2	-1.3	0.0	0.0	2.2	0.7
Beds: 50-75	114	114	0.2	-2.0	-0.3	-0.3	2.0	-0.3
Beds: 76 +	70	71	0.3	-2.5	0.0	0.0	2.3	-0.5

¹ This column includes the impact of the updates in columns (3) and (4) in Table 18 above, and of the final IPF market basket increase factor for FY 2022 (2.7 percent), reduced by 0.7 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 18 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 1,519 IPFs included in the analysis for FY 2019 claims or the 1,534 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 1.9 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 3.1 percent in FY 2021.

Thus, we are finalizing our proposal to adjust the outlier threshold amount in this final 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 0.1 percent increase in payments because we would expect the outlier portion of total payments to increase from approximately 1.9 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 1.1 percent decrease in payments because we would expect the outlier portion of total payments to decrease from approximately 3.1 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 18), across all hospital groups, is 0.1 percent based on the FY 2019 claims, or -1.1 percent based on the FY 2020 claims. Based on the FY 2019 claims, the largest increase in payments due to this change is estimated to be 0.4 percent for teaching IPFs with more than 30 percent interns and residents to beds. Among teaching IPFs, this same provider facility type would experience the largest estimated decrease in payments if we were to 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 final 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 final rule. That is, the impact represented in this column reflects the final updated COLA factors and the update from the FY 2021 IPF wage index to the final 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 77.2 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 0.6 percent for IPFs in the South Atlantic region,

and the largest decrease in payments to be –0.5 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 final changes reflected in this final rule for FY 2022 to the estimates for FY 2021 (without these changes). The average estimated increase for all IPFs is approximately 2.1 percent based on the FY 2019 claims, or 0.9 percent based on the FY 2020 claims. These estimated net increases include the effects of the 2016-based market basket update of 2.7 percent reduced by the productivity adjustment of 0.7 percentage point, as required by section 1886(s)(2)(A)(i) of the Act. They also include the overall estimated 0.1 percent increase 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 final updates to the IPF wage index, the labor-related share, and the final 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 continues to be due to the update to the outlier fixed dollar loss threshold, which is the same result we observed in the FY 2022 IPF PPS proposed rule (86 FR 19524). Estimated outlier payments increased and estimated total PPS payments decreased, when comparing FY 2020 to FY 2019. As a result, we continue to believe that FY 2019 claims, rather than FY 2020 claims, are the best available data for setting the FY 2022 final outlier fixed dollar loss threshold. Furthermore, the distributional effects of the updates presented in column 4 of Table 18 (the budget-neutral update to the IPF wage index, the LRS, and the final updated COLA factors) are very similar when using the FY 2019 or FY 2020 claims data. Therefore, we believe the FY 2019 claims are the best available data for estimating payments in this FY 2022 final rulemaking, and we are finalizing our proposal 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 2.1 percent in urban areas and 2.2 percent in rural areas based on this finalized policy. Overall, IPFs are estimated to experience a net increase in payments as a result of the updates in this final rule. The largest payment increase is estimated at 2.7 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 finalized 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 final 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 an annualized estimate of \$512,065 reduction in information collection burden as a result our measure removals. Therefore, we expect that the final 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 final rule and in accordance with section 1886(s)(4)(A)(i) of the Act, we will apply a 2 percentage point reduction to 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 final 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 policies finalized in this final rule, we estimate a total decrease in burden of 287,924 hours across all IPFs, resulting in a total decrease in information collection burden of \$512,065 across all IPFs. As discussed in section VI. of this final 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 policies in this final rule, that year is FY 2023. Further information on these estimates can be found in section VI. of this final 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 final rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will be directly impacted and will review this final rule, we assume that the total number of unique commenters on the most recent IPF proposed rule will be the number of reviewers of this final rule. For this FY 2022 IPF PPS final rule, the most recent IPF proposed rule was the FY 2022 IPF PPS proposed rule, and we received 898 unique comments on this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this final rule. It is possible that not all commenters reviewed the FY 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 final 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 final rule; therefore, for the purposes of our estimate, we assume that each reviewer reads approximately 50 percent of this final rule.

Using the May, 2020 mean (average) wage information from the BLS for medical and health service managers (Code 11-9111), we estimate that the cost of reviewing this final rule is \$114.24 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 128 minutes (2.13 hours) for the staff to review half of this final rule, which is approximately 32,000 words. For each IPF that reviews the final rule, the estimated cost is (2.13 x \$114.24) or \$243.33. Therefore, we estimate that the total cost of reviewing this final rule is \$ 218,510.34 (\$243.33 x 898 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 finalizing our proposal 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 2.7 percent, reduced by the statutorily required productivity adjustment of 0.7 percentage point along with the wage index budget neutrality adjustment to update the payment rates; and finalizing 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 final rule, we also considered using FY 2020 claims data to determine the final 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 finalizing our proposal 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 19, 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 final rule. Table 19 provides our best estimate of the increase in Medicare payments under the IPF PPS as a result of the changes presented in this final rule and based on the data for 1,519 IPFs with data available in the PSF and with claims in our FY 2019 MedPAR claims dataset. Table 19 also includes our best estimate of the cost savings for the 1,634 IPFs eligible for the IPFQR Program. Lastly, Table 19 also includes our best estimate of the costs of reviewing and understanding this final rule.

TABLE 19: 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	0.2	-	-	2020	-	FY 2022
Annualized Monetized Costs Savings	-0.51	-0.38	-0.64	2019	7%	FY 2023 – FY 2031
	-0.44	-0.33	-0.54	2019	3%	FY 2023 – FY 2031
Annualized Monetized Transfers from Federal Government to IPF Medicare Providers	80	-	-	FY 2022	-	FY 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 18, we estimate that the overall revenue impact of this final rule on all IPFs is to increase estimated Medicare payments by approximately 2.1 percent. As a result, since the estimated impact of this final rule is a net increase in revenue across almost all categories of IPFs, the Secretary has determined that this final 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 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. As discussed in section V.C.1 of this final rule, the rates and policies set forth in this final rule will not have an adverse impact on the rural hospitals based on the data of the 239 rural excluded psychiatric units and 60 rural psychiatric hospitals in our database of 1,519 IPFs for which data were available. Therefore, the Secretary has certified that this final 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 final rule does not mandate any requirements for state, local, or tribal governments, or for the private sector. This final 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 final rule does not impose substantial direct costs on state or local governments or preempt state law.

I, Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on July 23, 2021.

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 is amending 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 system.

* * * * *

(d) * * *

(1) * * *

(iii) * * *

(F) *Closure of an IPF or IPF residency training program*—(1) *Closure of an IPF*. 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.

* * * * *

5. 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: July 27, 2021.

Xavier Becerra,

Secretary,

Department of Health and Human Services.

[FR Doc. 2021-16336 Filed: 7/29/2021 4:15 pm; Publication Date: 8/4/2021]