DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 412

[CMS-1783-F]

RIN 0938-AV06

Medicare Program; FY 2024 Inpatient Psychiatric Facilities Prospective Payment System

- Rate Update

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (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. Additionally, this final rule rebases and revises the IPF market basket to reflect a 2021 base year. These changes will be effective for IPF discharges occurring during the Fiscal Year (FY) beginning October 1, 2023 through September 30, 2024 (FY 2024). In addition, this final rule discusses quality measures and reporting requirements under the Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program with changes beginning with the FY 2025 payment determination through changes beginning with the FY 2028 payment determination.

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

FOR FURTHER INFORMATION CONTACT: Mollie Knight (410) 786–7948 or Bridget Dickensheets (410) 786–8670, 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-Turner, (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 fiscal year (FY) 2024 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, Addenda B to this final rule show the complete listing of ICD-10 Clinical Modification (CM) and Procedure Coding System (PCS) codes, the FY 2024 IPF PPS comorbidity adjustment, and electroconvulsive therapy (ECT) procedure codes. Addenda A and B to this final rule are available online at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html.

Tables setting forth the FY 2024 Wage Index for Urban Areas Based on Core Based Statistical Area (CBSA) Labor Market Areas and the FY 2024 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 rebases and revises the market basket for the Inpatient Psychiatric Facility Prospective Payment System (IPF PPS) to reflect a 2021 base year, revises the labor-related share, and 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 2024, (beginning October 1, 2023 through September 30, 2024).

This rule also modifies our regulations to make it easier for hospitals to open new excluded psychiatric units paid under the IPF PPS. In addition, this final rule includes a summary of the public comments received to inform revisions to IPF PPS payments for FY 2025, as required by the Consolidated Appropriations Act, 2023 (hereafter referred to as CAA, 2023) (Pub. L. 117- 328). Lastly, this final rule discusses quality measures and reporting requirements

B. Summary of the Major Provisions

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

under the Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program.

- For the IPF PPS, we are finalizing our proposal to--
- Modify the regulations to allow the status of a hospital psychiatric unit to be changed from not excluded to excluded, and therefore paid under the IPF PPS, at any time during a cost reporting period if certain requirements are met.
 - Rebase and revise the IPF market basket to reflect a 2021 base year.
- Adjust the 2021-based IPF market basket update (3.5 percent) for economy-wide productivity (0.2 percentage point) as required by section 1886(s)(2)(A)(i) of the Social Security Act (the Act), resulting in a final IPF payment rate update of 3.3 percent for FY 2024.
- Make technical rate setting updates: The IPF PPS payment rates will be adjusted annually for inflation, as well as statutory and other policy factors.

This rule updates:

- ++ The IPF PPS Federal per diem base rate from \$865.63 to \$895.63.
- ++ The IPF PPS Federal per diem base rate for providers who failed to report quality data to \$878.29.
- ++ The electroconvulsive therapy (ECT) payment per treatment from \$372.67 to \$385.58 .
- ++ The ECT payment per treatment for providers who failed to report quality data to \$378.12.

- ++ The labor-related share from 77.4 percent to 78.7 percent.
- ++ The wage index budget-neutrality factor to 1.0016.
- ++ The fixed dollar loss threshold amount from \$24,630 to \$33,470 to maintain estimated outlier payments at 2 percent of total estimated aggregate IPF PPS payments.
- 2. Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program

For the IPFQR Program, we are finalizing our proposals to--

- Adopt the Facility Commitment to Health Equity measure beginning with the FY 2026 payment determination;
- Adopt the Screening for Social Drivers of Health measure beginning with voluntary reporting of calendar year (CY) 2024 data followed by mandatory reporting of CY 2025 data for the FY 2027 payment determination;
- Adopt the Screen Positive Rate for Social Drivers of Health measure beginning with voluntary reporting of CY 2024 data followed by mandatory reporting of CY 2025 data for the FY 2027 payment determination;
- Adopt the Psychiatric Inpatient Experience (PIX) survey to measure patient experience of care in the IPF setting beginning with voluntary reporting of CY 2025 data followed by mandatory reporting of CY 2026 data for the FY 2028 payment determination;
- Modify the Coronavirus disease 2019 (COVID-19) Vaccination Coverage Among
 Health Care Personnel (HCP) measure to align the measure with updated measure specifications
 developed by the Centers for Disease Control and Prevention (CDC), which address refinements
 reflecting the availability, and FDA authorization, of Moderna and Pfizer-BioNTech COVID-19
 vaccines for use as booster doses, beginning with fourth quarter CY 2023 data for the FY 2025
 payment determination and, following this first single-quarter reporting period, reporting for the
 full calendar year beginning with CY 2024 data for the FY 2026 payment determination;
- Remove the following two measures beginning with the FY 2025 payment determination and subsequent years:

- ++ Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification (HBIPS-5); and
- ++ Tobacco Use Brief Intervention Provided or Offered and Tobacco Use Brief Intervention Provided (TOB-2/2a) measure;
- Adopt a data validation pilot program starting with data submitted in CY 2025 and continuing until a full data validation program is proposed and adopted in future rulemaking; and
- Codify the IPFQR Program's procedural requirements related to statutory authority, participation and withdrawal, data submission, quality measure retention and removal, extraordinary circumstances exceptions, and public reporting at 42 CFR 412.433 Procedural requirements under the IPFQR Program.

C. Summary of Impacts

Provision Description	Total Transfers & Cost Reductions
FY 2024 IPF PPS payment update	The overall economic impact of this final rule is an estimated \$70 million in increased
payment apaate	payments to IPFs during FY 2024.
FY 2024 IPFQR	The overall economic impact of the IPFQR
Program update.	Program updates in this final rule is an
	estimated decrease of 380,897 hours in
	information collection burden resulting in a
	savings of \$8,150,478.

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
payment perspective 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 Social Security Act (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; that 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) of the Act 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 consider such reduction in computing the payment amount for a subsequent RY. Section 4125 of division FF, title IV, subtitle C, the CAA, 2023 requires that not later than FY 2028 each IPF will submit data through the use of a standardized assessment instrument which includes data on functional status; cognitive function; special services treatments, and interventions for psychiatric conditions; impairments; and other categories deemed appropriate. In addition, section 4125 of the CAA, 2023 requires that a patients' perspective of care quality measure be added to the IPFQR Program not later than for FY 2031. Information regarding the newly adopted Psychiatric Inpatient Experience (PIX) survey measure is provided in section VI.D.5 of this final rule.

Section 4125 of the CAA, 2023 also requires revisions to the Medicare prospective payment system (PPS) for psychiatric hospitals and psychiatric units. Specifically, section 4125(a) of the CAA, 2023 amends section 1886(s) of the Act by adding a new paragraph (5) that requires the Secretary to collect data and information beginning no later than October 1, 2023, as the Secretary determines appropriate, to inform revisions to IPF PPS payments. In addition, the Secretary is required to implement revisions to the methodology for determining the payment rates under the IPF PPS for FY 2025 as the Secretary determines appropriate.

To implement and periodically update the IPF PPS, we have published various proposed and final rules and notices in the **Federal Register**. For more information regarding these

documents, see the CMS website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/.

B. Overview of the IPF PPS

On November 15, 2004, we published the IPF PPS final rule in the **Federal Register** (69 FR 66922). The November 2004 IPF PPS final rule 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, as well as 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 has additional payment policies for outlier cases, interrupted stays, and a per treatment payment for patients who undergo 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. In the November 2004 IPF PPS final rule (69 FR 66922), 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 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 PPS proposed rule (68 FR 66923; 66928 through 66933) and our November 15, 2004 IPF PPS 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 2004 IPF PPS 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 1st. 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 1st. 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 July 29, 2022 in the **Federal Register** titled, "Medicare Program; FY 2023 Inpatient Psychiatric Facilities Prospective Payment System—Rate Update and Quality Reporting—Request for Information" (87 FR 46846), which updated the IPF PPS payment rates for FY 2023. That final rule updated the IPF PPS Federal per diem base rates that were published in the FY 2022 IPF PPS Rate Update final rule (86 FR 42608) in accordance with our established policies.

III. Analysis of and Responses to Public Comments

We received 2,506 public comments that pertain to proposed IPF PPS payment policies, requests for information, and the proposed updates to the IPFQR Program. Comments were

from Inpatient Psychiatric Facilities, health systems, national and state level provider and patient advocacy organizations, the Medicare Payment Advisory Commission (MedPAC), and individuals. We reviewed each comment and grouped related comments, after which we placed them in categories based on subject matter or section(s) of the regulation affected. Summaries of the public comments received and our responses to those comments are provided in the appropriate sections in the preamble of this final rule.

IV. Provisions of the FY 2024 IPF PPS Final Rule and Responses to Comments

A. Rebasing and Revising of the Market Basket for the IPF PPS

1. Background

Originally, the input price index 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 market basket applicable to the IPF PPS in the FY 2020 IPF PPS final rule (84 FR 38426 through 38447), where we adopted a 2016-based IPF market basket. The 2016-based IPF market basket used Medicare cost report data for both Medicare-participating freestanding psychiatric hospitals and hospital-based psychiatric units. 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). For the FY 2024 IPF PPS proposed rule, we proposed to rebase and revise the IPF market basket to reflect a 2021 base year.

2. Overview of the 2021-Based IPF Market Basket

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

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

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

Therefore, we rebase the market basket periodically so that the cost weights reflect recent changes in the mix of goods and services that IPFs purchase to furnish inpatient care between base periods.

3. Rebasing and Revising of the IPF Market Basket

As discussed in the FY 2020 IPF PPS final rule (84 FR 38426 through 38447), the 2016-based IPF market basket reflects the Medicare cost reports for both freestanding and hospital-based IPFs. Beginning with FY 2024, we proposed to rebase and revise the IPF market basket to a 2021 base year reflecting the 2021 Medicare cost report data submitted by both freestanding and hospital-based IPFs. We provide a detailed description of our proposed methodology used to develop the 2021-based IPF market basket below. This proposed methodology is generally similar to the methodology used to develop the 2016-based IPF market basket. We solicited public comment on our proposed methodology for developing the 2021-based IPF market basket.

Comment: Several commenters supported CMS's proposal to rebase and revise the market basket to reflect more recent data, noting that the changes in the cost weights were consistent with their expectations or experience. One commenter, however, proposed that CMS wait to rebase the IPF market basket until FY 2022 data is available. The commenter stated that, due to the increased demand for hospital care during the initial year following the outbreak of COVID-19 in the United States, they assume that a base year of FY 2021 would not necessarily reflect costs in FY 2024. Though inflation was particularly high during FY 2021, the commenter noted that FY 2022 would be further removed from the initial outbreak of COVID-19 in the United States and the massive changes in healthcare that occurred during that time. Similarly, one commenter supported the proposal to rebase but recommended CMS plan to rebase and revise the market basket and labor-related share to reflect a 2023 base year to fully incorporate the cost structures from the Public Health Emergency (PHE) as well as the evolving hospital workforce shortage.

Response: We appreciate the commenters' support regarding the proposed IPF market basket. For the proposed rebasing and revising, we used the most current and complete set of Medicare cost report data (2021) at the time of rulemaking to determine the major base year cost weights (Wages and Salaries, Employee Benefits, Contract Labor, Professional Liability Insurance, Pharmaceuticals, Home Office/Related Organization Contract Labor, and Capital).

As stated in the FY 2024 IPF PPS proposed rule (88 FR 21241), many commenters expressed concern in response to the FY 2023 IPF PPS proposed rule, in which we did not propose to rebase the IPF market basket. The commenters stated at that time that the 2016-based IPF market basket did not reflect the current costs of IPFs, particularly the use of contract labor. Therefore, based on the typical timeframe for rebasing the market baskets and in response to commenters' concerns expressed in FY 2023 IPF rulemaking, we proposed to rebase and revise the IPF market basket for FY 2024. We understand the commenters' concerns that the impact of the PHE may have resulted in increased costs compared to 2016. However, we believe it is appropriate to rebase the market basket regularly and to reflect more recent IPF cost structures. It has been our longstanding practice to rebase the IPF market basket (as well as other CMS market baskets) on a regular basis to ensure it reflects a more up-to-date input cost structure of IPFs so that the price change in the market basket best reflects input prices faced by IPFs. Because complete 2022 IPF Medicare cost report data is currently unavailable, we believe it is more appropriate to update the base year cost weights to 2021 to reflect changes over this period rather than to delay the rebasing for another year or two in order to use 2022 or 2023 Medicare cost report data as suggested by the commenter. We regularly rebase every 4 to 5 years because more recent data is typically more reflective of IPF cost structures. Therefore, we are using the most recent cost report data we have, which is 2021 cost report data, as it is more reflective of IPF cost structures than 2016 data. For example, the 2021-based IPF market basket reflects the higher compensation cost weight (as compared to the 2016-based IPF market basket) as a result of an increase in the contract labor cost weight (calculated using the 2021 Medicare cost report

data) as noted by the commenters in response to the FY 2023 IPF proposed rule (87 FR 46849). Additionally, we will continue to monitor the Medicare cost report data to assess whether a more frequent rebasing of the IPF market basket is appropriate through future notice and comment rulemaking.

<u>Final Decision</u>: We are finalizing our proposal to rebase the IPF market basket to reflect a 2021 base year for FY 2024.

We provide a summary of the more detailed public comments received on our proposed methodology for developing the 2021-based IPF market basket and our responses in the following sections.

- a. Development of Cost Categories and Weights for the 2021-Based IPF Market Basket
- (1) Use of Medicare Cost Report Data

We proposed a 2021-based IPF market basket that consists of seven major cost categories and a residual derived from the 2021 Medicare cost reports (CMS Form 2552-10, OMB No. 0938-0050) for freestanding and hospital-based IPFs. The seven major cost categories are Wages and Salaries, Employee Benefits, Contract Labor, Pharmaceuticals, Professional Liability Insurance (PLI), Home Office/Related Organization Contract Labor, and Capital. The cost reports include providers whose cost reporting period began on or after October 1, 2020 and before October 1, 2021. As noted previously, the current IPF market basket is based on 2016 Medicare cost reports and therefore, reflects the 2016 cost structure for IPFs. As described in the FY 2023 IPF PPS final rule (87 FR 46849), we received comments on the FY 2023 IPF PPS proposed rule (87 FR 19418 through 19419) where stakeholders expressed concern that the proposed market basket update inadequately reflected the input price inflation experienced by IPFs, particularly as a result of the COVID-19 PHE. These commenters stated that the PHE, along with inflation, has significantly driven up operating costs. Specifically, some commenters noted changes to labor markets that led to the use of more contract labor, a trend that we verified in analyzing the Medicare cost report data through 2021. Therefore, we believe it is appropriate

to incorporate more recent data to reflect updated cost structures for IPFs, and so we proposed to use 2021 as the base year, because we believe that the Medicare cost reports for this year represent the most recent complete set of Medicare cost report data available for developing the proposed IPF market basket at the time of this rulemaking. Given the potential impact of the PHE on the Medicare cost report data, we will continue to monitor these data going forward, and any changes to the IPF market basket will be proposed in future rulemaking.

Similar to the Medicare cost report data used to develop the 2016-based IPF market basket, the Medicare cost report data for 2021 show large differences between some providers' Medicare length of stay (LOS) and total facility LOS. Our goal has always been to measure cost weights that are reflective of case mix and practice patterns associated with providing services to Medicare beneficiaries. Therefore, we proposed to limit our selection of Medicare cost reports used in the 2021-based IPF market basket to those facilities that had a Medicare LOS within a comparable range of their total facility average LOS. The Medicare average LOS for freestanding IPFs is calculated from data reported on line 14 of Worksheet S-3, part I. The Medicare average LOS for hospital-based IPFs is calculated from data reported on line 16 of Worksheet S-3, part I. To derive the 2021-based IPF market basket, for those IPFs with an average facility LOS of greater than or equal to 15 days, we proposed to include IPFs where the Medicare LOS is within 50 percent (higher or lower) of the average facility LOS. For those IPFs whose average facility LOS is less than 15 days, we proposed to include IPFs where the Medicare LOS is within 95 percent (higher or lower) of the facility LOS. We proposed to apply this LOS edit to the data for IPFs to exclude providers that serve a population whose LOS will indicate that the patients served are not consistent with a LOS of a typical Medicare patient. This is the same LOS edit applied to the 2016-based IPF market basket.

Applying these trims to the approximate 1,370 total cost reports (freestanding and hospital-based) resulted in roughly 1,250 IPF Medicare cost reports with an average Medicare LOS of 13 days, average facility LOS of 10 days, and Medicare utilization (as measured by

Medicare inpatient IPF days as a percentage of total facility days) of 16 percent. Providers excluded from the 2021-based IPF market basket (about 120 Medicare cost reports) had an average Medicare LOS of 21 days, average facility LOS of 41 days, and a Medicare utilization of 3 percent. Of those excluded, about 62 percent of these were freestanding providers; on the other hand, freestanding providers represent about 38 percent of all IPFs. We note that 70 percent of those excluded from the 2016-based IPF market basket using this LOS edit were freestanding providers.

We then proposed to use the cost reports for IPFs that met this requirement to calculate the costs for the seven major cost categories (Wages and Salaries, Employee Benefits, Contract Labor, Professional Liability Insurance, Pharmaceuticals, Home Office/Related Organization Contract Labor, and Capital) for the market basket. These are the same categories used for the 2016-based IPF market basket. Also, as described in section IV.A.3.a.(4) of this final rule, and as done for the 2016-based IPF market basket, we proposed to use the Medicare cost report data to calculate the detailed capital cost weights for the Depreciation, Interest, Lease, and Other Capital-related cost categories. We also proposed to rename the Home Office Contract Labor cost category to the Home Office/Related Organization Contract Labor cost category to be more consistent with the Medicare cost report instructions.

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

(a) Total Medicare Allowable Costs

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

For hospital-based IPFs, we proposed that total Medicare allowable costs would be equal to the total costs for the IPF inpatient unit after the allocation of overhead costs (Worksheet B, part I, column 26, line 40) and a proportion of total ancillary costs reported on Worksheet B, part I, column 26, lines 50 through 76 (excluding 52 and 75), 90 through 91, and 93.

We proposed to calculate total ancillary costs attributable to the hospital-based IPF by first deriving an "IPF ancillary ratio" for each ancillary cost center. The IPF ancillary ratio is defined as the ratio of IPF Medicare ancillary costs for the cost center (as reported on Worksheet D–3, column 3 for hospital-based IPFs) to total Medicare ancillary costs for the cost center (equal to the sum of Worksheet D–3, column 3 for all relevant PPSs [that is, IPPS, IRF, IPF and skilled nursing facility (SNF)]). For example, if hospital-based IPF Medicare laboratory costs represent about 2 percent of the total Medicare laboratory costs for the entire facility, then the IPF ancillary ratio for laboratory costs would be 2 percent. We believe it is appropriate to use only a portion of the ancillary costs in the market basket cost weight calculations since the hospital-based IPF only utilizes a portion of the facility's ancillary services. We believe the ratio of reported IPF Medicare costs to reported total Medicare costs provides a reasonable estimate of the ancillary services utilized, and costs incurred, by the hospital-based IPF. We proposed that this IPF ancillary ratio for each cost center is also used to calculate Wages and Salaries and Capital costs as described below.

Then, for each ancillary cost center, we proposed to multiply the IPF ancillary ratio for the given cost center by the total facility ancillary costs for that specific cost center (as reported on Worksheet B, part I, column 26) to derive IPF ancillary costs. For example, the 2 percent IPF ancillary ratio for laboratory cost center would be multiplied by the total ancillary costs for laboratory (Worksheet B, part I, column 26, line 60). The IPF ancillary costs for each cost center

are then added to total costs for the IPF inpatient unit after the allocation of overhead costs (Worksheet B, part I, column 26, line 40) to derive total Medicare allowable costs.

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

(b) Wages and Salaries Costs

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

For hospital-based IPFs, we proposed to derive Wages and Salaries costs as the sum of the following salaries attributable to the hospital-based IPF: Inpatient routine salary costs (Worksheet A, column 1, line 40); overhead salary costs; ancillary salary costs; and a portion of overhead salary costs attributable to the ancillary departments.

(i) Overhead Salary Costs

We proposed to calculate the portion of overhead salary cost attributable to hospital-based IPFs by first calculating an IPF overhead salary ratio, which is equal to the ratio of total facility overhead salaries (as reported on Worksheet A, column 1, lines 4-18) to total facility noncapital overhead costs (as reported on Worksheet A, column 1 and 2, lines 4-18). We then proposed to multiply this IPF overhead salary ratio by total noncapital overhead costs (sum of Worksheet B, part I, columns 4 through 18, line 40, less Worksheet B, part II, columns 4 through 18, line 40). This methodology assumes the proportion of total costs related to salaries for the overhead cost center is similar for all inpatient units (that is, acute inpatient or inpatient psychiatric).

(ii) Ancillary Salary Costs

We proposed to calculate hospital-based IPF ancillary salary costs for a specific cost center (Worksheet A, column 1, lines 50 through 76 (excluding 52 and 75), 90 through 91, and 93) as salary costs from Worksheet A, column 1, multiplied by the IPF ancillary ratio for each cost center as described in section IV.A.3.a.(1)(a) of this final rule. The sum of these costs represents hospital-based IPF ancillary salary costs.

(iii) Overhead Salary Costs for Ancillary Cost Centers

We proposed to calculate the portion of overhead salaries attributable to each ancillary department (lines 50 through 76 (excluding 52 and 75), 90 through 91, and 93) by first calculating total noncapital overhead cost attributable to each specific ancillary department (sum of Worksheet B, part I, columns 4-18, less Worksheet B, part II, column 26). We then identify the portion of these total noncapital overhead cost for each ancillary department that is attributable to the hospital-based IPF by multiplying these costs by the IPF ancillary ratio as described in section IV.A.3.a.(1)(a) of this final rule. We then sum these estimated IPF Medicare allowable noncapital overhead costs for all ancillary departments (cost centers 50 through 76, 90 through 91, and 93). Finally, we then identify the portion of these IPF Medicare allowable

noncapital overhead cost that are attributable to Wages and Salaries by multiplying these costs by the IPF overhead salary ratio as described in section IV.A.3.a.(1)(b)(i) of this final rule. This is the same methodology used to derive the 2016-based IPF market basket.

(c) Employee Benefits Costs

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

For the 2021 Medicare cost report data, the majority of IPF providers did not report data on Worksheet S-3, part V. Two percent of freestanding IPFs and roughly 48 percent of hospital-based IPFs reported Employee Benefits data on Worksheet S-3, part V. Two percent of freestanding IPFs and roughly 13 percent of hospital-based IPFs reported Contract Labor data on Worksheet S-3, part V. We continue to encourage all providers to report these data on the Medicare cost report.

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

For hospital-based IPFs, we proposed to calculate total benefit cost as the sum of inpatient unit benefit cost, a portion of ancillary departments benefit costs, and a portion of overhead benefits attributable to both the routine inpatient unit and the ancillary departments. For those hospital-based IPFs that report Worksheet S-3, part V data, we proposed inpatient unit benefit costs be equal to Worksheet S-3, part V, column 2, line 3. Given the limited reporting on Worksheet S-3, part V, we proposed that for those hospital-based IPFs that do not report these data, we calculate inpatient unit benefits cost using a portion of benefits cost reported for

Excluded areas on Worksheet S-3, part II. We proposed to calculate the ratio of inpatient unit salaries (Worksheet A, column 1, line 40) to total excluded area salaries (sum of Worksheet A, column 1, lines 20, 23, 40 through 42, 44, 45, 46, 94, 95, 98 through 101, 105 through 112, 114, 115 through 117, 190 through 194). We then proposed to apply this ratio to Excluded area benefits (Worksheet S-3, part II, column 4, line 19) to derive inpatient unit benefits cost for those providers that do not report benefit costs on Worksheet S-3, part V.

We proposed the ancillary departments benefits and overhead benefits (attributable to both the inpatient unit and ancillary departments) costs are derived by first calculating the sum of hospital-based IPF overhead salaries as described in section IV.A.3.a.(1)(b)(i) of this final rule, hospital-based IPF ancillary salaries as described in section IV.A.3.a.(1)(b)(ii) of this final rule and hospital-based IPF overhead salaries for ancillary cost centers as described in section IV.A.3.a.(1)(b)(iii) of this final rule. This sum is then multiplied by the ratio of total facility benefits to total facility salaries, where total facility benefits is equal to the sum of Worksheet S-3, part II, column 4, lines 17-25, and total facility salaries is equal to Worksheet S-3, part II, column 4, line 1.

(d) Contract Labor Costs

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

Worksheet S-3, part II, column 4, lines 11 and 13, to derive Contract Labor costs.

For hospital-based IPFs, we proposed that Contract Labor costs be equal to Worksheet S-3, part V, column 1, line 3. Reporting of this data continues to be somewhat limited; therefore, we continue to encourage all providers to report these data on the Medicare cost report. Given the limited reporting on Worksheet S-3, part V, we proposed that for those hospital-based IPFs that do not report these data, we calculate Contract Labor costs using a portion of contract labor costs reported on Worksheet S-3, part II. We proposed to calculate the ratio of contract labor costs (Worksheet S-3, part II, column 4, lines 11 and 13) to PPS salaries (Worksheet S-3, part II, column 4, line 1 less the sum of Worksheet S-3, part II, column 4, lines 3, 401, 5, 6, 7, 701, 8, 9, 10 less Worksheet A, column 1, line 20 and 23). We then proposed to apply this ratio to total inpatient routine salary costs (Worksheet A, column 1, line 40) to derive contract labor costs for those providers that do not report contract labor costs on Worksheet S-3, part V.

(e) Pharmaceuticals Costs

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

For hospital-based IPFs, we proposed to calculate pharmaceuticals costs as the sum of a portion of the non-salary pharmacy costs and a portion of the non-salary drugs charged to patient costs reported for the total facility. We proposed that non-salary pharmacy costs attributable to the hospital-based IPF would be calculated by multiplying total pharmacy costs attributable to the hospital-based IPF (as reported on Worksheet B, part I, column 15, line 40) by the ratio of total non-salary pharmacy costs (Worksheet A, column 2, line 15) to total pharmacy costs (sum of Worksheet A, columns 1 and 2 for line 15) for the total facility. We proposed that non-salary drugs charged to patient costs attributable to the hospital-based IPF would be calculated by multiplying total non-salary drugs charged to patient costs (Worksheet B, part I, column 0,

line 73 plus Worksheet B, part I, column 15, line 73 less Worksheet A, column 1, line 73) for the total facility by the ratio of Medicare drugs charged to patient ancillary costs for the IPF unit (as reported on Worksheet D-3 for hospital-based IPFs, column 3, line 73) to total Medicare drugs charged to patient ancillary costs for the total facility (equal to the sum of Worksheet D-3, column 3, line 73 for all relevant PPS [that is, IPPS, IRF, IPF and SNF]).

(f) Professional Liability Insurance Costs

For freestanding and hospital-based IPFs, we proposed that Professional Liability
Insurance (PLI) costs (often referred to as malpractice costs) would be equal to premiums, paid
losses and self-insurance costs reported on Worksheet S-2, columns 1 through 3, line 118 – the
same data used for the 2016-based IPF market basket. For hospital-based IPFs, we proposed to
assume that the PLI weight for the total facility is similar to the hospital-based IPF unit since the
only data reported on this worksheet is for the entire facility, as we currently have no means to
identify the proportion of total PLI costs that are only attributable to the hospital-based IPF.
However, when we derive the cost weight for PLI for both hospital-based and freestanding IPFs,
we use the total facility medical care costs as the denominator as opposed to total Medicare
allowable costs. For freestanding IPFs and hospital-based IPFs, we proposed to derive total
facility medical care costs as the sum of total costs (Worksheet B, part I, column 26, line 202)
less non-reimbursable costs (Worksheet B, part I, column 26, lines 190 through 201). Our
assumption is that the same proportion of expenses are used among each unit of the hospital.

(g) Home Office/Related Organization Contract Labor Costs

For hospital-based IPFs, we proposed to calculate the Home Office/Related Organization Contract Labor costs using data reported on Worksheet S-3, part II, column 4, lines 1401, 1402, 2550, and 2551. Similar to the PLI costs, these costs are for the entire facility. Therefore, when we derive the cost weight for home office/related organization contract labor costs, we use the total facility medical care costs as the denominator (reflecting the total facility costs (Worksheet B, part I, column 26, line 202) less the nonreimbursable costs reported on lines 190 through 201).

(h) Capital Costs

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

For hospital-based IPFs, we proposed that capital costs would be equal to IPF inpatient capital costs (as reported on Worksheet B, part II, column 26, line 40) and a portion of IPF ancillary capital costs. We calculate the portion of ancillary capital costs attributable to the hospital-based IPF for a given cost center by multiplying total facility ancillary capital costs for the specific ancillary cost center (as reported on Worksheet B, part II, column 26) by the IPF ancillary ratio as described in section IV.A.3.a.(1)(a) of this final rule.

(2) Final Major Cost Category Computation

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

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

For the PLI cost weight, for each of the providers, we first divide the PLI costs by total facility medical care costs to obtain a PLI cost weight for the universe of IPF providers. We then proposed to trim the data to remove outliers by: (1) requiring that PLI costs are greater than zero and are less than total facility medical care costs; and (2) excluding the top and bottom 5 percent of the major cost weight trimming freestanding and hospital-based providers separately. After removing these outliers, we are left with a trimmed data set for both freestanding and hospital-based providers. We proposed to separately sum the costs for each category (freestanding and hospital-based) across all remaining providers. We next divide this by the sum of total facility medical care costs across all remaining providers to obtain both a freestanding cost weight and hospital-based cost weight. Lastly, we proposed to weight these two cost weights together using the Medicare allowable costs from the sample of freestanding and hospital-based IPFs that passed the PLI trim (63 percent for hospital-based and 37 percent for freestanding IPFs) to derive a PLI cost weight for the 2021-based IPF market basket.

For the Home Office/Related Organization Contract Labor cost weight, for each of the providers, we first divide the home office/related organization contract labor costs by total facility medical care costs to obtain a Home Office/Related Organization Contract Labor cost weight for the universe of IPF providers. Similar to the other market basket costs weights, we proposed to trim the Home Office/Related Organization Contract Labor cost weight to remove outliers. Since not all hospital-based IPFs will have home office/related organization contract labor costs (approximately 80 percent of hospital-based IPFs report having a home office), we proposed to trim the top one percent of the Home Office/Related Organization Contract Labor

cost weight. Using this proposed methodology, we calculate a Home Office/Related Organization Contract Labor cost weight for hospital-based IPFs of 5.1 percent.

Freestanding IPFs are not required to complete Worksheet S-3, part II. Therefore, to estimate the Home Office/Related Organization Contract Labor cost weight for freestanding IPFs, we proposed the following methodology:

Step 1: Using hospital-based IPFs with a home office and also passing the 1 percent trim as described, we calculate the ratio of the Home Office/Related Organization Contract Labor cost weight to the Medicare allowable non-salary, non-capital costs weight (Medicare allowable non-salary, non-capital costs as a percent of total Medicare allowable costs).

Step 2: We identify freestanding IPFs that report a home office on Worksheet S-2, line 140 – roughly 87 percent of freestanding IPFs. We proposed to calculate a Home Office/Related Organization Contract Labor cost weight for these freestanding IPFs by multiplying the ratio calculated in Step 1 by the Medicare allowable non-salary, noncapital cost weight for those freestanding IPFs with a home office.

Step 3: We then calculate the freestanding IPF cost weight by multiplying the Home Office/Related Organization Contract Labor cost weight in Step 2 by the total Medicare allowable costs for freestanding IPFs with a home office as a percent of total Medicare allowable costs for all freestanding IPFs (87 percent), which derives a freestanding Home Office/Related Organization Contract Labor cost weight of 4.2 percent.

To calculate the overall Home Office/Related Organization Contract Labor cost weight for the 2021-based IPF market basket, we proposed to weight together the freestanding Home Office/Related Organization Contract Labor cost weight (4.2 percent) and the hospital-based Home Office Contract Labor/Related Organization cost weight (5.1 percent) using total Medicare allowable costs from the sample of hospital-based IPFs that passed the one percent trim and the universe of freestanding IPFs. The resulting overall cost weight for Home Office/Related Organization Contract Labor is 4.7 percent (4.2 percent x 44 percent +

5.1 percent x 56 percent). This is the same methodology used to calculate the Home Office/Related Organization Contract Labor cost weight in the 2016-based IPF market basket.

Finally, we proposed to calculate the residual "All Other" cost weight that reflects all remaining costs that are not captured in the seven cost categories listed. See Table 1 for the resulting cost weights for these major cost categories that we obtain from the Medicare cost reports.

TABLE 1: Major Cost Categories as Derived from Medicare Cost Reports

Major Cost Categories	2021-Based IPF Market Basket (Percent)	2016-Based IPF Market Basket (Percent)
Wages and Salaries	50.4	51.2
Employee Benefits	13.7	13.5
Contract Labor	2.8	1.3
Professional Liability Insurance (Malpractice)	1.0	0.9
Pharmaceuticals	3.6	4.7
Home Office/Related Organization Contract Labor	4.7	3.5
Capital	7.2	7.1
All Other	16.7	17.9

As we did for the 2016-based IPF market basket, we proposed to allocate the Contract Labor cost weight to the Wages and Salaries and Employee Benefits cost weights based on their relative proportions under the assumption that contract labor costs are comprised of both wages and salaries, and employee benefits. The Contract Labor allocation proportion for Wages and Salaries is equal to the Wages and Salaries cost weight as a percent of the sum of the Wages and Salaries cost weight and the Employee Benefits cost weight. For the proposed rule, the rounded percentage is 79 percent; therefore, we proposed to allocate 79 percent of the Contract Labor cost weight to the Wages and Salaries cost weight and 21 percent to the Employee Benefits cost weight. This allocation was 81/19 in the 2016-based IPF market basket (84 FR 38430). Table 2 shows the Wages and Salaries and Employee Benefit cost weights after Contract Labor cost weight allocation for both the 2021-based IPF market basket and 2016-based IPF market basket.

TABLE 2: Wages and Salaries and Employee Benefits Cost Weights After Contract Labor Allocation

Major Cost Categories	2021-Based IPF Market Basket	2016-Based IPF Market Basket
Wages and Salaries	52.6	52.2
Employee Benefits	14.3	13.8

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

(3) Derivation of the Detailed Operating Cost Weights

To further divide the "All Other" residual cost weight estimated from the 2021 Medicare cost report data into more detailed cost categories, we proposed to use the 2012 Benchmark Input-Output (I-O) "Use Tables/Before Redefinitions/Purchaser Value" for North American Industry Classification System (NAICS) 622000, Hospitals, published by the Bureau of Economic Analysis (BEA). This data is publicly available at http://www.bea.gov/industry/io_annual.htm. For the 2016-based IPF market basket, we also used the 2012 Benchmark I-O data, the most recent data available at the time (84 FR 38431).

The BEA Benchmark I–O data are scheduled for publication every 5 years with the most recent data available for 2012. The 2012 Benchmark I–O data are derived from the 2012 Economic Census and are the building blocks for BEA's economic accounts. Thus, they represent the most comprehensive and complete set of data on the economic processes or mechanisms by which output is produced and distributed. BEA also produces Annual I–O estimates; however, while based on a similar methodology, these estimates reflect less comprehensive and less detailed data sources and are subject to revision when benchmark data becomes available. Instead of using the less detailed Annual I–O data, we proposed to inflate the 2012 Benchmark I–O data forward to 2021 by applying the annual price changes from the respective price proxies to the appropriate market basket cost categories that are obtained from the 2012 Benchmark I–O data. We repeat this practice for each year. We then proposed to

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¹ http://www.bea.gov/papers/pdf/IOmanual_092906.pdf.

calculate the cost shares that each cost category represents of the inflated 2012 data. These resulting 2021 cost shares are applied to the "All Other" residual cost weight to obtain the detailed cost weights for the 2021-based IPF market basket. For example, the cost for Food: Direct Purchases represents 5.0 percent of the sum of the "All Other" 2012 Benchmark I–O Hospital Expenditures inflated to 2021; therefore, the Food: Direct Purchases cost weight represents 5.0 percent of the proposed 2021-based IPF market basket's "All Other" cost category (16.7 percent), yielding a "final" Food: Direct Purchases cost weight of 0.8 percent in the 2021-based IPF market basket (0.05 * 16.7 percent = 0.8 percent).

Using this methodology, we proposed to derive seventeen detailed IPF market basket cost category weights from the 2021-based IPF market basket residual cost weight (16.7 percent).

These categories are: (1) Electricity and Other Non-Fuel Utilities; (2) Fuel: Oil and Gas;
(3) Food: Direct Purchases; (4) Food: Contract Services; (5) Chemicals; (6) Medical Instruments;
(7) Rubber and Plastics; (8) Paper and Printing Products; (9) Miscellaneous Products; (10)

Professional Fees: Labor-Related; (11) Administrative and Facilities Support Services; (12)

Installation, Maintenance, and Repair Services; (13) All Other Labor-Related Services; (14)

Professional Fees: Nonlabor-Related; (15) Financial Services; (16) Telephone Services; and (17)

All Other Nonlabor-Related Services.

We did not receive any comments on our methodology to use the BEA I-O data to derive the detailed operating cost weights. We are finalizing this methodology as we proposed. We note that we did receive one comment on the derivation of the Professional Fees: Labor-Related cost weight, which we discuss in section IV.A.5 of this final rule.

(4) Derivation of the Detailed Capital Cost Weights

As described in section IV.A.3.a.(2) of this final rule, we proposed a Capital-Related cost weight of 7.2 percent as obtained from the 2021 Medicare cost reports for freestanding and hospital-based IPF providers. We proposed to then separate this total Capital-Related cost weight into more detailed cost categories.

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

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

For hospital-based IPFs, data for these four categories are not reported separately for the hospital-based IPF; therefore, we proposed to derive these proportions using data reported on Worksheet A-7 for the total facility. We are assuming the cost shares for the overall hospital are representative for the hospital-based IPF unit. For example, if depreciation costs make up 60 percent of total capital costs for the entire facility, we believe it is reasonable to assume that the hospital-based IPF would also have a 60 percent proportion because it is a unit contained within the total facility. This is the same methodology used for the 2016-based IPF market basket (84 FR 38431).

To combine each detailed capital cost weight for freestanding and hospital-based IPFs into a single capital cost weight for the 2021-based IPF market basket, we proposed to weight together the shares for each of the categories (Depreciation, Interest, Lease, and Other Capital- Related costs) based on the share of total capital costs each provider type represents of the total capital costs for all IPFs for 2021. Applying this methodology results in proportions of total capital-related costs for Depreciation, Interest, Lease and Other Capital-Related costs that are representative of the universe of IPF providers. This is the same methodology used for the 2016-based IPF market basket (84 FR 38432).

Lease costs are unique in that they are not broken out as a separate cost category in the 2021-based IPF market basket. Rather, we proposed to proportionally distribute these costs

among the cost categories of Depreciation, Interest, and Other Capital-Related costs, reflecting the assumption that the underlying cost structure of leases is similar to that of Capital-Related costs in general. As was done for the 2016-based IPF market basket, we proposed to assume that 10 percent of the lease costs as a proportion of total Capital-Related costs represent overhead and assign those costs to the Other Capital-Related cost category accordingly. We proposed to distribute the remaining lease costs proportionally across the three cost categories (Depreciation, Interest, and Other Capital-Related) based on the proportion that these categories comprise of the sum of the Depreciation, Interest, and Other Capital-Related cost categories (excluding lease expenses). This would result in three primary Capital-Related cost categories in the 2021-based IPF market basket: Depreciation, Interest, and Other Capital-Related costs. This is the same methodology used for the 2016-based IPF market basket (84 FR 38432). The allocation of these lease expenses is shown in Table 3.

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

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

For freestanding IPFs, we proposed to use depreciation data from Worksheet A-7 of the 2021 Medicare cost reports. However, for hospital-based IPFs, we determined that the fixed percentage for the entire facility may not be representative of the hospital-based IPF unit due to the entire facility likely employing more sophisticated movable assets that are not utilized by the hospital-based IPF. Therefore, for hospital-based IPFs, we proposed to calculate a fixed

percentage using: (1) building and fixture capital costs allocated to the hospital-based IPF unit as reported on Worksheet B, part I, column 1, line 40; and (2) building and fixture capital costs for the top five ancillary cost centers utilized by hospital-based IPFs accounting for 82 percent of hospital-based IPF ancillary total costs: Clinic (Worksheet B, part I, column 1, line 90), Drugs Charged to Patients (Worksheet B, part I, column 1, line 73), Emergency (Worksheet B, part I, column 1, line 91), Laboratory (Worksheet B, part I, column 1, line 60) and Radiology - Diagnostic (Worksheet B, part I, column 1, line 54). We proposed to weight these two fixed percentages (inpatient and ancillary) using the proportion that each capital cost type represents of total capital costs in the 2021-based IPF market basket. We proposed to then weight the fixed percentages for hospital-based and freestanding IPFs together using the proportion of total capital costs each provider type represents. For both freestanding and hospital-based IPFs, this is the same methodology used for the 2016-based IPF market basket (84 FR 38432).

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

Table 3 provides the proposed detailed capital cost share composition estimated from the 2021 IPF Medicare cost reports. These detailed capital cost share composition percentages are applied to the total Capital-Related cost weight of 7.2 percent explained in detail in sections IV.A.3.a.(1)(h) and IV.A.3.a.(2) of this final rule.

TABLE 3: Capital Cost Share Composition for the 2021-based IPF Market Basket

	Capital Cost Share Composition before Lease Expense Allocation	Capital Cost Share Composition after Lease Expense Allocation
Depreciation	55%	68%
Building and Fixed Equipment	40%	48%
Movable Equipment	16%	19%
Interest	17%	21%
Government/Nonprofit	11%	13%
For Profit	6%	7%
Lease	20%	-
Other Capital-Related	8%	12%

^{*}Detail may not add to total due to rounding.

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

(5) 2021-based IPF Market Basket Cost Categories and Weights

Table 4 compares the cost categories and weights for the finalized 2021-based IPF market basket compared to the 2016-based IPF market basket.

TABLE 4: 2021-based IPF Market Basket Cost Weights Compared to 2016-based IPF Market Basket Cost Weights

Cost Category	2021-based IPF Market Basket Cost Weight	2016-based IPF Market Basket Cost Weight
Total	100.0	100.0
Compensation	66.9	66.0
Wages and Salaries	52.6	52.2
Employee Benefits	14.3	13.8
Utilities	1.2	1.1
Electricity and Other Non-Fuel Utilities	0.7	0.8
Fuel: Oil and Gas	0.4	0.3
Professional Liability Insurance	1.0	0.9
All Other Products and Services	23.8	24.9
All Other Products	9.1	10.7
Pharmaceuticals	3.6	4.7
Food: Direct Purchases	0.8	0.9
Food: Contract Services	1.0	1.0
Chemicals	0.3	0.3
Medical Instruments	2.0	2.3
Rubber and Plastics	0.3	0.3
Paper and Printing Products	0.5	0.5
Miscellaneous Products	0.6	0.7
All Other Services	14.7	14.2
Labor-Related Services	7.9	7.7
Professional Fees: Labor-Related	4.7	4.4
Administrative and Facilities Support Services	0.6	0.6
Installation, Maintenance, and Repair Services	1.2	1.3

Cost Category	2021-based IPF Market Basket Cost Weight	2016-based IPF Market Basket Cost Weight
All Other: Labor-related Services	1.4	1.4
Nonlabor-Related Services	6.8	6.5
Professional Fees: Nonlabor-Related	4.9	4.5
Financial Services	0.7	0.8
Telephone Services	0.2	0.3
All Other: Nonlabor-Related Services	0.9	1.0
Capital-Related Costs	7.2	7.1
Depreciation	4.9	5.3
Building and Fixed Equipment	3.5	3.7
Movable Equipment	1.4	1.5
Interest Costs	1.5	1.2
Government/Nonprofit	1.0	0.9
For Profit	0.5	0.3
Other Capital-Related Costs	0.8	0.7

^{*}Detail may not add to total due to rounding.

b. Selection of Price Proxies

After developing the cost weights for the 2021-based IPF market basket, we proposed to select the most appropriate wage and price proxies currently available to represent the rate of price change for each expenditure category. For the majority of the cost weights, we base the price proxies on Bureau of Labor Statistics (BLS) data and grouped them into one of the following BLS categories:

- Employment Cost Indexes (ECIs): measure the rate of change in employment wage rates and employer costs for employee benefits per hour worked. These indexes are fixed-weight indexes and strictly measure the change in wage rates and employee benefits per hour. ECIs are superior to Average Hourly Earnings (AHE) as price proxies for input price indexes because they are not affected by shifts in occupation or industry mix, and because they measure pure price change and are available by both occupational group and by industry. The industry ECIs are based on the NAICS and the occupational ECIs are based on the Standard Occupational Classification System (SOC).
- <u>Producer Price Indexes (PPI)</u>: measure the average change over time in the selling prices received by domestic producers for their output. The prices included in the PPI are from the first commercial transaction for many products and some services (https://www.bls.gov/ppi/).

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

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

- Reliability: indicates that the index is based on valid statistical methods and has low sampling variability. Widely accepted statistical methods ensure that the data were collected and aggregated in a way that can be replicated. Low sampling variability is desirable because it indicates that the sample reflects the typical members of the population. (Sampling variability is variation that occurs by chance because only a sample was surveyed rather than the entire population.)
- <u>Timeliness</u>: implies that the proxy is published regularly, preferably at least once a quarter. The market baskets are updated quarterly and, therefore, it is important for the underlying price proxies to be up-to-date, reflecting the most recent data available. We believe that using proxies that are published regularly (at least quarterly, whenever possible) helps to ensure that we are using the most recent data available to update the market basket. We strive to use publications that are disseminated frequently, because we believe that this is an optimal way to stay abreast of the most current data available.
- Availability: means that the proxy is publicly available. We prefer that our proxies are publicly available because this will help ensure that our market basket updates are as transparent to the public as possible. In addition, this enables the public to be able to obtain the price proxy data on a regular basis.
- Relevance: means that the proxy is applicable and representative of the cost category weight to which it is applied. The CPIs, PPIs, and ECIs that we proposed in this regulation meet

these criteria. Therefore, we believe that they continue to be the best measure of price changes for the cost categories to which they would be applied.

Table 13 lists all price proxies that we proposed to use for the 2021-based IPF market basket. A detailed explanation of the price proxies we proposed for each cost category weight is provided below.

- (1) Price Proxies for the Operating Portion of the 2021-Based IPF Market Basket
- (a) Wages and Salaries

There is not a published wage proxy that we believe represents the occupational distribution of workers in IPFs. To measure wage price growth in the 2021-based IPF market basket, we proposed to apply a proxy blend based on six occupational subcategories within the Wages and Salaries category, which would reflect the IPF occupational mix, as was done for the 2016-based IPF market basket.

We proposed to use the National Industry-Specific Occupational Employment and Wage estimates for NAICS 622200, Psychiatric & Substance Abuse Hospitals, published by the BLS Occupational Employment and Wage Statistics (OEWS) program, as the data source for the wage cost shares in the wage proxy blend. We note that in the spring of 2021, the Occupational Employment Statistics (OES) program began using the name Occupational Employment and Wage Statistics (OEWS) to better reflect the range of data available from the program. Data released on or after March 31, 2021 reflect the new program name. We proposed to use May 2021 OEWS data. Detailed information on the methodology for the national industry-specific occupational employment and wage estimates survey can be found at http://www.bls.gov/oes/current/oes_tec.htm. For the 2016-based IPF market basket, we used May 2016 OES data.

Based on the OEWS data, there are six wage subcategories: Management; NonHealth Professional and Technical; Health Professional and Technical; Health Service; NonHealth

Service; and Clerical. Table 5 lists the 2021 occupational assignments for the six wage subcategories; these are the same occupational groups used in the 2016-based IPF market basket.

TABLE 5: 2021 Occupational Assignments for IPF Wage Blend

2021 Occupational Groupings				
Group 1	Management			
11-0000	Management Occupations			
Group 2	NonHealth Professional & Technical			
13-0000	Business and Financial Operations Occupations			
15-0000	Computer and Mathematical Occupations			
19-0000	Life, Physical, and Social Science Occupations			
23-0000	Legal Occupations			
25-0000	Educational Instruction and Library Occupations			
27-0000	Arts, Design, Entertainment, Sports, and Media Occupations			
Group 3	Health Professional & Technical			
29-1021	Dentists, General			
29-1031	Dietitians and Nutritionists			
29-1051	Pharmacists			
29-1071	Physician Assistants			
29-1122	Occupational Therapists			
29-1123	Physical Therapists			
29-1125	Recreational Therapists			
29-1126	Respiratory Therapists			
29-1127	Speech-Language Pathologists			
29-1129	Therapists, All Other			
29-1141	Registered Nurses			
29-1171	Nurse Practitioners			
29-1215	Family Medicine Physicians			
29-1216	General Internal Medicine Physicians			
29-1223	Psychiatrists			
29-1229	Physicians, All Other			
29-1292	Dental Hygienists			
29-1299	Healthcare Diagnosing or Treating Practitioners, All Other			
Group 4	Health Service			
21-0000	Community and Social Service Occupations			
29-2010	Clinical Laboratory Technologists and Technicians			
29-2034	Radiologic Technologists and Technicians			
29-2042	Emergency Medical Technicians			
29-2051	Dietetic Technicians			
29-2052	Pharmacy Technicians			
29-2053	Psychiatric Technicians			
29-2061	Licensed Practical and Licensed Vocational Nurses			
29-2072	Medical Records Specialists			

	2021 Occupational Groupings
29-2099	Health Technologists and Technicians, All Other
29-9021	Health Information Technologists and Medical Registrars
29-9099	Healthcare Practitioners and Technical Workers, All Other
31-0000	Healthcare Support Occupations
Group 5	NonHealth Service
33-0000	Protective Service Occupations
35-0000	Food Preparation and Serving Related Occupations
37-0000	Building and Grounds Cleaning and Maintenance Occupations
39-0000	Personal Care and Service Occupations
41-0000	Sales and Related Occupations
47-0000	Construction and Extraction Occupations
49-0000	Installation, Maintenance, and Repair Occupations
51-0000	Production Occupations
53-0000	Transportation and Material Moving Occupations
Group 6	Clerical
43-0000	Office and Administrative Support Occupations

Total expenditures by occupation (that is, occupational assignment) were calculated by taking the OEWS number of employees multiplied by the OEWS annual average salary. These expenditures were aggregated based on the six groups in Table 5. We next calculated the proportion of each group's expenditures relative to the total expenditures of all six groups. These proportions, listed in Table 6, represent the weights used in the wage proxy blend. We then proposed to use the published wage proxies in Table 6 for each of the six groups (that is, wage subcategories) as we believe these six price proxies are the most technically appropriate indices available to measure the price growth of the Wages and Salaries cost category. These are the same price proxies used in the 2016-based IPF market basket (84 FR 38437).

TABLE 6: 2021-Based IPF Market Basket Wage Proxy Blend

Wage Subcategory	2021-based Wage Blend Weights	2016-based Wage Blend Weights	Price Proxy	BLS Series ID
Healthcare Professional and Technical	36.9%	34.9%	ECI for Wages and Salaries for All Civilian workers in Hospitals	CIU10262200000000I
Healthcare Service	34.4%	36.3%	ECI for Wages and Salaries for All Civilian workers in Healthcare and Social Assistance	CIU10262000000000I
NonHealthcare Service	7.5%	8.9%	ECI for Wages and Salaries for Private Industry workers in	CIU2020000300000I

Wage Subcategory	2021-based Wage Blend Weights	2016-based Wage Blend Weights	Price Proxy	BLS Series ID
			Service Occupations	
NonHealthcare Professional and Technical	7.3%	7.0%	ECI for Wages and Salaries for Private Industry workers in Professional, Scientific, and Technical Services	CIU20254000000000I
Management	ment 7.8% ECI for Wages and Salaries for Private industry workers in Management, Business, and Financial		CIU2020000110000I	
Administrative Support and Clerical	6.1%	6.1%	ECI for Wages and Salaries for Private Industry workers in Office and Administrative Support	CIU2020000220000I
Total	100.0	100.0		

A comparison of the yearly changes from FY 2021 to FY 2024 for the 2021-based IPF wage blend and the 2016-based IPF wage blend is shown in Table 7. The average annual growth rate is the same for both price proxies over 2021-2024.

TABLE 7: Fiscal Year Growth in the 2021-based IPF Wage Proxy Blend and 2016-based IPF Wage Proxy Blend

	2021	2022	2023	2024	Average 2021 - 2024
2021-based IPF Wage Proxy Blend	3.0	5.5	5.4	4.1	4.5
2016-based IPF Wage Proxy Blend	3.1	5.6	5.4	4.1	4.6

^{**}Source: IHS Global Inc., 2nd Quarter 2023 forecast with historical data through 1st Quarter 2023.

(b) Employee Benefits

To measure benefits price growth in the 2021-based IPF market basket, we proposed to apply a benefits proxy blend based on the same six subcategories and the same six blend weights for the wage proxy blend. These subcategories and blend weights are listed in Table 8.

The benefit ECIs, listed in Table 8, are not publicly available. Therefore, an "ECIs for Total Benefits" is calculated using publicly available "ECIs for Total Compensation" for each subcategory and the relative importance of wages within that subcategory's total compensation. This is the same benefits ECI methodology that we implemented in our 2016-based IPF market basket as well as used in the IPPS, SNF, Home Health Agency (HHA), IRF, LTCH, and End-Stage Renal Disease (ESRD) market baskets. We believe that the six price proxies listed in

Table 8 are the most technically appropriate indices to measure the price growth of the Employee Benefits cost category in the 2021-based IPF market basket.

TABLE 8: 2021-Based IPF Market Basket Benefits Proxy Blend and 2016-based IPF Benefit Proxy Blend

Wage Subcategory	2021-based Benefit Blend Weight	2016-based Benefit Blend Weight	Price Proxy
Healthcare Professional and Technical	36.9%	34.9%	ECI for Total Benefits for All Civilian workers in Hospitals
Healthcare Service	34.4%	36.3%	ECI for Total Benefits for All Civilian workers in Healthcare and Social Assistance
NonHealthcare Service	7.5%	8.9%	ECI for Total Benefits for Private Industry workers in Service Occupations
NonHealthcare Professional and Technical	7.3%	7.0%	ECI for Total Benefits for Private Industry workers in Professional, Scientific, and Technical Services
Management	7.8%	6.8%	ECI for Total Benefits for Private industry workers in Management, Business, and Financial
Administrative Support and Clerical	6.1%	6.1%	ECI for Total Benefits for Private Industry workers in Office and Administrative Support
Total	100.0	100.0	

A comparison of the yearly changes from FY 2021 to FY 2024 for the 2021-based IPF benefit proxy blend and the 2016-based IPF benefit proxy is shown in Table 9. The average annual growth rate is the same for both price proxies over 2021 through 2024.

TABLE 9: Fiscal Year Growth in the 2021-based IPF Benefit Proxy Blend and 2016-based IPF Benefit Proxy Blend

	2021	2022	2023	2024	Average 2021- 2024
2021-based IPF Benefit Proxy Blend	2.4	4.4	4.5	3.7	3.8
2016-based IPF Benefit Proxy Blend	2.4	4.4	4.5	3.7	3.8

Source: IHS Global Inc., 2nd Quarter 2023 forecast with historical data through 1st Quarter 2023.

(c) Electricity and Other Non-Fuel Utilities

We proposed to use the PPI Commodity Index for Commercial Electric Power (BLS series code WPU0542) to measure the price growth of this cost category (which we proposed to rename from Electricity to Electricity and Other Non-Fuel Utilities). This is the same price proxy used in the 2016-based IPF market basket (84 FR 38438).

(d) Fuel: Oil and Gas

Similar to the 2016-based IPF market basket, for the 2021-based IPF market basket, we proposed to use a blend of the PPI for Petroleum Refineries and the PPI Commodity for Natural Gas. Our analysis of the Bureau of Economic Analysis' 2012 Benchmark Input-Output data (use table before redefinitions, purchaser's value for NAICS 622000 [Hospitals]), shows that Petroleum Refineries expenses account for approximately 90 percent and Natural Gas expenses account for approximately 10 percent of Hospitals' (NAICS 622000) total Fuel: Oil and Gas expenses. Therefore, we proposed to use a blend of 90 percent of the PPI for Petroleum Refineries (BLS series code PCU324110324110) and 10 percent of the PPI Commodity Index for Natural Gas (BLS series code WPU0531) as the price proxy for this cost category. This is the same blend that was used for the 2016-based IPF market basket (84 FR 38438).

(e) Professional Liability Insurance

We proposed to use the CMS Hospital Professional Liability Index to measure changes in PLI premiums. To generate this index, we collect commercial insurance premiums for a fixed level of coverage while holding non-price factors constant (such as a change in the level of coverage). This is the same proxy used in the 2016-based IPF market basket (84 FR 38438).

(f) Pharmaceuticals

We proposed to use the PPI for Pharmaceuticals for Human Use, Prescription (BLS series code WPUSI07003) to measure the price growth of this cost category. This is the same proxy used in the 2016-based IPF market basket (84 FR 38438).

(g) Food: Direct Purchases

We proposed to use the PPI for Processed Foods and Feeds (BLS series code WPU02) to measure the price growth of this cost category. This is the same proxy used in the 2016-based IPF market basket (84 FR 38438).

(h) Food: Contract Purchases

We proposed to use the CPI for Food Away From Home (BLS series code CUUR0000SEFV) to measure the price growth of this cost category. This is the same proxy used in the 2016-based IPF market basket (84 FR 38438).

(i) Chemicals

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

Table 10 shows the weights for each of the four PPIs used to create the blended Chemical proxy for the 2021-based IPF market basket. This is the same blend that was used for the 2016-based IPF market basket (84 FR 38439).

TABLE 10: Blended Chemical PPI Weights

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

(i) Medical Instruments

We proposed to use a blended price proxy for the Medical Instruments category, as shown in Table 11. The 2012 Benchmark I–O data shows the majority of medical instruments and supply costs are for NAICS 339112— Surgical and medical instrument manufacturing costs (approximately 56 percent) and NAICS 339113—Surgical appliance and supplies manufacturing costs (approximately 43 percent). Therefore, we proposed to use a blend of these two price proxies. To proxy the price changes associated with NAICS 339112, we proposed to use the PPI

for Surgical and medical instruments (BLS series code WPU1562). This is the same price proxy we used in the 2016-based IPF market basket. To proxy the price changes associated with NAICS 339113, we proposed to use a 50/50 blend of the PPI for Medical and surgical appliances and supplies (BLS series code WPU1563) and the PPI for Miscellaneous products, Personal safety equipment and clothing (BLS series code WPU1571). We proposed to include the latter price proxy as it will reflect personal protective equipment including but not limited to face shields and protective clothing. The 2012 Benchmark I–O data does not provide specific expenses for these products; however, we recognize that this category reflects costs faced by IPFs.

TABLE 11: Blended Medical Instruments PPI Weights

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

(k) Rubber and Plastics

We proposed to use the PPI for Rubber and Plastic Products (BLS series code WPU07) to measure price growth of this cost category. This is the same proxy used in the 2016-based IPF market basket (84 FR 38439).

(1) Paper and Printing Products

We proposed to use the PPI for Converted Paper and Paperboard Products (BLS series code WPU0915) to measure the price growth of this cost category. This is the same proxy used in the 2016-based IPF market basket (84 FR 38439).

(m) Miscellaneous Products

We proposed to use the PPI for Finished Goods Less Food and Energy (BLS series code WPUFD4131) to measure the price growth of this cost category. This is the same proxy used in the 2016-based IPF market basket (84 FR 38439).

(n) Professional Fees: Labor-Related

We proposed to use the ECI for Total Compensation for Private Industry workers in Professional and Related (BLS series code CIU2010000120000I) to measure the price growth of this category. This is the same proxy used in the 2016-based IPF market basket (84 FR 38439).

(o) Administrative and Facilities Support Services

We proposed to use the ECI for Total Compensation for Private Industry workers in Office and Administrative Support (BLS series code CIU2010000220000I) to measure the price growth of this category. This is the same proxy used in the 2016-based IPF market basket (84 FR 38439).

(p) Installation, Maintenance, and Repair Services

We proposed to use the ECI for Total Compensation for Civilian workers in Installation, Maintenance, and Repair (BLS series code CIU1010000430000I) to measure the price growth of this cost category. This is the same proxy used in the 2016-based IPF market basket (84 FR 38439).

(q) All Other: Labor-Related Services

We proposed to use the ECI for Total Compensation for Private Industry workers in Service Occupations (BLS series code CIU2010000300000I) to measure the price growth of this cost category. This is the same proxy used in the 2016-based IPF market basket (84 FR 38439).

(r) Professional Fees: Nonlabor-Related

We proposed to use the ECI for Total Compensation for Private Industry workers in Professional and Related (BLS series code CIU2010000120000I) to measure the price growth of this category. This is the same proxy used in the 2016-based IPF market basket (84 FR 38439).

(s) Financial Services

We proposed to use the ECI for Total Compensation for Private Industry workers in Financial Activities (BLS series code CIU201520A000000I) to measure the price growth of this cost category. This is the same proxy used in the 2016-based IPF market basket (84 FR 38439).

(t) Telephone Services

We proposed to use the CPI for Telephone Services (BLS series code CUUR0000SEED) to measure the price growth of this cost category. This is the same proxy used in the 2016-based IPF market basket (84 FR 38439).

(u) All Other: Nonlabor-Related Services

We proposed to use the CPI for All Items Less Food and Energy (BLS series code CUUR0000SA0L1E) to measure the price growth of this cost category. This is the same proxy used in the 2016-based IPF market basket (84 FR 38439).

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

Table 13 lists all price proxies that we are finalizing for the 2021-based IPF market basket.

- (2) Price Proxies for the Capital Portion of the 2021-Based IPF Market Basket
- (a) Capital Price Proxies Prior to Vintage Weighting

We proposed to use the same price proxies for the capital-related cost categories in the 2021-based IPF market basket as were used in the 2016-based IPF market basket, which are provided in Table 13 and described below. Specifically, we proposed to proxy:

- Depreciation: Building and Fixed Equipment cost category by BEA's Chained Price
 Index for Nonresidential Construction for Hospitals and Special Care Facilities (BEA
 Table 5.4.4. Price Indexes for Private Fixed Investment in Structures by Type).
- Depreciation: Movable Equipment cost category by the PPI for Machinery and Equipment (BLS series code WPU11).
- Nonprofit Interest cost category by the average yield on domestic municipal bonds (Bond Buyer 20-bond index).
 - For-profit Interest cost category by the iBoxx AAA Corporate Bond Yield index
- Other Capital-Related cost category by the CPI-U for Rent of Primary Residence (BLS series code CUUS0000SEHA).

We believe these are the most appropriate proxies for IPF capital-related costs that meet our selection criteria of relevance, timeliness, availability, and reliability. We also proposed to vintage weight the capital price proxies for Depreciation and Interest to capture the long-term consumption of capital. This vintage weighting method is similar to the method used for the 2016-based IPF market basket (84 FR 38440) and is described below.

(b) Vintage Weights for Price Proxies

Because capital is acquired and paid for over time, capital-related expenses in any given year are determined by both past and present purchases of physical and financial capital. The vintage-weighted capital-related portion of the 2021-based IPF market basket is intended to capture the long-term consumption of capital, using vintage weights for depreciation (physical capital) and interest (financial capital). These vintage weights reflect the proportion of capital-related purchases attributable to each year of the expected life of building and fixed equipment, movable equipment, and interest. We proposed to use vintage weights to compute vintage-weighted price changes associated with depreciation and interest expenses.

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

The methodology used to calculate the vintage weights for the 2021-based IPF market basket is the same as that used for the 2016-based IPF market basket (84 FR 38439 through 38441) with the only difference being the inclusion of more recent data.

To calculate the vintage weights for depreciation and interest expenses, we first need a time series of capital-related purchases for building and fixed equipment and movable equipment. We found no single source that provides an appropriate time series of capital-related purchases by hospitals for all of the above components of capital purchases. The early Medicare cost reports did not have sufficient capital-related data to meet this need. Data we obtained from the American Hospital Association (AHA) do not include annual capital-related purchases. However, we are able to obtain data on total expenses back to 1963 from the AHA. Consequently, we proposed to use data from the AHA Panel Survey and the AHA Annual Survey to obtain a time series of total expenses for hospitals. We then proposed to use data from the AHA Panel Survey supplemented with the ratio of depreciation to total hospital expenses obtained from the Medicare cost reports to derive a trend of annual depreciation expenses for 1963 through 2020, which is the latest year of AHA data available. We proposed to separate these depreciation expenses into annual amounts of building and fixed equipment depreciation and movable equipment depreciation as determined earlier. From these annual depreciation amounts, we derive annual end-of-year book values for building and fixed equipment and movable equipment using the expected life for each type of asset category. While data is not available that is specific to IPFs, we believe this information for all hospitals serves as a reasonable alternative for the pattern of depreciation for IPFs.

To continue to calculate the vintage weights for depreciation and interest expenses, we also need to account for the expected lives for Building and Fixed Equipment, Movable Equipment, and Interest for the 2021-based IPF market basket. We proposed to calculate the expected lives using Medicare cost report data from freestanding and hospital-based IPFs. The expected life of any asset can be determined by dividing the value of the asset (excluding fully depreciated assets) by its current year depreciation amount. This calculation yields the estimated expected life of an asset if the rates of depreciation were to continue at current year levels, assuming straight-line depreciation. We proposed to determine the expected life of building and

fixed equipment separately for hospital-based IPFs and freestanding IPFs, and then weight these expected lives using the percent of total capital costs each provider type represents. We proposed to apply a similar method for movable equipment. Using these proposed methods, we determined the average expected life of building and fixed equipment to be equal to 25 years, and the average expected life of movable equipment to be equal to 12 years. For the expected life of interest, we believe vintage weights for interest should represent the average expected life of building and fixed equipment because, based on previous research described in the FY 1997 IPPS final rule (61 FR 46198), the expected life of hospital debt instruments and the expected life of buildings and fixed equipment are similar. We note that for the 2016-based IPF market basket, the expected life of building and fixed equipment is 22 years, and the expected life of movable equipment is 11 years (84 FR 38441).

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

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

The vintage weights for each asset type are deemed to represent the average purchase pattern of the asset over its expected life (in the case of building and fixed equipment and interest, 25 years, and in the case of movable equipment, 12 years). For each asset type, we used the time series of annual capital-related purchase amounts available from 2020 back to 1964. These data allow us to derive thirty-three 25-year periods of capital-related purchases for building and fixed equipment and interest, and forty-six 12-year periods of capital-related purchases for movable equipment. For each 25-year period for building and fixed equipment and interest, or 12-year period for movable equipment, we calculate annual vintage weights by dividing the capital-related purchase amount in any given year by the total amount of purchases over the entire 25-year or 12-year period. This calculation is done for each year in the 25-year or 12-year period and for each of the periods for which we have data. We then calculate the average vintage weight for a given year of the expected life by taking the average of these vintage weights across the multiple periods of data. The vintage weights for the capital-related portion of the 2021-based IPF market basket and the 2016-based IPF market basket are presented in Table 12.

TABLE 12: 2021-Based IPF Market Basket and 2016-based IPF Market Basket Vintage Weights for Capital-Related Price Proxies

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

	Building and Fixed Equipment		Movable Equipment		Interest	
Year*	2021-based 25 years	2016-based 22 years	2021 based 12 years	2016-based 11 years	2021 based 25 years	2016 based 22 years
19	0.045	0.053			0.054	0.068
20	0.045	0.053			0.055	0.069
21	0.045	0.052			0.057	0.070
22	0.045	0.052			0.058	0.072
23	0.045				0.060	
24	0.045				0.061	
25	0.044				0.062	
Total	1.000	1.000	1.000	1.000	1.000	1.000

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

The process of creating vintage-weighted price proxies requires applying the vintage weights to the price proxy index where the last applied vintage weight in Table 12 is applied to the most recent data point. We have provided on the CMS website an example of how the vintage weighting price proxies are calculated, using example vintage weights and example price indices. The example can be found at http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html in the zip file titled "Weight Calculations as described in the IPPS FY 2010 Proposed Rule."

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

(3) Summary of Price Proxies of the 2021-Based IPF Market Basket

Table 13 shows both the operating and capital price proxies that we are finalizing for the 2021-based IPF market basket.

TABLE 13: Price Proxies for the 2021-based IPF Market Basket

Cost Description	Price Proxies	Weight
Total		100.0
Compensation		66.9
Wages and Salaries	Blended Wages and Salaries Price Proxy	52.6
Employee Benefits	Blended Employee Benefits Price Proxy	14.3
Utilities		1.2
Electricity and Other Non-Fuel		
Utilities	PPI for Commercial Electric Power	0.7
Fuel: Oil and Gas	Blend of PPIs*	0.4
Professional Liability Insurance		1.0
	CMS Hospital Professional Liability Insurance Premium	
Malpractice	Index	1.0
All Other Products and Services		23.8
All Other Products		9.1

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

Cost Description	Price Proxies	Weight
Pharmaceuticals	PPI for Pharmaceuticals for Human Use, Prescription	3.6
Food: Direct Purchases	PPI for Processed Foods and Feeds	0.8
Food: Contract Services	CPI-U for Food Away From Home	1.0
Chemicals	Blend of PPIs*	0.3
Medical Instruments	Blend of PPIs*	2.0
Rubber and Plastics	PPI for Rubber and Plastic Products	0.3
Paper and Printing Products	PPI for Converted Paper and Paperboard Products	0.5
Miscellaneous Products	PPI for Finished Goods Less Food and Energy	0.6
All Other Services		14.7
Labor-Related Services		7.9
	ECI for Total compensation for Private industry workers in	
Professional Fees: Labor-Related	Professional and related	4.7
Administrative and Facilities	ECI for Total compensation for Private industry workers in	
Support Services	Office and administrative support	0.6
Installation, Maintenance & Repair	ECI for Total compensation for Civilian workers in	
Services	Installation, maintenance, and repair	1.2
	ECI for Total compensation for Private industry workers in	
All Other: Labor-related Services	Service occupations	1.4
Nonlabor-Related Services		6.8
Professional Fees: Nonlabor-	ECI for Total compensation for Private industry workers in	
Related	Professional and related	4.9
	ECI for Total compensation for Private industry workers in	
Financial Services	Financial activities	0.7
Telephone Services	CPI-U for Telephone Services	0.2
All Other: Nonlabor-Related		
Services	CPI-U for All Items Less Food and Energy	0.9
Capital-Related Costs		7.2
Depreciation		4.9
	BEA chained price index for nonresidential construction for	
	hospitals and special care facilities - vintage weighted (25	
Building and Fixed Equipment	years)	3.5
	PPI for machinery and equipment - vintage weighted (12	l
Movable Equipment	years)	1.4
Interest Costs		1.5
	Average yield on domestic municipal bonds (Bond Buyer 20	1.0
Government/Nonprofit	bonds) - vintage weighted (25 years)	1.0
F . D . C.	Average Yield on iBoxx AAA Corporate Bonds – vintage	0.5
For Profit	weighted (25 years)	0.5
Other Capital-Related Costs	CPI-U for Rent of primary residence	0.8

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

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

4. FY 2024 Market Basket Update and Productivity Adjustment

a. FY 2024 Market Basket Update

For FY 2024 (that is, beginning October 1, 2023 and ending September 30, 2024), we proposed to use an estimate of the proposed 2021-based IPF market basket increase factor to update the IPF PPS base payment rate. Consistent with historical practice, we estimate the

^{*}Details on the series and weight for each price proxy used in the PPI blends is provided in section IV.A.3.b.

market basket update for the IPF PPS based on IHS Global Inc.'s (IGI) forecast. IGI is a nationally recognized economic and financial forecasting firm with which CMS contracts to forecast the components of the market baskets.

Using IGI's fourth quarter 2022 forecast with historical data through the third quarter of 2022, the projected proposed 2021-based IPF market basket increase factor for FY 2024 was 3.2 percent. We also proposed that if more recent data were subsequently available (for example, a more recent estimate of the market basket increase factor) we would use such data, to determine the FY 2024 update in the final rule.

Based on IGI's second quarter 2023 forecast with historical data through the first quarter of 2023, the 2021-based IPF market basket increase percentage for FY 2024 is 3.5 percent. For comparison, the current 2016-based IPF market basket is also projected to increase by 3.5 percent in FY 2024 based on IGI's second quarter 2023 forecast. Table 14 compares the 2021-based IPF market basket and the 2016-based IPF market basket percent changes. On average, the two indexes produce similar updates to one another, with the 4-year average historical growth rates (for FY 2019-FY 2022) of the 2021-based IPF market basket being equal to 3.2 percent compared to the 2016-based IPF market basket with 3.2 percent.

TABLE 14: 2021-Based IPF Market basket and 2016-Based IPF Market Basket Percent Changes, FY 2019 through FY 2026

Fiscal Year (FY)	2021-Based IPF Market Basket Index Percent Change	2016-Based IPF Market Basket Index Percent Change
Historical data:		
FY 2019	2.4	2.5
FY 2020	2.1	2.2
FY 2021	2.8	2.9
FY 2022	5.3	5.3
Average 2019-2022	3.2	3.2
Forecast:		
FY 2023	4.8	4.8
FY 2024	3.5	3.5
FY 2025	3.0	3.0
FY 2026	2.9	2.9
Average 2023-2026	3.6	3.6

Note: These market basket percent changes do not include any further adjustments as may be statutorily required. Source: IHS Global Inc. 2nd quarter 2023 forecast.

b. Productivity Adjustment

Section 1886(s)(2)(A)(i) of the Act requires the application of the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act to the IPF PPS for the RY beginning in 2012 (that is, a RY that coincides with a FY) and each subsequent RY. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (as projected by the Secretary for the 10-year period ending with the applicable FY, year, cost reporting period, or other annual period) (the "productivity adjustment"). The United States Department of Labor's Bureau of Labor Statistics (BLS) publishes the official measures of productivity for the United States economy. We note that previously the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act, was published by BLS as private nonfarm business multifactor productivity. Beginning with the November 18, 2021 release of productivity data, BLS replaced the term multifactor productivity (MFP) with total factor productivity (TFP). BLS noted that this is a change in terminology only and will not affect the data or methodology. As a result of the BLS name change, the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act is now published by BLS as private nonfarm business total factor productivity. However, as mentioned above, the data and methods are unchanged. We refer readers to www.bls.gov for the BLS historical published TFP data. A complete description of IGI's TFP projection methodology is available on the CMS website at https://www.cms.gov/research-statistics-dataand-systems/statistics-trends-and-reports/medicareprogramratesstats/marketbasketresearch. In addition, in the FY 2022 IPF PPS final rule (86 FR 42611), we noted that effective with FY 2022

and forward, CMS changed the name of this adjustment to refer to it as the productivity adjustment rather than the MFP adjustment.

Using IGI's fourth quarter 2022 forecast, the 10-year moving average growth of TFP for FY 2024 was projected to be 0.2 percent. Thus, in accordance with section 1886(s)(2)(A)(i) of the Act, we proposed to calculate the FY 2024 market basket update, which is used to determine the applicable percentage increase for the IPF payments, using IGI's fourth quarter 2022 forecast of the proposed 2021-based IPF market basket. We proposed to then reduce this percentage increase by the estimated productivity adjustment for FY 2024 of 0.2 percentage point (the 10-year moving average growth of TFP for the period ending FY 2024 based on IGI's fourth quarter 2022 forecast). Therefore, the proposed FY 2024 IPF update was equal to 3.0 percent (3.2 percent market basket update reduced by the 0.2 percentage point productivity adjustment). Furthermore, we proposed that if more recent data became available after the publication of the proposed rule and before the publication of the final rule (for example, a more recent estimate of the productivity adjustment), we would use such data, if appropriate, to determine the FY 2024 productivity adjustment in the final rule.

Using IGI's second quarter 2023 forecast, the 10-year moving average growth of TFP for FY 2024 is projected to be 0.2 percent. Thus, in accordance with section 1886(s)(2)(A)(i) of the Act, we calculate the FY 2024 market basket update, which is used to determine the applicable percentage increase for the IPF payments, using IGI's second quarter 2023 forecast of the 2021-based IPF market basket. We then reduce this percentage increase by the estimated productivity adjustment for FY 2024 of 0.2 percentage point (the 10-year moving average growth of TFP for the period ending FY 2024 based on IGI's second quarter 2023 forecast). Therefore, the FY 2024 IPF update is equal to 3.3 percent (3.5 percent market basket update reduced by the 0.2 percentage point productivity adjustment).

We invited public comment on our proposals for the FY 2024 market basket update and productivity adjustment. The following is a summary of the public comments received on the proposed FY 2024 market basket update and productivity adjustment.

Comment: Several commenters expressed concern about the proposed 2021-based IPF market basket increase factor for FY 2024 of 3.2 percent. They stated that hospitals throughout the country face enormous cost pressures, with labor costs (due to increased demand and workforce shortages) leading to this dramatic increase in overall cost pressure. They also noted the significant cost increases for drugs, medical supplies, and personal protective equipment since before the PHE. The commenters stated that the cumulative effect of this inflationary pressure coupled with the proposed low Medicare payment increases for FY 2024 will continue to have negative effects on IPF operating margins. They cited that the Medicare Payment Advisory Commission determined that Medicare has failed to cover the cost of caring for patients in hospital-based and freestanding nonprofit IPFs since at least 2016.

The commenters also noted that CMS proposed that if more recent data became available after the publication of the proposed rule and before the publication of the final rule that CMS would use such data to determine the FY 2024 update in the final rule. They recommended CMS use more recent data and implement a payment rate for FY 2024 that more accurately reflects current costs, rather than relying on data that preceded the extraordinary inflation they are experiencing. Some commenters suggested CMS use other methods to determine the market basket update, such as the average growth rate in allowable Medicare costs per risk-adjusted discharge for IPFs between FY 2019 and FY 2021 to calculate the FY 2024 final rule market basket update. They stated that if CMS fails to provide an adequate market basket update, they are deeply concerned inadequate payments will result in reduced access to inpatient psychiatric services for Medicare beneficiaries.

Response: We appreciate the commenters' concerns regarding inflationary pressure facing IPFs and the proposed FY 2024 market basket update. As stated in Section IV.A.2 in this

final rule, the IPF market basket (including the proposed 2021-based and other CMS market baskets) is a fixed-weight, Laspeyres-type index that measures price changes over time. Since the inception of the IPF PPS, the IPF payment rates (with the exception of statutorily mandated updates) have been updated by a projection of a market basket percentage increase, which is designed to measure price inflation for IPF providers and does not reflect increases in costs associated with changes in the volume or intensity of input goods and services (such as the quantity of labor used). In this way, the IPF market basket is consistent in concept and methodology with market baskets used for other CMS PPS updates, including IPPS, SNF, and HHA. The longstanding IPF market basket methodology establishes a market basket that appropriately reflects expectations, based on the latest available data, of price inflation for IPF providers for FY 2024. It would be inappropriate for the IPF market basket to reflect the method proposed by the commenter where the update would be based on increases in Medicare allowable costs per risk-adjusted discharge from a past period, since that measure would incorporate changes in costs that are not solely reflective of price inflation that is intended to be captured by the market basket update in the IPF PPS.

The projection of the 2021-based IPF market basket is based on the most recent forecast from IHS Global Inc. – a nationally recognized economic and financial forecasting firm with which CMS contracts to forecast the price proxies of the market baskets. For this final rule, based on the more recent IGI second quarter 2023 forecast with historical data through the first quarter of 2023, the projected 2021-based IPF market basket increase factor for FY 2024 is 3.5 percent, which is 0.3 percentage point higher than the projected FY 2024 market basket increase factor in the proposed rule, and reflects an increase in compensation prices of 4.0 percent. We note that the 10-year historical average (2013-2022) growth rate of the 2021-

based IPF market basket is 2.4 percent with an average growth rate in compensation prices of 2.5 percent.

Therefore, consistent with our historical practice of estimating market basket increases based on the best available data, we are finalizing a market basket increase percentage of 3.5 percent for FY 2024.

Comment: Several commenters expressed concern about the application of the productivity adjustment, stating that the PHE has had unimaginable impacts on hospital productivity. They state that even before the PHE, OACT indicated that hospital productivity will be less than the general economy-wide productivity, which is the measure that is required by law to be used to derive the productivity adjustment. Given that CMS is required by statute to implement a productivity adjustment to the market basket update, commenters asked the agency to work with the Congress to permanently eliminate this unjustified reduction to hospital payments. Further, they asked CMS to use its authority under section 1886(s) of the Act to remove the productivity adjustment for any fiscal year that was covered under PHE determination (that is, 2020 (0.4 percent), 2021 (0.0 percent), 2022 (0.7 percent), and 2023 (0.3 percent)) from the calculation of the market basket update for FY 2024 and any year thereafter.

Response: Section 1886(s)(2)(A)(i) of the Act requires the application of the productivity adjustment described in section 1886(b)(3)(xi)(II) of the Act. As required by statute, the FY 2024 productivity adjustment is derived based on the 10-year moving average growth in economy-wide productivity for the period ending FY 2024. We recognize the concerns of the commenters regarding the appropriateness of the productivity adjustment; however, we are required pursuant to section 1886(s)(2)(A)(i) of the Act to apply the specific productivity adjustment described here. Because that provision specifically requires application of the

productivity adjustment, we do not believe section 1886(s) of the Act permits the Secretary discretion to remove it from the calculation of the market basket update.

Comment: Commenters noted that CMS has underestimated the IPF market basket increase over the last several years. They encouraged CMS to utilize its exceptions and adjustments authority to apply a one-time adjustment to course correct for its significantly lower estimates of costs for FYs 2021 through 2023. They stated that failing to correct CMS's gross underestimation of the payment updates during the pandemic will further perpetuate inaccuracies in the payment rate moving forward, resulting in a permanent cut to IPF payments.

Response: The IPF market basket updates are set prospectively, which means that the update relies on a mix of both historical data for part of the period for which the update is calculated and forecasted data for the remainder. For instance, the FY 2024 market basket update in this final rule reflects historical data through the first quarter of CY 2023 and forecasted data through the third quarter of CY 2024. While there is no precedent to adjust for market basket forecast error in the IPF payment update, a forecast error can be calculated by comparing the actual market basket increase for a given year less the forecasted market basket increase. Due to the uncertainty regarding future price trends, forecast errors can be both positive and negative. Regarding the comment that the IPF market basket increase over the last several years has been underestimated, we disagree with this assertion, as from 2012 through 2020, the forecasted market basket updates for each payment year for IPFs were higher than the actual market basket updates. For this final rule, we have incorporated more recent historical data and forecasts to capture the price and wage pressures facing IPFs. We believe IGI's second quarter 2023 forecast of the FY 2024 percentage increase in the 2021-based IPF market basket is the best available projection of inflation to determine the applicable percentage increase for the IPF payments in FY 2024.

<u>Final Decision</u>: After consideration of public comments, we are finalizing a FY 2024 IPF payment rate update of 3.3 percent (3.5 percent IPF market basket percentage increase reduced by the 0.2 percentage point productivity adjustment).

5. Labor-Related Share for FY 2024

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 applies 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.

We proposed to include in the labor-related share the sum of the relative importance of the following cost categories: Wages and Salaries, Employee Benefits, Professional Fees: Labor-Related, Administrative and Facilities Support Services, Installation, Maintenance, and Repair Services, All Other: Labor-Related Services, and a portion of the Capital-Related cost weight from the 2021-based IPF market basket. These are the same categories as the 2016-based IPF market basket.

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

As was done in the 2016-based IPF market basket, we proposed to determine the proportion of legal, accounting and auditing, engineering, and management consulting services that meet our definition of labor-related services based on a survey of hospitals conducted by CMS in 2008. We notified the public of our intent to conduct this survey on December 9, 2005, (70 FR 73250) and did not receive any public comments in response to the notice (71 FR 8588). A discussion of the composition of the survey and post-stratification can be found in the FY 2010 IPPS/LTCH PPS final rule (74 FR 43850 through 43856). Based on the weighted results of the survey, we determined that hospitals purchase, on average, the following portions of contracted professional services outside of their local labor market:

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

We proposed to apply each of these percentages to the respective 2012 Benchmark I–O cost category underlying the professional fees cost category to determine the Professional Fees: Nonlabor-Related costs. The Professional Fees: Labor-Related costs were determined to be the difference between the total costs for each Benchmark I–O category and the Professional Fees: Nonlabor-Related costs. This is the same methodology that we used to separate the 2016-based IPF market basket professional fees category into Professional Fees: Labor-Related and Professional Fees: Nonlabor-Related cost categories (84 FR 38445).

Effective for transmittal 18, (https://www.cms.gov/Regulations-and-
Guidance/Guidance/Transmittals/Transmittals/r18p240i) the hospital Medicare cost report
(CMS Form 2552-10, OMB No. 0938-0050) is collecting information on whether a hospital
purchased professional services (for example, legal, accounting, tax preparation, bookkeeping,
payroll, advertising, and/or management/consulting services) from an unrelated organization and
if the majority of these expenses were purchased from unrelated organizations located outside of

the main hospital's local area labor market. We encourage all providers to provide this information so we can potentially use these data in future rulemaking to determine the labor-related share.

In the 2021-based IPF market basket, nonmedical professional fees that were subject to allocation based on these survey results represent 3.3 percent of total costs (and are limited to those fees related to Accounting & Auditing, Legal, Engineering, and Management Consulting services). Based on our survey results, we proposed to apportion 2.1 percentage points of the 3.3 percentage point figure into the Professional Fees: Labor-Related share cost category and designate the remaining 1.2 percentage point into the Professional Fees: Nonlabor-Related cost category.

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

Similar to the 2016-based IPF market basket, we proposed for the 2021-based IPF market basket to use the Medicare cost reports for both freestanding IPF providers and hospital-based IPF providers to determine the home office labor-related percentages. The Medicare cost report requires a hospital to report information regarding its home office provider. Using information on the Medicare cost report, we then compare the location of the IPF with the location of the IPF's home office. We proposed to classify an IPF with a home office located in its respective labor market if the IPF and its home office are located in the same metropolitan statistical area (MSA). We then determine the proportion of the Home Office/Related Organization Contract Labor cost weight that should be allocated to the labor-related share based on the percent of total

Medicare allowable costs for those IPFs that had home offices located in their respective local labor markets of total Medicare allowable costs for IPFs with a home office. We determined an IPF's and its home office's MSA using their zip code information from the Medicare cost report. Using this methodology, we determined that 46 percent of IPFs' Medicare allowable costs were for home offices located in their respective local labor markets. Therefore, we are allocating 46 percent of the Home Office/Related Organization Contract Labor cost weight (2.1 percentage points = 4.7 percent times 46 percent) to the Professional Fees: Labor-Related cost weight and 54 percent of the Home Office/Related Organization Contract Labor cost weight to the Professional Fees: Nonlabor-Related cost weight (2.5 percentage points = 4.7 percent times 54 percent). The same methodology was used for the 2016-based IPF market basket (84 FR 38445).

In summary, we apportioned 2.1 percentage points of the non-medical professional fees and 2.1 percentage points of the Home Office/Related Organization Contract Labor cost weight into the Professional Fees: Labor-Related cost category. This amount was added to the portion of professional fees that we already identified as labor-related using the I-O data such as contracted advertising and marketing costs (approximately 0.5 percentage point of total costs), resulting in a Professional Fees: Labor-Related cost weight of 4.7 percent.

Comment: One commenter appreciated CMS's proposal to increase the labor-related share based on data that better reflects increased labor costs as a percentage of an IPF's overall cost structure. However, they disagreed with CMS's proposal to exclude from the labor-related share the proportion of non-medical professional services fees presumed to have been purchased outside of the hospital's labor market. The commenter disagreed with CMS's assertion/assumption that services purchased from national firms are not affected by the local labor market. The commenter stated that when hospitals seek professional services, the services they are seeking (such as, accounting, engineering, or management consulting) typically are not so unique that they could only be provided by regional or national firms. The commenter stated

that CMS's own survey data support this conclusion, as approximately 64 percent of these services are sourced from firms in the local market. The commenter stated that costs of services purchased from firms outside the hospital's labor market should be included with the labor-related share of costs.

The commenter requested that CMS provide evidence that pricing for professional services provided by regional and national firms to hospitals is offered in a national market that is not subject to geographic cost variation. The commenter urged that, unless the agency can produce strong evidence that prices for professional services provided by firms outside of a hospital's local labor market are homogenous, CMS restore the 1.2 percentage points it proposed to reclassify to Professional Services: Nonlabor-Related to the Professional Services: Labor-Related category.

Response: We respectfully disagree with the commenter and continue to believe it is appropriate that a proportion of Accounting & Auditing, Legal, Engineering, and Management Consulting services costs purchased by hospitals should be excluded from the labor-related share.

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

As acknowledged by the commenter and confirmed by the survey of hospitals conducted by CMS in 2008 (as stated above), professional services can be purchased from local firms as well as national and regional professional services firms. It is not necessarily the case, as

asserted by the commenter, that these national and regional firms have fees that match those in the local labor market even though providers have the option to utilize those firms. That is, fees for services purchased from firms outside the local labor market may differ from those that would be purchased in the local labor market for any number of reasons (including but not limited to, the skill level of the contracted personnel, higher capital costs, etc.). As noted earlier in this section of this final rule, the definition for the labor-related share requires the services to be purchased in the local labor market; therefore, CMS's allocation of approximately 64 percent of the Professional Fees cost weight allocated to the Professional Fees: Labor-Related cost weight based on the 2008 survey results² is consistent with the commenter's assertion that not all Professional Fees services are purchased in the local labor market. We believe it is reasonable to conclude that costs of those professional services purchased directly within the local labor market are directly related to local labor market conditions (which are reflected in the IPF's respective wage index) and, thus, should be included in the labor-related share. The remaining approximately 36 percent of Professional Fees costs which are purchased outside the local labor market reflects different and additional factors outside the local labor market and, thus, should be excluded from the labor-related share. In addition, we note the compensation costs of professional services provided by hospital employees (which would reflect the local labor market) are included in the labor-related share, as they are included in the Wages and Salaries and Benefit cost weights.

Therefore, for the reasons discussed, we believe our proposed methodology of allocating only a portion of Professional Fees to the Professional Fees: Labor-Related cost category is appropriate. As stated previously, effective for transmittal 18 (https://www.cms.gov/Regulations-and-

Guidance/Guidance/Transmittals/Transmittals/r18p240i), the hospital Medicare Cost Report

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² The 64 percent value is based on a survey conducted by CMS in 2008 as detailed in the FY 2010 IPPS/LTCH PPS final rule (74 FR 43850 through 43856). This was also used to determine the Professional Fees: Labor-Related cost weight in the 2016-based IPF market basket.

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

Comment: One commenter did not support the proposed increase to the labor-related share. This commenter stated that any increase to the labor-related share percentage penalizes any facility that has a wage index less than 1.0. The commenter further stated that across the country, there is a growing disparity between high-wage and low-wage states that harms hospitals in many rural and underserved communities. The commenter stated that limiting the increase in the labor-related share would help mitigate that growing disparity and recommended that CMS consider excluding the labor portion of capital-related costs for FY 2024 and going forward.

Response: As discussed in section IV.D.1.a, the IPF PPS wage index is applied to the labor-related portion of an IPF's payment to provide an adjustment for geographic wage levels. The methodology to use the relative importance values for the labor-related cost categories from the most recent IPF market basket is consistent with the determination of the labor-related share since the implementation of the IPF PPS in 2007. The labor-related cost categories reflect IPF costs that are related to, influenced by, or vary with the local labor market, which would include a portion of the capital-related costs since the construction costs for capital infrastructure would be influenced by the local labor market. Therefore, we disagree with the commenter that we should exclude the labor portion of capital-related costs for FY 2024 and going forward.

<u>Comment</u>: One commenter disagreed with the assumption that home office compensation costs that occur outside of a hospital's labor market are not subject to geographic wage variation and stated that they do not believe that the proposed reclassification to the Professional Fees:

Non-Labor-Related cost category is justified. The commenters stated that the proposed methodology fails to consider that the home office is essentially a part of the hospital, and thus the hospital, along with its home office, is operating in multiple labor markets. The commenters stated that the home office's portion of the hospital's labor costs should not be excluded from the labor-related share simply because they are not in the same labor market as the hospital.

The commenter conducted their own analysis of the Medicare cost report data showing that providers with a home office outside of their local labor market had wage indexes both below 1 as well as greater than 1. The commenter stated that those hospitals in a labor market with a wage index greater than 1 had mean home office average hourly wage costs that were greater than the mean home office average hourly wage costs of those hospitals in a labor market with a wage index less than 1. The commenter claimed that these data indicate that, contrary to CMS' assertion, home office salary, wage, and benefit costs for hospitals with home offices outside of their labor market are subject to geographic wage variation. The commenter requested that CMS allocate the full 4.7 percentage points of the Home Office/Related Organization cost weight to the labor-related share.

Response: 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), to provide an adjustment for geographic wage levels, the labor-related portion of an IPF's payment is adjusted using an appropriate wage index. 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 (representing the wage level in the geographic area of the hospital compared to the national average hospital wage level as specified under Section 1886(d)(3)(E)) to account for geographic differences in IPF labor costs. Therefore, consistent with the definition of labor-related share used for IPPS hospitals, we have included a cost category in the labor-related share for IPFs if the costs are

labor-intensive and vary with the local labor market (that is, the geographic area of the hospital).

As the commenter stated, and as validated with the Medicare cost report data, a hospital's home office can be located outside the hospital's local labor market. For other types of professional services, we only include the costs for services purchased directly within the geographic area of the hospital in the labor-related share because they reflect the local labor market conditions that are consistent with the intent of the geographic adjustment. We believe it is reasonable to conclude that costs of those home office services purchased directly within the geographic area of the hospital should also be included in the labor-related share because they are impacted by local labor market conditions. As we have previously discussed in the RY 2007 final rule (71 FR 27066), we believe that the actual location of an IPF (as opposed to the location of affiliated providers) is most appropriate for determining the wage adjustment, because the prevailing wages in the area in which the IPF is located influence the cost of a case. And as we do for professional services, we believe home office costs that are not in the same geographic area as the hospital should be excluded from the labor-related share because they are influenced by factors outside of the hospital's local labor market. To implement this approach, we proposed a methodology that relies on the Medicare cost report data for hospitals reporting home office information to determine whether their home office is in the same geographic area of the hospital (which we define as the hospital's Metropolitan Statistical Area). Our methodology determined that 46 percent of the Home Office/Related Organization cost weight (reflecting compensation costs) are associated with the geographic area of the hospital, whereas the remaining 54 percent of home office costs are purchased outside the geographic area of the hospital. Therefore, we believe our proposed methodology of only allocating the portion of the Home Office/Related Organization cost weight (46 percent) into the Professional Fees: Labor-Related cost weight that are purchased in the same geographic area as the hospital is appropriate as it is consistent with the intent of the geographic adjustment. In addition, we note that the compensation costs for hospital employees, which would reflect the local labor market performing the same tasks as

home office personnel are included in the labor-related share as they are included in the Wages and Salaries and Employee Benefits cost weights.

As stated, we proposed to include in the labor-related share the sum of the relative importance of Wages and Salaries, Employee Benefits, Professional Fees: Labor-Related, Administrative and Facilities Support Services, Installation, Maintenance, and Repair Services, All Other: Labor-Related Services, and a portion of the Capital-Related cost weight from the 2021-based IPF market basket, as this meets our definition of the labor-related share with costs that are labor intensive and vary with the local labor market.

<u>Final Decision</u>: After consideration of public comments, we are finalizing the 2021-based IPF market basket proposed labor-related cost categories and base year cost weights as proposed.

We also proposed that if more recent data were subsequently available, we would use such data to determine the FY 2024 labor-related share in the final rule. Based on IGI's second quarter 2023 forecast for the 2021-based IPF market basket, the sum of the FY 2024 relative importance for Wages and Salaries, Employee Benefits, Professional Fees: Labor-Related, Administrative and Facilities Support Services, Installation Maintenance & Repair Services, and All Other: Labor-Related Services is 75.6 percent. The portion of Capital-Related costs that is influenced by the local labor market is estimated to be 46 percent, which is the same percentage applied to the 2016-based IPF market basket (84 FR 38446 through 38447). Since the relative importance for Capital-Related costs is 6.8 percent of the 2021-based IPF market basket in FY 2024, we took 46 percent of 6.8 percent to determine the labor-related share of Capital-Related costs for FY 2024 of 3.1 percent. Therefore, the total labor-related share for FY 2024 based on more recent data is 78.7 percent (the sum of 75.6 percent for the operating costs and 3.1 percent for the labor-related share of Capital-Related costs). Table 15 shows the FY 2024 labor-related share using the 2021-based IPF market basket relative importance and the FY 2023 labor-related share using the 2016-based IPF market basket.

	FY 2024 Labor-related Share based on 2021- based IPF Market Basket ¹	FY 2023 Labor-related Share based on 2016- based IPF Market Basket ²
Wages and Salaries	53.4	53.2
Employee Benefits	14.2	13.5
Professional Fees: Labor-Related ³	4.7	4.3
Administrative and Facilities Support Services	0.6	0.6
Installation, Maintenance and Repair Services	1.2	1.3
All Other: Labor-Related Services	1.5	1.5
Subtotal	75.6	74.4
Labor-related portion of Capital-Related (46%)	3.1	3.0
Total Labor-Related Share (LRS)	78.7	77.4

^{1.} IHS Global Inc. 2nd quarter 2023 forecast.

The FY 2024 labor-related share using the 2021-based IPF market basket is about 1.0 percentage point higher than the FY 2023 labor-related share using the 2016-based IPF market basket. This higher labor-related share is primarily due to the incorporation of the 2021 Medicare cost report data, which increased the Compensation cost weight by 0.9 percentage point compared to the 2016-based IPF market basket, as shown in Table 1 and Table 2 in section IV.A.3.a.(2) of this final rule.

B. Updates to the IPF PPS Rates for FY Beginning October 1, 2023

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).

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,

^{2.} Based on IHS Global Inc. 2nd quarter 2022 forecast as published in the Federal Register (87 FR 46851).

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

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 Tax Equity and Fiscal Responsibility Act (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. The 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 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 2024. Addendum B to this final rule shows the ECT procedure codes for FY 2024 and is available on our website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html.

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

The current (FY 2023) Federal per diem base rate is \$865.63, and the ECT payment per treatment is \$372.67. For the final FY 2024 Federal per diem base rate, we applied the payment rate update of 3.3 percent—that is, the 2021-based IPF market basket increase for FY 2024 of 3.5 percent less the productivity adjustment of 0.2 percentage point—and the wage index budget-neutrality factor of 1.0016 (as discussed in section IV.D.1 of this final rule) to the FY 2023 Federal per diem base rate of \$865.63, yielding a final Federal per diem base rate of \$895.63 for FY 2024. Similarly, we applied the 3.3 percent payment rate update and the 1.0016 wage index budget-neutrality factor to the FY 2023 ECT payment per treatment of \$372.67, yielding a final ECT payment per treatment of \$385.58 for FY 2024.

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 data under the IPFQR Program 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 points 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 1.3 percent payment rate update—that is, the IPF market basket increase for FY 2024 of 3.5 percent less the productivity adjustment of 0.2 percentage point for an update of 3.3 percent, and further reduced by 2.0 percentage points in accordance with section 1886(s)(4)(A)(i) of the Act—and the wage index budget-neutrality factor of 1.0016 to the FY 2023 Federal per diem base rate of \$865.63, yielding a Federal per diem base rate of \$878.29 for FY 2024.
- For IPFs that fail to meet requirements under the IPFQR Program, we applied a 1.3 percent annual payment rate update and a 1.0016 wage index budget-neutrality factor to the FY 2023 ECT payment per treatment of \$372.67 yielding an ECT payment per treatment of \$378.12 for FY 2024.

Lastly, we proposed that if more recent data became available, we would use such data, if appropriate, to determine the FY 2024 Federal per diem base rate and ECT payment per treatment for the final rule.

Finally, we note that in the April 10, 2023 IPF PPS proposed rule (88 FR 21259), there were two technical errors in describing the calculation of the FY 2024 proposed base rate and electroconvulsive therapy (ECT) payment per treatment for IPFs that fail to meet requirements under the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program. In describing the calculation of the FY 2024 Federal per diem base rate for IPFs that fail to meet requirements under the IPFQR Program, we inadvertently stated that we applied the market basket update, reduced by 2.0 percentage points to the FY 2024 Federal per diem base rate and FY 2024 ECT payment per treatment. In accordance with our longstanding methodology, and with the actual

calculation of these proposed payment updates, the description of these calculations should have used the FY 2023 Federal per diem rate and FY 2023 ECT payment per treatment rather than the FY 2024 Federal per diem rate and ECT payment per treatment. To be clear, these errors only affected the description of the starting values from which the rates were calculated, and the calculations themselves, as well as the rates indicated in the proposed rule, were correct and consistent with our longstanding methodology for updating the IPF Federal per diem base rate and ECT payment per treatment.

C. 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 proposed to use the existing regression-derived adjustment factors established in 2005 for FY 2024. 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. 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's 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 PPS proposed rule (68 FR 66923; 66928 through 66933) and the November 15, 2004 IPF PPS 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 2024, we did not propose any changes to the IPF MS-DRG adjustment factors.

In the FY 2015 IPF PPS final rule published August 6, 2014, in the **Federal Register** titled, "Inpatient Psychiatric Facilities Prospective Payment System—Update for FY Beginning October 1, 2014 (FY 2015)" (79 FR 45945 through 45947), we finalized conversions of the ICD-9-CM-based MS-DRGs to ICD-10-CM/PCS-based MS-DRGs, which were implemented on October 1, 2015. As discussed in the FY 2015 IPF PPS proposed rule (79 FR 26047) in more detail, every year, changes to the ICD-10-CM and the ICD-10-PCS coding system are addressed in the IPPS proposed and final rules. The changes to the codes are effective October 1 of each year and must be used by acute care hospitals as well as other providers to report diagnostic and procedure information. In accordance with § 412.428(e), the IPF PPS has always incorporated

ICD-10-CM and ICD-10-PCS coding changes made in the annual IPPS update and will continue to do so. We will continue to publish coding changes in a Transmittal/Change Request, similar to how coding changes are announced by the IPPS and LTCH PPS. The coding changes relevant to the IPF PPS are also published in the IPF PPS proposed and final rules, or in IPF PPS update notices. 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 2024, we proposed to continue making 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.

As we did not propose any changes to the IPF MS-DRG adjustment factors, we are retaining the existing IPF MS-DRG adjustment factors for FY 2024.

The diagnoses for each IPF MS-DRG will be updated as of October 1, 2023, using the final FY 2024 IPPS ICD-10-CM/PCS code sets. The FY 2024 IPPS/LTCH PPS final rule will include tables of the changes to the ICD-10-CM/PCS code sets, which underlie the FY 2024 IPF MS-DRGs. Both the FY 2024 IPPS final rule and the tables of final changes to the ICD-10-CM/PCS code sets, which underlie the FY 2024 MS-DRGs, will be 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-10-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 and FY 2022, there were 18 ICD-10-CM codes deleted from the final IPF Code First table. For FY 2023, there were 2 ICD-10-CM codes deleted and 48 ICD-10-CM codes added to the IPF Code First table.

For FY 2024, there were no proposed changes to the Code First Table. For this final rule, we are finalizing the deletion of 1 ICD-10-CM code and the addition of 5 ICD-10-CM codes as "code first" codes. There are 26 codes whose "code first" codes are being updated in the IPF Code First Table to reflect these changes In accordance with our longstanding practice for the IPF PPS and with § 412.428(e), we are adopting these latest ICD-10-CM changes for October, 2023 and describing these changes in this FY 2024 IPF PPS final rule. The FY 2024 Code First

table is shown in Addendum B on the CMS website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html.

b. 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, LOS, or both treatment and LOS.

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

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

appropriate for comorbidity adjustment.

As noted previously, it is our policy to maintain the same diagnostic coding set for IPFs that is used under the IPPS for providing the same psychiatric care. The 17 comorbidity categories formerly defined using ICD-9-CM codes were converted to ICD-10-CM/PCS in our FY 2015 IPF PPS final rule (79 FR 45947 through 45955). The goal for converting the comorbidity categories is referred to as replication, meaning that the payment adjustment for a given patient encounter is the same after ICD-10-CM implementation as it would be if the same record had been coded in ICD-9-CM and submitted prior to ICD-10-CM/PCS implementation on October 1, 2015. All conversion efforts were made with the intent of achieving this goal. For FY 2024, we proposed to use the same comorbidity adjustment factors in effect in FY 2023. The FY 2024 comorbidity adjustment factors are found in Addendum A, available on the CMS website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-

Payment/InpatientPsychFacilPPS/tools.html.

For FY 2024, we proposed to add 2 ICD-10-CM codes and remove 1 ICD-10-CM code from the Chronic Renal Failure category. We did not receive any comments on this proposal, and we are finalizing these changes as proposed. In addition, we are adding 2 ICD-10-CM codes to the Chronic Obstructive Pulmonary Disease category, 1 ICD-10-CM code to the Infectious Disease category, 4 ICD-10-CM codes to the Poisoning category, 6 ICD-10-PCS codes for the Oncology Treatment Procedure category. For the Oncology Treatment Diagnosis Category, we are adding 12 ICD-10-CM codes and deleting 2 ICD-10-CM codes. Finally, for the Acute Renal Failure Category, we are adding 1 ICD-10-CM code and deleting 1 ICD-10_CM code. In accordance with our longstanding practice for the IPF PPS and with § 412.428(e), we are adopting these latest ICD-10-CM changes for October, 2023 and describing these changes in this FY 2024 IPF PPS final rule.

The FY 2024 comorbidity codes are shown in Addenda B, available on the CMS 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 2024 ICD-10-CM codes to remove codes that were site "unspecified" in terms of laterality from the FY 2024 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 will 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 2024 ICD-10-CM/PCS codes were site "unspecified" by laterality; therefore, we are not removing any of the new codes.

c. 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 2024, we proposed continuing to use the patient age adjustments currently in effect for FY 2023, as shown in Addendum A of this final rule (see https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html).

As we did not propose any changes to the patient age adjustment factors, we are retaining the existing patient age adjustment factors for FY 2024.

d. Variable Per Diem Adjustments

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

For FY 2024, we proposed to use the variable per diem adjustment factors currently in effect in FY 2023, as shown in Addendum A to this final rule (available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-

<u>Payment/InpatientPsychFacilPPS/tools.html</u>). A complete discussion of the variable per diem adjustments appears in the November 2004 IPF PPS final rule (69 FR 66946).

As we did not propose any changes to the variable per diem adjustment factors, we are retaining the existing variable per diem adjustment factors for FY 2024.

D. 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), 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 42 CFR 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 that we 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 PPS 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 RY 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 2024, we proposed to continue using the concurrent pre-floor, pre-reclassified IPPS hospital wage index as the basis for the IPF wage index.

We proposed to apply the IPF wage index adjustment to the labor-related share of the national base rate and ECT payment per treatment. The labor-related share of the national rate and ECT payment per treatment would change from 77.4 percent in FY 2023 to 78.7 percent in FY 2024. This percentage reflects the labor-related share of the 2021-based IPF market basket for FY 2024 (see section IV.A of this final rule).

<u>Comment</u>: Several commenters urged CMS to revise the IPF wage index methodology. Specifically, a few commenters suggested CMS revise the policy so that the post-reclassification and post-floor hospital IPPS wage index is used to calculate the wage index for IPFs. The commenter believes that the continued use of the pre-reclassification and pre-floor hospital inpatient wage index is unreasonable because it places IPFs at a disadvantage in the labor markets in which they operate relative to hospitals in the same markets.

Other commenters suggested CMS exercise its authority to refine the IPF PPS by applying the pre-floor, pre-reclassified IPPS hospital wage index for the CBSA in which the nearest IPPS hospital is located where the pre-floor, pre-classified IPPS hospital wage index for the CBSA in which the IPF is located only includes data from a closed IPPS hospital.

Commenters stated they believe the closed hospital data is more likely to be unreliable such that the application of the pre-floor, pre-reclassified IPPS hospital wage index would result in an inappropriately deflated wage index value. Commenters further asserted that the closure of the only IPPS hospital in the CBSA would suggest that the community is currently underserved, and would make it particularly appropriate to ensure that aberrant wage index data does not serve as an impediment to new IPF services in a community.

Response: We appreciate the commenters' recommendations. We did not propose the specific policies suggested by commenters, but we will take them into consideration to potentially inform future rulemaking. We do not believe that the continued use of the prereclassification and pre-floor hospital inpatient wage index for FY 2024 is unreasonable or that this policy puts IPFs at a disadvantage relative to hospitals in the labor markets in which they operate. As we have previously discussed in the RY 2007 final rule (71 FR 27066), we believe that the actual location of an IPF (as opposed to the location of affiliated providers) is most appropriate for determining the wage adjustment, because the prevailing wages in the area in which the IPF is located influence the cost of a case. In that same RY 2007 final rule (71 FR 27066), we also stated that we believe the "rural floor" is required only for the acute care hospital payment system, because section 4410 of the Balanced Budget Act of 1997 (Pub. L 105–33) applies specifically to acute care hospitals and not excluded hospitals and excluded units. As we have previously discussed, the IPF wage index is intended to be a relative measure of the value of labor in prescribed labor market areas (87 FR 46857). There is a variety of reasons why our longstanding IPF wage index policy has not applied floors or reclassifications, which as we previously noted, are not applied to the IPF wage index by statute. For example, applying floors and reclassifications to the IPF wage index would significantly increase administrative burden, both for IPFs and for CMS, that would be associated with IPFs reclassifying from one CBSA to another, and it would significantly increase the complexity of the methodology. Furthermore, because floors and reclassifications would be applied budgetneutrally under the wage index, these policies would increase the wage index for some IPFs while reducing IPF PPS payments for all other IPFs, which would upset the long-settled expectations with which IPFs across the country have been operating. For these reasons, we believe using the pre-floor, pre-reclassified IPPS hospital wage index is the most appropriate data to use as a proxy for an IPF wage index.

Regarding the suggestion to apply the wage index for the CBSA of the nearest IPPS hospital in cases when an IPF's CBSA includes only a closed IPPS hospital, we disagree with the commenter that wage data from a hospital that has subsequently closed is more likely to be unreliable and that such data would inappropriately deflate the wage index for that CBSA. Rather, following the longstanding methodology for calculating the wage index, wage data from the period during which the hospital was open would be comparable to wage data from the same period for hospitals located in other geographical areas, and would provide an appropriate relative measure of the value of labor in that CBSA's labor market area compared to others. We do not believe that such wage data or the wage index of a CBSA in this situation would serve as an impediment for either new or existing IPF services in a community. In addition, we recognize that in some cases, the closure of the only IPPS hospital in the CBSA could suggest that the community is underserved; however, in other cases, the lack of an IPPS hospital could be due to other factors, such as when an area's only IPPS hospital converts to another hospital type such as a CAH. We note that at this time, there is only one urban CBSA with no IPPS hospitals; however, there are also no IPFs located in this CBSA.

Lastly, as discussed in the FY 2024 IPPS proposed rule (88 FR 26966) in constructing the proposed FY 2024 wage index, wage data was included for facilities that were IPPS hospitals in FY 2020, inclusive of those facilities that have since terminated their participation in the program as hospitals, as long as those data did not fail any of our edits for reasonableness. We believe that including the wage data for these hospitals is, in general, appropriate to reflect the economic conditions in the various labor market areas during the relevant past period and to

ensure that the current wage index represents the labor market area's current wages as compared to the national average of wages.

<u>Final Decision</u>: After consideration of the comments received, we are finalizing our proposal for FY 2024 to continue to use the concurrent pre-floor, pre-reclassified IPPS hospital wage index as the basis for the IPF wage index.

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 77.4 percent in FY 2023 to 78.7 percent in FY 2024. This percentage reflects the labor-related share of the 2021-based IPF market basket for FY 2024 (see section IV.A.5 of this final 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 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/wp-content/uploads/2020/03/Bulletin-20-01.pdf. 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 Micropolitan Statistical Areas 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 IV.D.1.b.ii of this final rule, 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.

In the FY 2023 IPF PPS final rule (87 FR 46856 through 46859), we finalized a permanent 5-percent cap on any decrease to a provider's wage index from its wage index in the prior year, and we stated that we would apply this cap in a budget-neutral manner. Additionally, we finalized a policy that a new IPF would be paid the wage index for the area in which it is geographically located for its first full or partial FY with no cap applied because a new IPF would not have a wage index in the prior FY. We amended the IPF PPS regulations at § 412.424(d)(1)(i) to reflect this permanent cap on wage index decreases. We refer readers to the FY 2023 IPF PPS final rule for a more detailed discussion about this policy.

ii. Micropolitan Statistical Areas (MSA)

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. 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 2024, we proposed to apply a 17 percent payment adjustment for IPFs located in a rural area as defined at § 412.64(b)(1)(ii)(C) (see 69 FR 66954 for a complete discussion of the adjustment for rural locations).

d. 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 2024, we proposed 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 2024 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 2024 update to the wage indexes (based on the FY 2020 hospital cost report data) and the labor-related share in a budget-neutral manner:

Step 1: Simulate estimated IPF PPS payments, using the FY 2023 IPF wage index values (available on the CMS website) and labor-related share (as published in the FY 2023 IPF PPS final rule (87 FR 46846).

Step 2: Simulate estimated IPF PPS payments using the FY 2024 IPF wage index values (available on the CMS website) and FY 2024 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 2024 budget-neutral wage adjustment factor of 1.0016.

Step 4: Apply the FY 2024 budget-neutral wage adjustment factor from step 3 to the FY 2023 IPF PPS Federal per diem base rate after the application of the market basket update described in section IV.A of this final rule, to determine the FY 2024 IPF PPS Federal per diem base rate.

2. 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 fulltime equivalent (FTE) interns and residents training in the IPF and the IPF's average daily census.

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 + [the number of FTE residents training in the IPF's average daily census]). 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 final 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 (69 FR 66955). 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 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 propose updates to the teaching adjustment factors until we more fully analyze IPF PPS data. Therefore, in this FY 2024 final rule, we are retaining the coefficient value of 0.5150 for the teaching adjustment to the Federal per diem base rate.

Comment: One commenter recommended CMS update its methodology for calculating the IPF teaching adjustment, particularly in recognition of the Congress authorizing the awarding of new Medicare-reimbursable residency positions under the CAA, 2023 and the Consolidated Appropriations Act, 2021 (hereafter referred to as CAA, 2021) (Pub. L. 116-260). This commenter suggested CMS collect information on awards of new Medicare residency positions under section 126 of division CC, CAA, 2021 and section 4122 of CAA, 2023 from those hospitals subject to the IPF so that it can provide resident FTE cap increases under the IPF for those hospitals that receive awards for psychiatry programs.

One commenter requested that CMS permit IPFs to aggregate and adjust their FTE caps through affiliation agreements. The commenter noted training residents often indirectly increases the hospital's operational costs, but freestanding IPFs that take over this role are unable to receive any corresponding payment increase that was previously available to the host-hospital distinct part unit (DPU).

Response: We appreciate the commenter's suggestion regarding potential changes to the IPF teaching adjustment to recognize new Medicare-reimbursable residency positions under the CAA, 2023 and the CAA, 2021. The CAA, 2021 and CAA, 2023 established resident slots for direct medical education and indirect medical education, which are paid under the IPPS. We will take this comment into consideration to potentially inform future rulemaking for the IPF PPS.

Regarding the commenter's suggestion to recognize affiliation agreements, we did not propose to recognize affiliation agreements for the IPF PPS teaching adjustment and are not making a change to this policy. As we previously stated in the RY 2005 IPF PPS final rule (69 FR 66956), our intent is not to affect affiliation agreements and rotational arrangements for hospitals that have residents that train in more than one hospital. We have not implemented a provision concerning affiliation agreements specifically pertaining to the FTE caps used in the teaching adjustment under the IPF PPS.

<u>Final Decision</u>: We are finalizing as proposed to calculate the IPF teaching adjustment according to our established methodology.

3. Cost of Living Adjustment (COLA) 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) (Pub. L. 111-84, October 28, 2009), for FY 2010 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 PPS 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 believe 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 2022, the COLA factors were updated in FY 2022 IPPS/LTCH rulemaking (86 FR 45547). As such, we also updated the IPF PPS COLA factors for FY 2022 (86 FR 42621 through 42622) to reflect the updated COLA factors finalized in the FY 2022 IPPS/LTCH rulemaking. Table 16 shows the IPF PPS COLA factors effective for FY 2022 through FY 2025.

TABLE 16: IPF PPS Cost-of-Living- Adjustment Factors: IPFs Located in Alaska and Hawaii

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

The IPF PPS COLA factors for FY 2024 are also shown in Addendum A to this final rule, which is available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html.

4. 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 this final 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 2024, we proposed 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).

As we did not propose any changes to the ED adjustment, we are retaining the existing ED adjustment for FY 2024.

E. Other Proposed Payment Adjustments and Policies

1. Outlier Payment Overview

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

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

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

2. Update to the Outlier Fixed Dollar Loss Threshold Amount

In accordance with the update methodology described in § 412.428(d), we proposed 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 the FY 2022 IPF PPS final rule, we finalized the use of FY 2019 claims rather than the more recent FY 2020 claims for updating the outlier fixed dollar loss threshold (86 FR 42623). We noted that our use of the FY 2019 claims to set the final outlier fixed dollar loss threshold for FY 2022 deviated from our longstanding practice of using the most recent available year of claims but remained otherwise consistent with the established outlier update methodology. We explained that we finalized 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 "coronavirus disease 2019" (abbreviated "COVID–19") Public Health Emergency (PHE) appeared to have significantly impacted the FY 2020 IPF claims. We further stated that we intended 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 (86 FR 42624).

In the FY 2023 IPF PPS final rule (87 FR 46862 through 46864) we noted that we observed an overall increase in average cost per day and an overall decrease in the number of covered days. However, we identified that some providers had significant increases in their charges, resulting in higher-than-normal estimated cost per day that would skew our estimate of outlier payments for FY 2022 and FY 2023. We finalized our proposal for FY 2023 to use the latest available FY 2021 claims, in accordance with our longstanding practice, to simulate payments for determining the final FY 2023 IPF PPS outlier fixed dollar loss threshold amount.

In addition, we finalized a methodology for FY 2023 to exclude providers from our impact simulations whose change in simulated cost per day is outside 3 standard deviations from the mean.

For the FY 2024 IPF PPS proposed rule, consistent with our longstanding practice, we analyzed the most recent available data for simulating IPF PPS payments in FY 2023. Based on an analysis of these updated data, we estimated that IPF outlier payments as a percentage of total estimated payments were approximately 3.0 percent in FY 2023. We analyzed the change in providers' charges from the FY 2021 claims that were used to simulate payments for determining the final FY 2023 IPF PPS outlier threshold, and the latest available FY 2022 claims. In contrast to our analysis of FY 2021 claims for the FY 2023 IPF PPS proposed and final rules, we did not find the same level of significant increases in charges in the FY 2022 claims that we believe would skew our estimate of outlier payments for FY 2023 and FY 2024. Therefore, we proposed to update the outlier threshold amount to \$34,750. This would allow us to maintain estimated outlier payments at 2 percent of total estimated aggregate IPF payments for FY 2024. This proposed update was an increase from the FY 2023 threshold of \$24,630. We solicited comments on this proposed increase to the outlier threshold for FY 2024, and whether we should consider alternative methodologies for FY 2024. Specifically, we were interested in understanding whether commenters believe it would be appropriate to exclude providers from our FY 2024 impact simulations whose change in simulated cost per day is outside 3 standard deviations from the mean, following the same methodology we applied in FY 2023. We noted that our analysis for the FY 2024 proposed rule showed that the FY 2024 outlier fixed dollar loss threshold amount would be closer to \$30,000 if we were to exclude providers based on the same methodology finalized for FY 2023. We were also interested in other methodologies that commenters believe might be appropriate to consider, including why commenters believe applying such a methodology would be appropriate for establishing the outlier threshold for FY 2024.

Comment: We received five comments in response to the FY 2024 IPF PPS pertaining to an alternative IPF PPS outlier policy. Commenters included state-level and national provider associations. One commenter stated the increase in the outlier threshold amount should be limited to no more than the market basket update for the year but did not provide a rationale for this suggestion. Two commenters recommended CMS mitigate the financial impact that imperfect outlier threshold estimates have on IPFs. Four commenters requested that CMS explain in greater detail the factors driving the increase and that CMS examine its methodology and consider making changes to mitigate increases to the outlier threshold. Commenters also requested information on how the proposed increase would affect the IPF field and its patients.

Response: We appreciate the suggestions from commenters regarding mitigating the financial impact of the outlier threshold on IPFs and the use of alternative methodologies for estimating the outlier threshold. We are not finalizing any of the alternative methodologies that commenters suggested, but we are providing additional information about the drivers and impact of the increase to the outlier threshold, as commenters requested.

As we previously noted in the FY 2023 final rule (87 FR 46863), we observed two main trends in the claims data for FY 2020 and FY 2021. In summary, these were an increase in average cost per day and a decrease in total IPF PPS payments corresponding with a decrease in covered IPF PPS days. Both of these trends continued in the FY 2022 claims data used for this FY 2024 IPF PPS final rule. First, we observed that average cost per day increased approximately 8 percent when comparing the simulated FY 2022 IPF PPS payments from the FY 2023 IPF PPS final rule to the simulated FY 2023 IPF PPS payments that we used to estimate the outlier percentage for this FY 2024 IPF PPS final rule. In the FY 2022 IPF PPS proposed rule (86 FR 19526), we explained that we estimate the costs per case based on the covered charges on each IPF claim and the IPF's most recent CCR. The second continued trend that we observed was that the number of covered days continued to decrease in the FY 2022 claims. The number of covered days in the FY 2022 claims were approximately 12 percent lower than the

number of covered days in the FY 2021 claims used for FY 2023 final rulemaking, before applying the statistical trim for the FY 2023 IPF PPS final rule (87 FR 46862). This decrease in covered days corresponds with a decrease of approximately 10 percent in the total simulated FY 2023 IPF PPS payments compared to total simulated FY 2022 IPF PPS payments used for FY 2023 final rulemaking. In addition, when comparing the data used for this FY 2024 IPF PPS final rule with the statistically trimmed data used for the FY 2023 IPF PPS final rule, the covered days for FY 2024 were approximately 8 percent lower than FY 2023, and total simulated FY 2023 IPF PPS payments that we used to estimate the outlier percentage for this FY 2024 IPF PPS final rule were approximately 4 percent lower than total simulated FY 2022 IPF PPS payments. Because we calculate the outlier fixed dollar loss threshold amount so that outlier payments represent 2 percent of total estimated IPF PPS payments, the decrease to the number of days and total estimated IPF PPS payments increases the percentage of outlier payments relative to total payments, which contributes to the upward trend in the outlier fixed dollar loss threshold amount. In our simulated FY 2023 outlier payments using the FY 2023 IPF PPS outlier fixed dollar loss threshold of \$24,630, we estimated that 5,817 cases will receive outlier payments, with a mean outlier payment amount per outlier case of \$13,807.28. We observed that the distribution of simulated FY 2023 outlier payments is skewed right, which means that a large number of outlier cases receive relatively small amounts of outlier payments, and a smaller number of outlier cases receive relatively large outlier payments. Consequently, half of all simulated outlier cases receive outlier payments of \$7,543.65 or less, and 559 cases receive outlier payments of \$1,000 or less. We also observed that outlier payments are concentrated among certain types of IPFs. As shown in Table 40, in section VIII.C.2 of this final rule, urban government-owned IPF units are projected to experience the largest decreases in estimated payments as a result of the increase to the outlier fixed dollar loss threshold amount, because these providers had a larger share of outlier cases than other provider types. We did not observe that changes in case mix appear to be driving the increase in the outlier percentage. In the

simulated FY 2023 IPF PPS payments, we observed that approximately 79 percent of outlier cases are for DRG 885 (Psychoses), which aligns with the proportion of IPF PPS cases that typically receive that DRG. We estimate that the average outlier payment for cases with DRG 885 is \$14,485.21, which is comparable to the average outlier payment for all cases.

Regarding the suggestion to limit increases to the outlier threshold to no more than the market basket update, we are concerned that this methodology would not be technically appropriate for the IPF PPS outlier policy. As discussed earlier in this section, the longstanding IPF PPS 2-percent outlier policy was established based on the regression analysis and payment simulations used to develop the IPF PPS. We have previously explained that the 2-percent outlier policy 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. 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. For this FY 2024 IPF PPS final rule, we have simulated payments using the latest available data, and these payment simulations indicate that an increase to the outlier fixed dollar loss threshold is necessary in order to maintain outlier payments at 2 percent of total payments. We are concerned that limiting increases to the outlier fixed dollar loss threshold to no more than the market basket update percentage would not appropriately target outlier payments such that they remain at 2 percent of total IPF PPS payments and that such a policy would increase outlier payments above the 2 percent target for FY 2024. As we noted in the prior paragraph, we observe that the increase in the outlier fixed dollar loss threshold is driven in part by a continual downward trend in covered days over the past several years. We are concerned that it would not be appropriate to increase outlier payments to offset the fact that IPFs are providing fewer days of care for Medicare beneficiaries.

<u>Final Decision</u>: After consideration of the comments received, we are finalizing our proposal to update the fixed dollar loss threshold amount used under the IPF PPS outlier policy.

Based on the latest available data, we are finalizing an outlier fixed dollar loss threshold amount of \$33,470 for FY 2024.

3. 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 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 2024, we proposed 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 2024 is 2.1419 for rural IPFs, and 1.8026 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 Medicare Administrative Contractor (MAC) obtains inaccurate or incomplete data with which to calculate a CCR.

We proposed to update the FY 2024 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 2024, to be used in each of the three situations listed previously, using the most recent CCRs entered in the CY 2022 PSF, we provided 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).

Modification to the Regulation for Excluded Psychiatric Units Paid Under the IPF PPS
 Background

Under current regulation, in order to be excluded from the IPPS and paid under the IPF PPS or the IRF PPS, an IPF or IRF unit of a hospital must meet a number of requirements under 42 CFR 412.25. As discussed in the following paragraphs, both this regulation and the policies applying to excluded units (which include excluded IRF units and excluded IPF units) have been in effect since before both the IPF PPS and IRF PPS were established. Before the IRF PPS and the IPF PPS were established, excluded units were paid based on their costs, as reported on their

Medicare cost reports, subject to certain facility-specific cost limits. These cost-based payments were determined separately for operating and capital costs. Thus, under cost-based payments, the process of allocating costs to an IPF unit for reimbursement created significant administrative complexity. This administrative complexity necessitated strict regulations that allowed hospitals to open a new IPPS-excluded unit only at the start of a cost reporting period.

In the January 3, 1984 final rule (49 FR 235), CMS (then known as the Health Care Financing Administration) established policies and regulations for hospitals and units subject to and excluded from the IPPS. In that rule, we explained that section 1886(d) of the Act requires that the prospective payment system apply to inpatient hospital services furnished by all hospitals participating in the Medicare program except those hospitals or units specifically excluded by the law. We further explained our expectation that a hospital's status (that is, whether it is subject to, or excluded from, the prospective payment system) would generally be determined at the beginning of each cost reporting period. We also stated that this status would continue throughout the period, which is normally 1 year. Accordingly, we stated that changes in a hospital's (or unit's) status that result from meeting or failing to meet the criteria for exclusion would be implemented only at the start of a cost reporting period. However, we also acknowledged that under some circumstances involving factors external to the hospital, status changes could be made at times other than the beginning of the cost reporting period. For example, a change in status could occur if a hospital is first included under the prospective payment system and, after the start of its cost reporting period, is excluded because of its participation in an approved demonstration project or State reimbursement control program that begins after the hospital's cost reporting period has begun.

In the 1993 IPPS final rule (57 FR 39798 through 39799), we codified our longstanding policies regarding when a hospital unit can change its status from not excluded to excluded. We explained in that final rule that since the inception of the PPS for operating costs of hospital inpatient services in October 1983, certain types of specialty-care hospitals and hospital units

have been excluded from that system under section 1888(d)(1)(B) of the Act. We noted that these currently include psychiatric and rehabilitation hospitals and distinct part units, children's hospitals, and long-term care hospitals. We further explained that section 6004(a)(1) of Pub. L 101-239 amended section 1886(d)(1)(B) of the Act to provide that certain cancer hospitals are also excluded. We noted that the preamble to the January 3, 1984 final rule implementing the PPS for operating costs (49 FR 235) stated that the status of a hospital or unit (that is, whether it is subject to, or excluded from, the PPS) will be determined at the beginning of each cost reporting period. We noted that that same 1984 final rule also provided that changes in a hospital's or unit's status that result from meeting or failing to meet the criteria for exclusion will be implemented prospectively only at the start of a cost reporting period, that is, starting with the beginning date of the next cost reporting period (49 FR 243). However, we noted that this policy was not set forth in the regulations. In that 1993 IPPS final rule, we stated that we proposed revising §§ 412.22 and 412.25 to specify that changes in the status of each hospital or hospital unit would be recognized only at the start of a cost reporting period. We stated that, except in the case of retroactive payment adjustments for excluded rehabilitation units described in § 412.30(c), any change in a hospital's or unit's compliance with the exclusion criteria that occurs after the start of a cost reporting period would not be taken into consideration until the start of the following period. We noted that this policy would also apply to any unit that is added to a hospital during the hospital's cost reporting period. We also stated that we proposed revising § 412.25(a) to specify that as a requirement for exclusion, a hospital unit must be fully equipped and staffed, and be capable of providing inpatient psychiatric or rehabilitation care as of the first day of the first cost reporting period for which all other exclusion requirements are met. We explained that a unit that meets this requirement would be considered open regardless of whether there are any inpatients in the unit.

In the same 1993 IPPS final rule, we responded to commenters who objected to this policy, stating that it unnecessarily penalizes hospitals for factors beyond their control, such as

construction delays, that it discourages hospitals from making changes in their programs to meet community needs, or that it can place undue workload demands on regulatory agencies during certain time periods. In response, we explained that we believed that regulatory agencies, hospitals, and the public generally would benefit from policies that are clearly stated, can be easily understood by both hospitals and intermediaries, and can be simply administered. We stated that recognizing changes in status only at the beginning of cost reporting periods is consistent with these goals, while recognizing changes in the middle of cost reporting periods would introduce added complexity to the administration of the exclusion provisions. Therefore, we did not revise the proposed changes based on these comments.

In the FY 2000 IPPS final rule (64 FR 41531 through 41532), we amended the regulations at § 412.25(c) to allow a hospital unit to change from excluded to not excluded at any time during the cost reporting period. We explained the statutory basis and rationale for this change in the FY 2000 IPPS proposed rule (64 FR 24740) and noted that a number of hospitals suggested that we consider a change in our policy to recognize, for purposes of exclusion from the IPPS, reductions in number of beds in, or entire closure of, units at any time during a cost reporting period. In that FY 2000 IPPS proposed rule, we explained that hospitals indicated that the bed capacity made available as a result of these changes could be used as needed to provide additional services to meet patient needs in the acute care part of the hospital that is paid under the IPPS. We further explained that we evaluated the concerns of the hospitals and the effects on the administration of the Medicare program and the health care of beneficiaries of making these payment changes. As a result of that evaluation, we stated that we believed it was reasonable to adopt a more flexible policy in recognition of hospitals' changes in the use of their facilities. However, we noted that whenever a hospital establishes an excluded unit within the hospital, our Medicare fiscal intermediary would need to be able to determine costs of the unit separately from costs of the part of the hospital paid under the prospective payment system. At that time, we stated that the proper determination of costs ensured that the hospital was paid the correct

amount for services in each part of the facility, and that payments under the IPPS did not duplicate payments made under the rules that were applicable to excluded hospitals and units, or vice versa. For this reason, we did not believe it would be appropriate to recognize, for purposes of exclusion from the IPPS, changes in the bed size or status of an excluded unit that are so frequent that they interfere with the ability of the intermediary to accurately determine costs.

Moreover, we explained that section 1886(d)(1)(B) of the Act authorizes exclusion from the IPPS of specific types of hospitals and units, but not of specific admissions or stays, such as admissions for rehabilitation or psychiatric care, in a hospital paid under the IPPS. We stated that without limits on the frequency of changes in excluded units for purposes of proper Medicare payment, there was the potential for some hospitals to adjust the status or size of their excluded units so frequently that the units would no longer be distinct entities and the exclusion would effectively apply only to certain types of care.

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

period, rather than requiring that they could only begin being paid under the IRF PPS or the IPF PPS at the start of a cost reporting period. We believed that this suggestion was outside the scope of the FY 2012 IRF PPS proposed rule (76 FR 24214), because we did not propose any changes to the § 412.25(c). However, we stated that we would consider this suggestion for possible inclusion in future rulemaking.

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

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

In recent years, interested parties, such as hospitals, have written CMS to express concerns about what they see as the unnecessary restrictiveness of the requirements at § 412.25(c). Based on this feedback, we continued to explore opportunities to reduce burden for providers and clinicians, while keeping patient-centered care a priority. For instance, we considered whether this regulation might create unnecessary burden for hospitals and potentially delay necessary psychiatric beds from opening and being paid under the IPF PPS. As we

continued to review and reconsider regulations to identify ways to improve policy, we recognized that the requirement at § 412.25(c)(1), that hospital units can only be excluded at the start of a cost reporting period, may be challenging and potentially costly for facilities under some circumstances, for example, those that are expanding through new construction. Hospitals have indicated it is often difficult to predict the exact timing of the end of a construction project and construction delays may hamper a hospital's ability to have the construction of an excluded unit completed exactly at the start of a cost reporting period, which hospitals have said can lead to significant revenue loss if they are unable to be paid under the IPF PPS or IRF PPS until the start of the next cost reporting period.

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

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

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

In response to increased mental health needs, including the need for availability of inpatient psychiatric beds, we proposed changes to § 412.25(c) to allow greater flexibility for hospitals to open excluded units, while minimizing the amount of effort Medicare contractors would need to spend administering the regulatory requirements. Although we are cognizant that

there is need for mental health services and support for providers along a continuum of care, including a robust investment in community-based mental health services, this proposal was focused on inpatient psychiatric facility settings.

We proposed that changes to § 412.25(c) would apply to both IPFs and IRFs; therefore, revisions to § 412.25(c) would also affect IRFs in similar ways. Readers should refer to the FY 2024 IRF PPS proposed rule (88 FR 20981 through 20984) for discussion of proposed revisions to § 412.25(c) and unique considerations applicable to IRF units. As previously stated, the current requirements at § 412.25(c)(1) were originally established to manage the administrative complexity associated with cost-based reimbursement for excluded IPF and IRF units. Because IPF and IRF units are no longer paid under cost-based reimbursement, but rather under the IPF PPS and IRF PPS respectively, we believe that the restriction that limits an IPF or IRF unit to being excluded only at the start of a cost reporting period is no longer necessary. We amended our regulations in the FY 2012 IRF PPS final rule to address a regulation that, similarly, was previously necessary for cost-based reimbursement, but was not material to payment under the IRF PPS and IPF PPS. In that final rule, we explained that under cost-based payments, the facilities' capital costs were determined, in part, by their bed size and square footage. Changes in the bed size and square footage would complicate the facilities' capital cost allocation. We explained that under the IRF PPS and IPF PPS, a facility's bed size and square footage were not relevant for determining the individual facility's Medicare payment. Therefore, we believed it was appropriate to modify some of the restrictions on a facility's ability to change its bed size and square footage. Accordingly, we relaxed the restrictions on a facility's ability to increase its bed size and square footage. Under the revised requirements that we adopted in the FY 2012 IRF PPS final rule at § 412.25(b), an IRF or IPF can change (either increase or decrease) its bed size or square footage one time at any point in a given cost reporting period as long as it notifies the CMS Regional Office (RO) at least 30 days before the date of the proposed change, and maintains the information needed to accurately determine costs that are attributable

to the excluded units.

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

Accordingly, we proposed to modify the requirements currently in regulation at § 412.25(c)(1) to allow a hospital to change the status of an IPF unit any time within the cost reporting year, as long as the hospital notifies the CMS Regional Office and Medicare Administrative Contractor (MAC) in writing of the change at least 30 days before the date of the change, and that this change would remain in effect for the rest of that cost reporting year. We also proposed to maintain the current requirements of § 412.25(c)(2) which specify that, if an excluded unit becomes not excluded during a cost reporting year, the hospital must notify the MAC and CMS Regional Office in writing of the change at least 30 days before the change, and this change would remain in effect for the rest of that cost reporting year. Finally, we proposed to consolidate the requirements for § 412.25(c)(1) and § 412.25(c)(2) into a new § 412.25(c)(2) that would apply to IPF units and specify the requirements for an IPF unit to become excluded or not excluded. We stated that we believed this proposal would provide greater flexibility to hospitals to establish an excluded unit at a time other than the start of a cost reporting period. We solicited comments on the proposed changes.

Comment: We received unanimous commenter support on the proposal to modify the requirements to allow a hospital to open a new IPF unit any time within the cost reporting year, as long as the hospital notifies the CMS Regional Office and MAC in writing of the change at least 30 days before the date of the change. Commenters were appreciative of how this change would allow greater flexibility in how and when a unit could be designated to be excluded or not

from the IPPS. Commenters also stated this change could alleviate the problem of limited bed availability by allowing hospitals to be more responsive to the need for inpatient psychiatric beds in their communities.

Response: We thank commenters for their support and agree this modification will allow greater flexibility in how and when a unit could be designated to be excluded from the IPPS. We also agree this change will allow hospitals to be more responsive to the need for inpatient psychiatric beds.

Comment: One commenter requested that CMS allow certain units that have changed their status to change their status back at least one time during the same cost reporting period. Specifically, they believe that units that experience a status change on the first day of the cost reporting period should have the opportunity to revert to their original designation one time throughout the cost reporting period. They further clarified that, if an IPF unit specifies and communicates with the appropriate parties before the beginning of the next cost reporting year that it would want to reclassify, and then when the cost reporting period begins decides to revert, it should be allowed the opportunity to make the necessary changes.

Response: We do not fully understand the commenter's concern, but we believe the commenter is seeking clarification about whether a hospital unit would be permitted to change its status during the cost reporting year to revert to the status it held during the prior year. Under the proposed policy, a hospital unit would be permitted to change its status to either excluded or not excluded only one time during the cost reporting year, and would be required to maintain that status until the end of the cost reporting year. We are clarifying that changes made at the beginning of a cost reporting year would not limit the ability of the hospital unit to make a one-time status change during the same cost reporting year. Therefore, if the hospital unit starts the cost reporting year as excluded, it could become not excluded at any time during the cost reporting year; if the hospital unit starts the cost reporting year; if the hospital unit starts the cost reporting year as not excluded, it could become excluded at any time during the cost reporting year.

Final Decision: After consideration of the comments received, we are finalizing our proposal to modify the requirements currently in regulation at § 412.25(c)(1) to allow a hospital to change the status of an IPF unit from not excluded to excluded any time within the cost reporting year. We are also finalizing as proposed that a hospital will be required to notify the CMS Regional Office and MAC in writing of the change at least 30 days before the date of the change, and that this change would remain in effect for the rest of that cost reporting year. In addition, we are finalizing our proposal to maintain the current requirements of § 412.25(c)(2), which specify that, if an excluded unit becomes not excluded during a cost reporting year, the hospital must notify the MAC and CMS Regional Office in writing of the change at least 30 days before the change, and this change would remain in effect for the rest of that cost reporting year.

Lastly, we proposed an identical policy for rehabilitation units of hospitals in the FY 2024 IRF PPS proposed rule, specifying that the regulatory provision that would pertain to IRF units would appear in § 412.25(c)(1). We proposed discrete regulation text for each of the hospital unit types (that is, IRF units and IPF units) in order to solicit comments on issues that might impact one hospital unit type and not the other. We also stated that we may consider adopting one consolidated regulations text for both IRF and IPF units in the final rules if we finalize both of our proposals. We did not receive any comments regarding a consolidated regulation for both IRF and IPF units; nor did commenters raise any issues that would impact one hospital unit type and not the other. We are finalizing a consolidated regulation at § 412.25(c) that applies to both IPF hospital units and IRF hospital units.

V. Existing Data Collection and Request for Information (RFI) to Inform Revisions to the IPF PPS as Required by the CAA, 2023

A. Changes to IPF PPS in the CAA, 2023

As discussed in section IV.C.1 of this final rule, we proposed to continue using the existing regression-derived IPF PPS adjustment factors for FY 2024. In the FY 2023 IPF PPS proposed rule (87 FR 19428 through 19429), we discussed the background of these current IPF

PPS patient-level and facility-level adjustment factors, which are the regression-derived adjustment factors from the November 15, 2004 IPF PPS final rule and briefly discussed past analyses and areas of concern for future refinement, about which we previously solicited comments. Finally, in the FY 2023 proposed rule, we described the results of the latest analysis of the IPF PPS, which were summarized in a technical report posted to the CMS website³ accompanying the rule and solicited comments on certain topics from the report.

Section 4125 of the CAA, 2023 amended section 1886(s) of the Act to add new paragraph 1886(s)(5), which requires revisions to the methodology for determining the payment rates under the IPF PPS for FY 2025 and future years as the Secretary determines appropriate. Specifically, new section 1886(s)(5)(A) of the Act requires the Secretary to collect data and information as the Secretary as determines appropriate to revise payments under the IPF PPS. This data collection is required to begin no later than October 1, 2023, which is the start of FY 2024. In addition, new section 1886(s)(5)(D) of the Act requires that the Secretary implement by regulation revisions to the methodology for determining the payment rates for psychiatric hospitals and psychiatric units (that is, under the IPF PPS), for rate year 2025 (FY 2025) and for subsequent years if the Secretary determines it appropriate. The revisions may be based on a review of the data and information collection.

As noted above, section 1886(s)(5)(A) of the Act requires the Secretary to begin collecting, by not later than October 1, 2023, data and information as appropriate to inform revisions to the IPF PPS. New section 1886(s)(5)(B) of the Act, as added by the CAA, 2023 lists the following types of data and information as a non-exhaustive list of examples of what may be collected under this authority:

• Charges, including those related to ancillary services;

³ https://www.cms.gov/files/document/technical-report-medicare-program-inpatient-psychiatric-facilities-prospective-payment-system.pdf

- The required intensity of behavioral monitoring, such as cognitive deficit, suicidal ideations, violent behavior, and need for physical restraint; and
- Interventions, such as detoxification services for substance abuse, dependence on respirator, total parenteral nutritional support, dependence on renal dialysis, and burn care.

We note that our extensive years-long and ongoing data collection efforts are consistent with the types of data the CAA, 2023 suggests we might collect as well as the purpose for which the CAA, 2023 requires the data collection, as described in the following paragraphs.

B. Current Data and Information Collection Requirements

1. Charges, Including those Related to Ancillary Services

As specified at 42 CFR 413.20, hospitals are required to file cost reports on an annual basis and maintain sufficient financial records and statistical data for proper determination of costs payable under the Medicare program. Currently, IPFs and psychiatric units are required to report ancillary charges on cost reports.

In general, most providers allocate their Medicare costs using costs and charges as described at 42 CFR 413.53(a)(1)(i) and referred to as the Departmental Method. For cost reporting periods beginning on or after October 1, 1982, the Departmental Method, which is the ratio of beneficiary charges to total patient charges for the services of each ancillary department, is applied to apportion the cost of the department. Added to this amount is the cost of routine services for program beneficiaries, determined on the basis of a separate average cost per diem for all patients for general routine patient care areas as required at § 413.53(a)(1)(i) and (e).

The Departmental Method for apportioning allowable cost between Medicare and non-Medicare patients under the program is not readily adaptable to those hospitals that do not have a charge structure. Current cost reporting rules allow hospitals that do not have a charge structure to file an all-inclusive cost report using an alternative cost allocation method. These alternative methods as described in the CMS Pub. 15–1, chapter 22 of the Provider Reimbursement Manual (PRM), Methods A, B and E, in order of preference, must be approved by the MAC after

considering the data available and ascertaining which method can be applied to achieve equity, not merely greater reimbursement, in the allocation of costs for services rendered to Medicare beneficiaries.

Method A (Departmental Statistical Method) is used in the absence of charge data and where adequate departmental statistics are available. Where Method A was not used, the MAC may have granted specific permission for a hospital to continue to use on a temporary basis a less sophisticated Method B (Sliding Scale) or E (Percentage of Per Diem). A provider that elects and is approved under Method A, may not change to a Method B or E in a subsequent year. These alternative methods of apportionment are limited and available only to those hospitals that do not and never have had a charge structure for individual services rendered. Historically, most hospitals that were approved to file all-inclusive cost reports were Indian Health Services hospitals, government-owned psychiatric and acute care hospitals, and nominal charge hospitals.

In the FY 2016 IPF PPS final rule (80 FR 46693 through 46694), we discussed analysis conducted to better understand IPF industry practices for future IPF PPS refinements. This analysis revealed that in 2012 to 2013, over 20 percent of IPF stays show no reported ancillary costs, such as laboratory and drug costs, on cost reports or charges on claims. In the FY 2016 IPF PPS final rule (80 FR 46694), FY 2017 IPF PPS final rule (81 FR 50513), FY 2018 IPF PPS final rule (82 FR 36784), FY 2019 IPF PPS final rule (83 FR 38588) and FY 2020 IPF PPS final rule (84 FR 38458), we reminded providers that we pay only the IPF for services furnished to a Medicare beneficiary who is an inpatient of that IPF, except for certain professional services, and payments are considered to be payments in full for all inpatient hospital services provided directly or under arrangement (see 42 CFR 412.404(d)), as specified in 42 CFR 409.10.

On November 17, 2017, we issued Transmittal 12, which made changes to the hospital cost report form CMS-2552-10 (OMB No. 0938-0050), and included cost report Level I edit 10710S, effective for cost reporting periods ending on or after August 31, 2017. Edit 10710S required that cost reports from psychiatric hospitals include certain ancillary costs, or the cost

report will be rejected. On January 30, 2018, we issued Transmittal 13, which changed the implementation date for Transmittal 12 to be for cost reporting periods ending on or after September 30, 2017. CMS suspended edit 10710S effective April 27, 2018, pending evaluation of the application of the edit to all-inclusive-rate providers. CMS issued Transmittal 15 on October 19, 2018, reinstating the requirement that cost reports from psychiatric hospitals, except all-inclusive rate providers, include certain ancillary costs. For details, we refer readers to see these Transmittals, which are available on the CMS website at https://www.cms.gov/regulations-and-guidance/guidance/transmittals.

2. Required Intensity of Behavioral Monitoring and Interventions

As discussed in the November 2004 IPF PPS final rule (69 FR 66946), we encourage IPFs to code all diagnoses requiring active treatment during the IPF stay. These include ICD-10-CM codes that indicate the required intensity of behavioral monitoring, such as cognitive deficit, suicidal ideations, violent behavior, and need for physical restraint. The IPF PPS includes comorbidity and MS-DRG adjustment factors that increase IPF PPS payment for stays that include these codes. For example, ICD-10-CM codes X71 through X83 indicate self-harm. ICD-10-CM codes under R45 indicate emotional state including violent behavior. These and other ICD-10-CM codes indicate the required intensity of behavioral monitoring and should be reported on the IPF claims, if applicable.

The presence of certain ICD-10-CM codes as a principal or comorbid condition is used to adjust IPF PPS payments to reflect the resource intensity associated with these conditions. For example, codes that group to MS-DRG 884 Organic Disturbances & Intellectual Disabilities, and codes that are included in the IPF comorbidity category for Developmental Disabilities, result in increased payment for IPF stays for patients with cognitive deficit.

As we further discussed in the November 2004 IPF PPS final rule (69 FR 66938 through 66944), we developed comorbidity categories based on the clinical expertise of physicians to identify conditions that would require comparatively more costly treatment during an IPF stay

than other comorbid conditions. We used a regression analysis of administrative claims and cost report data to determine the adjustment factors associated with each comorbidity category. In addition, we used the same regression analysis to determine the adjustment factors associated with the 17 MS-DRGs that are included for payment adjustments under the IPF PPS (as identified in Addendum A). As discussed in section IV.C.2.b of this final rule, we routinely update the ICD-10-CM codes that are included in the MS-DRGs and comorbidity categories.

We also collect relevant demographic information such as patient age, and we collect information and adjust payment based on the length of IPF stays. Each of these adjustments reflects the difference in service intensity, as measured by increased or decreased costs, for different patients over the course of an IPF stay.

In addition, IPFs and psychiatric units report on claims the ICD-10-PCS codes for interventions including oncology treatment procedures, which is used for adjusting payment under the oncology comorbidity category, and ECT, which is paid for using a per treatment amount as discussed in section IV.B.2 of this final rule. Other ICD-10-CM diagnosis codes indicate the need for certain interventions, such as detoxification services or substance abuse (for example, F10.121, which is included in the drug and alcohol abuse comorbidity category), dependence on respirator (for example, Z99.11 included in the COPD category), and dependence on renal dialysis (for example, Z99.2 included in the chronic renal failure category). We note that the IPS PPF does not currently adjust for burn care but recognize there are ICD-10-CM/PCS codes that denote conditions and procedures related to burn care. As discussed in the previous paragraph, the IPF PPS includes comorbidity adjustments that reflect the higher relative costs for active treatment of these conditions. IPF patients with these conditions are costlier to treat primarily because of the costs associated with interventions and longer lengths of stay.

3. Request for Information on Data and Information Collection

As noted in section V.A of this final rule, our extensive years-long and ongoing data collection efforts are consistent with the types of data that the CAA, 2023 suggests we might

collect, as well as aligns with the purpose for which the CAA, 2023 requires the data collection. In this final rule, we are requesting information from the public to inform revisions to the IPF PPS required by section 4125(a) of the CAA, 2023. We are seeking information about specific additional data and information psychiatric hospitals and psychiatric units might report that could be appropriate and useful to help inform possible revisions to the methodology for payment rates under the IPF PPS for FY 2025 and future years if determined appropriate by the Secretary.

Section 1886(s)(5)(C) of the Act provides that the Secretary may collect additional data and information on cost reports, claims, or otherwise. Therefore, we also sought information about potential available data and information sources, including using additional elements of the current cost reports, claims, or other sources, taking into consideration factors such as the timing and availability of data, the quality of the potential data and information to be collected, and the potential administrative burden on providers, MACs, and CMS.

We solicited comment on the following topics:

- What other data and information would be beneficial for informing revisions to the IPF PPS payment methodologies that are currently obtainable through claims or cost report information? What codes, conditions, or other indicators should we examine in order to potentially identify this data from existing sources?
- What other data and information would be beneficial for informing revisions to the IPF PPS payment methodologies that are not routinely coded on claims or identifiable through cost report information? What are some potential alternative sources we could consider for collecting these data and information?
- What data and information that is currently reported on claims data could be used to inform revisions to the IPF PPS payment methodologies?
- As we discussed in the FY 2024 IPF PPS proposed rule, the current IPF PPS payment adjustments were derived from a regression analysis based on the FY 2002 MedPAR data file.

 The adjustment factors included for payment 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. Are there alternative methodological approaches or considerations that we should consider for future analysis?

- What if any additional data or information should we consider collecting that could address access to care in rural and isolated communities?
- 4. Request for Information about Charges for Ancillary Services

In conjunction with the FY 2023 IPF PPS proposed rule (87 FR 19428 through 19429), we posted a report on the CMS website that summarizes the results of the latest analysis of more recent IPF cost and claim information for potential IPF PPS adjustments and requested comments about the results summarized in the report. That report showed that approximately 23 percent of IPF stays were trimmed from the data set used in that analysis because they were stays at facilities where fewer than 5 percent of their stays had ancillary charges. This report is available online at https://www.cms.gov/medicare/inpatient-psychiatric-facility-pps/ipf-reports-and-educational-resources.

In response to the comment solicitation, we received a comment from MedPAC regarding facilities that do not report ancillary charges on most or any of their claims. Ancillary services are the services for which charges are customarily made in addition to routine services. These include services such as labs, drugs, radiology, physical and occupational therapy services, and other types of services that typically vary between stays. Generally, based on the nature of IPF services and the conditions of participation⁴ applicable to IPFs, we expect to see ancillary services and correlating charges, such as labs and drugs, on most IPF claims. Our ongoing analysis has found that certain providers, especially for-profit freestanding IPFs, are consistently reporting no ancillary charges or very minimal ancillary charges. MedPAC stated that it is not known: whether IPFs fail to report ancillary charges separately because they were appropriately

⁴ IPFs are subject to all hospital conditions of participation, including 42 CFR 482.25, which specifies that "The hospital must have pharmaceutical services that meet the needs of the patients," and 482.27, which specifies that "The hospital must maintain, or have available, adequate laboratory services to meet the needs of its patients."

bundled with all other charges into an all-inclusive per diem rate; if no ancillary charges were incurred because the IPF cares for a patient mix with lower care needs or inappropriately stints on care; or if ancillary charges for services furnished during the IPF stay are inappropriately billed outside of the IPF base rate (unbundling). MedPAC recommended CMS conduct further investigation into the lack of certain ancillary costs and charges and whether IPFs are providing necessary care and appropriately billing for inpatient psychiatric services under the IPF PPS.

As discussed in the previous section of this FY 2024 IPF PPS final rule, we requested information related to the specific types of data and information specified in the CAA, 2023, including the reporting of charges for ancillary services, such as labs and drugs, on IPF claims. We are interested in better understanding IPF industry practices pertaining to the billing and provision of ancillary services to inform future IPF PPS refinements. We are considering whether to require charges for ancillary services to be reported on claims and potentially reject claims if no ancillary services are reported, and whether to consider payment for such claims to be inappropriate or erroneous and subject to recoupment. Accordingly, we solicited comments on the following questions:

- What would be the appropriate level of ancillary charges CMS should expect to be reported on claims? Are there specific reasons that an IPF stay would include no ancillary services?
- What are the reasons that some providers are not reporting ancillary charges on their claims?
- Would it be appropriate for CMS to require and reject claims if there are no ancillary charges reported? Or should CMS consider adjusting payment to providers that do not report ancillary charges on their claims? For example, does the lack of ancillary charges on claims suggest a lack of reasonable and necessary treatment during the IPF stay, and would it be appropriate for CMS to only apply the IPF PPS patient-level adjustment factors for claims that include ancillary charges?

C. Social Drivers of Health

Social drivers of health (SDOH), also known as social determinants of health, are the conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks.⁵ Studies have shown that there is a correlation between the effects of low income and education and overall health status. One study derived that the lowest income and least educated individuals were consistently least healthy.⁶ We have previously demonstrated our commitment to advancing health equity and reducing health disparities. In the past, and in our ongoing efforts, we have strived to identify and implement policies, procedures, reporting protocols, and other initiatives in a number of our programs that address the impact of SDOH on an individual's health.

For the IPF Quality Reporting Program, as discussed in section VI.D below of this final rule, we are adopting the Facility Commitment to Health Equity measure for the FY 2026 payment determination and subsequent years, the Screening for Social Drivers of Health measure beginning with voluntary reporting of data reflecting care provided in 2024 beginning in CY 2025 with required reporting for the FY 2027 payment determination and subsequent years, and the Screen Positive Rate for Social Drivers of Health measure beginning with voluntary reporting of data beginning in CY 2024 with required reporting for the FY 2027 payment determination and subsequent years.

Additionally, in the technical report⁷ accompanying the FY 2023 IPF PPS proposed rule, we explained that we analyzed the costs associated with SDOH but found that our analysis was confounded by a low frequency of IPF claims reporting the applicable ICD-10 diagnosis codes. In response to the FY 2023 IPF PPS proposed rule we received 10 comments pertaining to the

⁵ https://health.gov/healthypeople/priority-areas/social-determinants-health

⁶ Paula A. Braveman, Catherine Cubbin, Susan Egerter, David R. Williams, and Elsie Pamuk, 2010:

Socioeconomic Disparities in Health in the United States: What the Patterns Tell Us

American Journal of Public Health 100, S186 S196, https://doi.org/10.2105/AJPH.2009.166082

 $^{^7\,}https://www.cms.gov/files/document/technical-report-medicare-program-inpatient-psychiatric-facilities-prospective-payment-system.pdf$

report on the analysis of patient-level and facility-level adjustment factors, and areas of interest for further research, including additional SDOH analysis.

Working in collaboration with a contractor, subsequent analysis has shown that other SDOH codes, such as Z59.9 Problem related to housing and economic circumstances, unspecified, are associated with statistically significant, higher costs. In general, our analysis found that claims that included SDOH codes had lower costs than claims that did not include such codes. This finding is counterintuitive; however, we note that studies have found that there are disparities in the reporting of SDOH codes, such as homelessness.⁸ Additionally, our analysis found that certain codes were associated with increased cost for IPF treatment. Specifically, the below SDOH codes in the analysis were found to be statistically significant and had a stay count of greater than 100. These codes had an adjustment factor above 1, suggesting that these conditions may increase relative costliness of IPF stays:

- Z559 Problems related to education and literacy, unspecified.
- Z599 Problems related to housing and economic circumstances, unspecified.
- Z600 Problems of adjustment to life-cycle transitions.
- Z634 Disappearance and death of family member.
- Z653 Problems related to other legal circumstances.
- Z659 Problems related to unspecified psychosocial circumstances.

We solicited comments on these findings and information about whether it would be appropriate to consider incorporating these codes into the IPF PPS in the future, for example as a patient-level adjustment. Specifically, for codes that are "unspecified," we sought information about what types of conditions or circumstances these codes might represent. We sought any information that commenters could provide about the reasons for including these codes on

 $^{{}^{8}\,}https://aspe.hhs.gov/reports/health-conditions-among-individuals-history-homelessness-research-brief-0}$

claims. We also requested information on what factors commenters believe we should consider in order to better understand the cost regression results presented above.

D. Public Comments Received in Response to CY 2024 IPF PPS Proposed Rule

We received 15 comments in response to the FY 2024 IPF PPS proposed rule pertaining to existing and future data collection to inform revisions to the IPF PPS as required by the CAA, 2023. Commenters offered various suggestions of patient characteristics and factors we could consider for analysis. Commenters included MedPAC, state-level and national provider and patient advocacy organizations, and health systems.

We thank commenters for their detailed responses to this comment solicitation. We will take these comments into consideration to potentially inform future rulemaking.

VI. Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program

A. Background and Statutory Authority

The Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program is authorized by section 1886(s)(4) of the Act, and it applies to psychiatric hospitals and psychiatric units paid by Medicare under the IPF PPS (see section VI.B. of this final rule). Section 1886(s)(4)(A)(i) of the Act requires the Secretary to reduce by 2 percentage points the annual update to the standard federal rate for discharges for the IPF occurring during such fiscal year⁹ for any IPF that does not comply with quality data submission requirements under the IPFQR Program, set forth in accordance with section 1886(s)(4)(C) of the Act, with respect to an applicable fiscal year.

Section 1886(s)(4)(C) of the Act requires IPFs to submit to the Secretary data on quality measures specified by the Secretary under section 1886(s)(4)(D) of the Act. Except as provided

⁹ 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).

in section 1886(s)(4)(D)(ii) of the Act, section 1886(s)(4)(D)(i) of the Act requires that any measure specified by the Secretary must have been endorsed by the consensus-based entity (CBE) with a contract under section 1890(a) of the Act. Section 1886(s)(4)(D)(ii) of the Act provides 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 CBE with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

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

For the IPFQR Program, we refer to the year in which an IPF would receive the 2percentage point reduction to the annual update to the standard federal rate as the *payment*determination year. An IPF generally meets IPFQR Program requirements by submitting data on
specified quality measures in a specified time and manner during a data submission period that
occurs prior to the payment determination year. These data reflect a period prior to the data
submission period during which the IPF furnished care to patients; this period is known as the
performance period. For example, for a measure affecting FY 2026 payment determination, for
which CY 2024 is the performance period and for which data are required to be submitted in CY
2025, if an IPF did not submit the data for this measure as specified during CY 2025 (even if the
IPF meets all other IPFQR Program requirements for the FY 2026 payment determination) we
would reduce by 2-percentage points that IPF's update for the FY 2026 payment determination
year.

In the FY 2024 IPF PPS proposed rule (88 FR 21273), we proposed to codify the IPFQR Program requirements governing IPF reporting on quality measures in a new regulation at § 412.433, which is the section preceding our existing regulation governing reconsideration and appeals procedures for IPFQR Program decisions in our regulations at § 412.434. Specifically,

we proposed to codify a general statement of the IPFQR Program authority and structure at § 412.433(a). Paragraph (a) will cite section 1886(s)(4) of the Act, which requires the Secretary to implement a quality reporting program for inpatient psychiatric hospitals and psychiatric units. Paragraph (a) will also state that IPFs paid under the IPF PPS as provided in section 1886(s)(1) of the Act that do not report data required for the quality measures selected by the Secretary in a form and manner, and at a time specified by the Secretary will incur a 2.0 percentage point reduction to the annual update to the standard federal rate with respect to the applicable fiscal year.

We solicited comments on this proposal.

<u>Comment</u>: One commenter requested clarification regarding whether there are penalties for facilities that do not meet all the reporting requirements for a specific year.

Response: The IPFQR Program is a pay-for-reporting program. IPFs are not, and will not be, penalized based on their performance on measures reported to CMS as part of the IPFQR Program. However, if an IPF does not comply with quality data submission requirements under the IPFQR Program for a given fiscal year, section 1886(s)(4)(A)(i) of the Act requires the Secretary to reduce by 2 percentage points the annual update to the standard federal rate for discharges for the IPF occurring during such fiscal year.

We specifically proposed to codify established IPFQR Program requirements, particularly those set forth in the statute at section 1886(s)(4) of the Act and our prior rulemaking, in a new regulation at § 412.433. Our proposal to codify penalties for an IPF's failure to submit data as required by the IPFQR Program at § 412.433(a) merely reiterates the penalty already required by the statute set forth at section 1886(s)(4) of the Act.

<u>Final Decision</u>: After consideration of the public comments we received, we are finalizing codification of the IPFQR Program requirements governing IPF reporting on quality measures at a new regulation at § 412.433. We are finalizing the regulation text as proposed except that we are correcting one typographical error in which the "Act" was inadvertently

referred to as the "act."

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 by Medicare under IPF PPS in accordance with § 412.404(b). Generally, psychiatric hospitals and psychiatric units within acute care and critical access hospitals (CAHs) 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).

C. Previously Finalized Measures

The current IPFQR Program includes 14 measures for the FY 2024 payment determination. For more information on these measures, we refer readers to Table 20 of this final rule (see section VI.G of this final rule).

D. Measure Adoption

We strive to put patients and caregivers first, ensuring they are empowered to partner with their clinicians in their healthcare decision-making 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 HHS, we believe the IPFQR Program helps to incentivize IPFs to improve healthcare quality and value while giving patients and providers the tools and information needed to make the best individualized decisions. Consistent with these goals, our objective in selecting quality measures

for the IPFQR Program 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 the CMS National Quality Strategy,¹⁰ the Behavioral Health Strategy,¹¹ the Framework for Health Equity,¹² and the Meaningful Measures Framework¹³ for information related to our priorities in selecting quality measures.

1. Measure Selection Process

Section 1890A of the Act requires that the Secretary establish and follow a prerulemaking process, in coordination with the consensus-based entity (CBE) with a contract under
section 1890 of the Act, to solicit input from certain groups regarding the selection of quality and
efficiency measures for the IPFQR Program. Before being proposed for inclusion in the IPFQR
Program, measures are placed on a list of Measures Under Consideration (MUC) list, which is
published annually on behalf of CMS by the consensus-based entity (CBE),¹⁴ with which the
Secretary must contract as required by section 1890(a) of the Act. Following publication on the
MUC list, a multi-stakeholder group convened by the CBE 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 this

¹⁰ Schreiber, M, Richards, A, et al. (2022). The CMS National Quality Strategy: A Person-Centered Approach to Improving Quality. Available at: https://www.cms.gov/blog/cms-national-quality-strategy-person-centered-approach-improving-quality. Accessed on February 20, 2023.

¹¹ CMS. (2022). CMS Behavioral Health Strategy. Available at https://www.cms.gov/cms-behavioral-health-strategy. Accessed on February 20, 2023.

¹² CMS. (2022). CMS Framework for Health Equity 2022-2032. Available at https://www.cms.gov/files/document/cms-framework-health-equity-2022.pdf. Accessed on February 20, 2023.

¹³ CMS. (2022). Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at https://www.cms.gov/medicare/meaningful-measures-framework/meaningful-measures-20-moving-measure-reduction-modernization. Accessed on February 20, 2023.

¹⁴ In previous years, we referred to the consensus-based entity by corporate name. We have updated this language to refer to the consensus-based entity more generally.

multi-stakeholder group in selecting all measures for the IPFQR Program.

Information about the multi-stakeholder group's input on each of our newly adopted measures is described in the following subsections. In our evaluation of the IPFQR Program measure set, we identified four measures that we believe are appropriate for adoption for the IPFQR Program:

- Facility Commitment to Health Equity;
- Screening for Social Drivers of Health;
- Screen Positive Rate for Social Drivers of Health; and
- Psychiatric Inpatient Experience (PIX) Survey.

These four measures are described in the following subsections.

- 2. Adoption of the Facility Commitment to Health Equity Measure Beginning with the CY 2024 Reporting Period (Data Submitted in CY 2025)/FY 2026 Payment Determination
- a. Background

Significant and persistent disparities in healthcare outcomes exist in the United States. For example, 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, being a member of a religious minority, living in a rural area, or being near or below the poverty level, is often

associated with worse health outcomes. 15 16 17 18 19 20 21 22 23 24 Numerous studies have shown that among Medicare beneficiaries, racial and ethnic minority individuals often receive clinical care of lower quality, report having worse care experiences, and experience more frequent hospital readmissions and procedural complications. 25 26 27 28 29 30 Readmission rates in the Hospital

¹⁵ Joynt KE, Orav E, Jha AK. (2011). Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA, 305(7), 675-681. Available at: https://jamanetwork.com/journals/jama/fullarticle/645647. Accessed on February 13, 2023.

¹⁶ Lindenauer PK, Lagu T, Rothberg MB, et al. (2013). Income Inequality and Thirty-Day Outcomes After Acute Myocardial Infarction, Heart Failure, and Pneumonia: Retrospective Cohort Study. BMJ, 346. Available at: https://doi.org/10.1136/bmj.f521. Accessed on February 13, 2023.

¹⁷ Trivedi AN, Nsa W, Hausmann LRM, et al. (2014). Quality and Equity of Care in U.S. Hospitals. N Engl J Med, 371(24), 2298-2308. Available at: https://www.nejm.org/doi/10.1056/NEJMsa1405003. Accessed on February 13, 2023.

¹⁸ Polyakova, M, Udalova V, et al. (2021). Racial Disparities In Excess All-Cause Mortality During The Early COVID-19 Pandemic Varied Substantially Across States. Health Affairs, 40(2), 307-316. Available at: https://doi.org/10.1377/hlthaff.2020.02142. Accessed on February 14, 2023.

¹⁹ Rural Health Research Gateway. (2018). Rural Communities: Age, Income, and Health Status. Rural Health Research Recap. Available at: https://www.ruralhealthresearch.org/assets/2200-8536/rural-communities-ageincome-health-status-recap.pdf. Accessed on February 14, 2023.

²⁰ HHS Office of Minority Health. (2020). Progress Report to Congress, 2020 Update on the Action Plan to Reduce Racial and Ethnic Health Disparities. Department of Health and Human Services. Available at: https://www.minorityhealth.hhs.gov/assets/PDF/Update HHS Disparities Dept-FY2020.pdf . Accessed on February 14, 2023.

²¹ Heslin KC, Hall JE. (2021). Sexual Orientation Disparities in Risk Factors for Adverse COVID-19- Related Outcomes, by Race/Ethnicity—Behavioral Risk Factor Surveillance System, United States, 2017–2019. MMWR Morb Mortal Wkly Rep., 70(5), 149. Available at: https://www.cdc.gov/mmwr/volumes/70/wr/mm7005a1.htm. Accessed on February 14, 2023.

²² Poteat TC, Reisner SL, Miller M, Wirtz AL. (2020). COVID-19 Vulnerability of Transgender Women With and Without HIV Infection in the Eastern and Southern U.S. medRxiv. Available at:

https://www.medrxiv.org/content/10.1101/2020.07.21.20159327v1.full.pdf. Accessed on February 14, 2023.

²³ Vu M, Azmat A, Radejko T, Padela AI. (2016). Predictors of Delayed Healthcare Seeking Among American Muslim Women. Journal of Women's Health, 25(6), 586-593. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5912720/. Accessed on February 14, 2023.

²⁴ Nadimpalli SB, Cleland CM, Hutchinson MK, Islam N, Barnes LL, Van Devanter N. (2016). The Association Between Discrimination and the Health of Sikh Asian Indians. Health Psychology, 35(4), 351–355. Available at: https://doi.org/10.1037/hea0000268. Accessed on February 14, 2023.

²⁵ CMS Office of Minority Health. (2020). Racial, Ethnic, and Gender Disparities in Healthcare in Medicare Advantage. Baltimore, MD: Centers for Medicare & Medicaid Services. Available at: https://www.cms.gov/files/document/2020-national-level-results-race-ethnicity-and-gender-pdf.pdf. Accessed on February 14, 2023.

²⁶ CMS Office of Minority Health. (2018). Guide to Reducing Disparities in Readmissions. Available at: https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH Readmissions Guide.pdf. Accessed on February 14, 2023.

²⁷ Singh JA, Lu X, et al. (2014). Racial Disparities in Knee and Hip Total Joint Arthroplasty: An 18-year analysis of national Medicare data. Ann Rheum Dis., 73(12), 2107-15. Available at: https://ard.bmj.com/content/73/12/2107.full. Accessed on February 14, 2023.

²⁸ Rivera-Hernandez M, Rahman M, Mor V, Trivedi AN. (2019). Racial Disparities in Readmission Rates among Patients Discharged to Skilled Nursing Facilities. J Am Geriatr Soc., 67(8), 1672-1679. Available at: https://doi.org/10.1111/jgs.15960. Accessed on February 14, 2023.

²⁹ Joynt KE, Orav E, Jha AK. (2011). Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA, 305(7), 675-681. Available at: https://jamanetwork.com/journals/jama/fullarticle/645647. Accessed on February 13, 2023.

³⁰ Tsai TC, Orav EJ, Joynt KE. (2014). Disparities in Surgical 30-day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. Ann Surg., 259(6), 1086–1090. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4107654/. Accessed on February 14, 2023.

Readmissions Reduction Program have been shown to be higher among Black and Hispanic Medicare beneficiaries with common conditions, including congestive heart failure and acute myocardial infarction.^{31 32 33 34 35} Data indicate that, even after accounting for factors such as socioeconomic conditions, members of racial and ethnic minority groups reported experiencing lower quality of healthcare.³⁶ Evidence of differences in quality of care received among people from racial and ethnic minority groups shows worse health outcomes, including a higher incidence of diabetes complications such as retinopathy.³⁷ Additionally, inequities in the social drivers of health (SDOH) affecting these groups, such as poverty and healthcare access, are interrelated and influence a wide range of health and quality-of-life outcomes and risks.³⁸

Because we are working toward the goal of all patients receiving high-quality healthcare, regardless of individual characteristics, we are committed to supporting healthcare organizations in building a culture of safety and equity that focuses on educating and empowering their workforce to recognize and eliminate health disparities. This includes patients receiving the

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³¹ Rodriguez F, Joynt KE, Lopez L, Saldana F, Jha AK. (2011). Readmission Rates for Hispanic Medicare Beneficiaries with Heart Failure and Acute Myocardial Infarction. Am Heart J., 162(2), 254–261 e253. Available at: https://www.sciencedirect.com/science/article/pii/S0002870311003966?viewFullText=true. Accessed on February 14, 2023.

³² Centers for Medicare & Medicaid Services. (2014). Medicare Hospital Quality Chartbook: Performance Report on Outcome Measures. Available at: https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/YNH Chartbook 2014 508Compliant FINAL.pdf. Accessed on February 14, 2023.

³³ CMS Office of Minority Health. (2018). Guide to Reducing Disparities in Readmissions. Available at: https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf. Accessed on February 14, 2023.

³⁴ Prieto-Centurion V, Gussin HA, Rolle AJ, Krishnan JA. (2013). Chronic Obstructive Pulmonary Disease Readmissions at Minority Serving Institutions. Ann Am Thorac Soc., 10(6), 680–684. Available at: https://doi.org/10.1513/AnnalsATS.201307-223OT. Accessed on February 14, 2023.

³⁵ Joynt KE, Orav E, Jha AK. (2011). Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA, 305(7), 675–681. Available at: https://jamanetwork.com/journals/jama/fullarticle/645647. Accessed on February 13, 2023.

³⁶ Nelson AR. (2003). Unequal Treatment: Report of the Institute of Medicine on Racial and Ethnic Disparities in Healthcare. The Annals of Thoracic Surgery, 76(4), S1377–S1381. https://www.annalsthoracicsurgery.org/action/showPdf?pii=S0003-4975%2803%2901205-0. Accessed on February 14, 2023.

³⁷ Peek, ME, Odoms-Young, A, et al. (2010). Race and Shared Decision-Making: Perspectives of African-Americans with diabetes. Social Science & Medicine, 71(1), 1–9. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2885527/. Accessed on February 14, 2023.

³⁸ Department of Health and Human Services. (2023). Healthy People 2030: Social Determinants of Health. Available at: https://health.gov/healthypeople/priority-areas/social-determinants-health. Accessed on February 20, 2023.

right care, at the right time, in the right setting for their condition(s), regardless of those characteristics.

In the FY 2022 IPF PPS final rule (86 FR 42625 through 42632), we summarized the comments we received in response to our Request for Information (RFI) on closing health equity gaps in our quality programs, specifically the IPFQR Program. In response to this RFI, several commenters recommended that we consider a measure of organizational commitment to health equity. These commenters further described how infrastructure supports delivery of equitable care. In the FY 2023 IPF PPS final rule (87 FR 46865 through 46873), we described our RFI on overarching principles for measuring equity and healthcare quality across our quality programs and summarized the comments we received in response to that RFI. Because we had specifically solicited comments on the potential for a structural measure assessing an IPF's commitment to health equity, many commenters provided input on a structural measure. While many commenters supported the concept, one commenter expressed concern with this measure concept and stated that there is no evidence that performance on this measure will lead to improved patient outcomes (87 FR 46872 through 46873). However, we believe that strong and committed leadership from IPF executives and board members is essential and can play a role in shifting organizational culture and advancing equity goals.

Additionally, studies demonstrate that facility leadership can positively influence culture for better quality, patient outcomes, and experience of care.^{39 40 41} A systematic review of 122 published studies showed that strong leadership that prioritized safety, quality, and the setting of clear guidance with measurable goals for improvement resulted in high-performing facilities

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³⁹ Bradley EH, Brewster AL, et al. (2018). How Guiding Coalitions Promote Positive Culture Change in Hospitals: A Longitudinal Mixed Methods Interventional Study. BMJ Qual Saf., 27(3), 218–225. Available at: https://qualitysafety.bmj.com/content/qhc/27/3/218.full.pdf. Accessed on February 14, 2023.

⁴⁰ Smith SA, Yount N, Sorra J. (2017). Exploring Relationships Between Hospital Patient Safety Culture and Consumer Reports Safety Scores. BMC Health Services Research, 17(1), 143. Available at: https://bmchealthservres.biomedcentral.com/articles/10.1186/s12913-017-2078-6. Accessed on February 14, 2023.

⁴¹ Keroack MA, Youngberg BJ, et al. (2007). Organizational Factors Associated with High Performance in Quality and Safety in Academic Medical Centers. Acad Med., 82(12), 1178–86. Available at: https://journals.lww.com/academicmedicine/Fulltext/2007/12000/Organizational_Factors_Associated_with_High.14

with better patient outcomes.⁴² Therefore, we believe leadership commitment to health equity will have a parallel effect in contributing to a reduction in health disparities.

Further, we note that the Agency for Healthcare Research and Quality (AHRQ) and The Joint Commission (TJC) identified that facility leadership plays an important role in promoting a culture of quality and safety.⁴³ ⁴⁴ ⁴⁵ For instance, AHRQ research shows that a facility's board can influence quality and safety in a variety of ways, not only through strategic initiatives, but also through more direct interactions with frontline workers.⁴⁶

In addition, the Institute of Healthcare Improvement's (IHI's) research of 23 health systems throughout the United States and Canada shows that health equity must be a priority championed by leadership teams to improve both patient access to needed healthcare services and outcomes among populations that have been disadvantaged by the healthcare system.⁴⁷ This IHI study specifically identified concrete actions to make advancing health equity a core strategy, including establishing this goal as a leader-driven priority alongside organizational development structures and processes.⁴⁸

Based upon these findings, we believe that IPF leadership can be instrumental in setting specific, measurable, attainable, realistic, and time-based (SMART) goals to assess progress towards achieving equity goals and ensuring high-quality care is accessible to all. Therefore,

⁴² Millar R, Mannion R, Freeman T, et al. (2013). Hospital Board Oversight of Quality and Patient Safety: A Narrative Review and Synthesis of Recent Empirical Research. The Milbank Quarterly, 91(4), 738–70. Available at: https://onlinelibrary.wiley.com/doi/10.1111/1468-0009.12032. Accessed February 14, 2023.

⁴³ Agency for Healthcare Research and Quality. Leadership Role in Improving Patient Safety. Patient Safety Primer, September 2019. Available at: https://psnet.ahrq.gov/primer/leadership-role-improving-safety. Accessed on February 14, 2023.

⁴⁴ Joint Commission on Accreditation of Healthcare Organizations, USA. The essential role of leadership in developing a safety culture. Sentinel Event Alert. 2017 (Revised June 2021). Available at: https://www.jointcommission.org/-/media/tjc/documents/resources/patient-safety-topics/sentinel-event/sea-57-safety-culture-and-leadership-final2.pdf. Accessed on February 15, 2023.

⁴⁵ See information on launch of new "Health Care Equity Certification" in July 2023 from Joint Commission on Accreditation of Healthcare Organizations, USA, available at: https://www.jointcommission.org/our-priorities/health-care-equity/health-care-equity-prepublication/. Accessed on February 15, 2023.

⁴⁶ Agency for Healthcare Research and Quality. Leadership Role in Improving Patient Safety. Patient Safety Primer. (2019). Available at: https://psnet.ahrq.gov/primer/leadership-role-improving-safety. Accessed on February 14, 2023.

⁴⁷ Mate KS and Wyatt R. (2017). Health Equity Must Be a Strategic Priority. NEJM Catalyst. Available at: https://catalyst.nejm.org/doi/full/10.1056/CAT.17.0556. Accessed on February 15, 2023.

⁴⁸ Mate KS and Wyatt R. (2017). Health Equity Must Be a Strategic Priority. NEJM Catalyst. Available at: https://catalyst.nejm.org/doi/full/10.1056/CAT.17.0556. Accessed on February 15, 2023.

consistent with the Hospital Inpatient Quality Reporting (IQR) Program's adoption of an attestation-based structural measure in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49191 through 49201), we proposed to adopt an attestation-based structural measure, Facility Commitment to Health Equity, to address health equity beginning with the CY 2024 reporting period/FY 2026 payment determination.

The first pillar of our strategic priorities⁴⁹ reflects our deep commitment to improvements in health equity by addressing the health disparities that underly our health system. In line with this strategic pillar, we developed this structural measure to assess facility commitment to health equity across five domains (described in Table 17 in section VI.D.2.b of this final rule) using a suite of organizational competencies aimed at achieving health equity for racial and ethnic minority groups, people with disabilities, members of the LGBTQ+ community, individuals with limited English proficiency, rural populations, religious minorities, and people facing socioeconomic challenges. We believe these elements are actionable focus areas, and assessment of IPFs' leadership commitment to them is foundational.

We also believe adoption of the Facility Commitment to Health Equity measure will incentivize IPFs to collect and utilize data to identify critical equity gaps, implement plans to address these gaps, and ensure that resources are dedicated toward addressing health equity initiatives. While many factors contribute to health equity, we believe this measure is an important step toward assessing IPFs' leadership commitment, and a fundamental step toward closing the gap in equitable care for all populations. We note that this measure is not intended to encourage IPFs to act on any one data element or domain, but instead encourages IPFs to analyze their own findings to understand if there are any demographic factors (for example, race, national origin, primary language, and ethnicity) as well as SDOHs (for example, housing status and food security) associated with underlying inequities and, in turn, develop solutions to deliver more

⁴⁹ Brooks-LaSure, C. (2021). My First 100 Days and Where We Go From Here: A Strategic Vision for CMS. Centers for Medicare & Medicaid. Available at: https://www.cms.gov/blog/my-first-100-days-and-where-we-gohere-strategic-vision-cms. Accessed on February 15, 2023. Also see https://www.cms.gov/cms-strategic-plan.

equitable care. Thus, the Facility Commitment to Health Equity measure aims to support IPFs in leveraging available data, pursuing focused quality improvement activities, and promoting efficient and effective use of resources.

The Facility Commitment to Health Equity measure aligns with the measure previously adopted in the Hospital IQR Program, and we refer readers to the FY 2023 IPPS/LTCH PPS final rule (87 FR 49191 through 49201) for more information regarding the measure's adoption in the Hospital IQR Program. The five domains of the Facility Commitment to Health Equity measure are adapted from the CMS Office of Minority Health's Building an Organizational Response to Health Disparities framework, which focuses on data collection, data analysis, culture of equity, and quality improvement.⁵⁰

The Facility Commitment to Health Equity measure also aligns with our efforts under the Meaningful Measures Framework, which identifies high-priority areas for quality measurement and improvement to assess core issues most critical to high-quality healthcare and improving patient outcomes.⁵¹ In 2021, we launched Meaningful Measures 2.0 to promote innovation and modernization of all aspects of quality, and to address a wide variety of settings, stakeholders, and measure requirements.⁵² We are addressing healthcare priorities and gaps with Meaningful Measures 2.0 by leveraging quality measures to promote equity and close gaps in care. The Facility Commitment to Health Equity measure supports these efforts and is aligned with the Meaningful Measures Area of "Equity of Care" and the Meaningful Measures 2.0 goal to "Leverage Quality Measures to Promote Equity and Close Gaps in Care." This measure also supports the Meaningful Measures 2.0 objective to commit to a patient-centered approach in

⁵⁰ CMS. (2021). Building an Organizational Response to Health Disparities [Fact Sheet]. Available at:

https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Health-Disparities-Guide.pdf. Accessed on February 15, 2023.

51 Centers for Medicare & Medicaid Services. Meaningful Measures Framework. Available at:

https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy. Accessed on February 15, 2023.

⁵² CMS. (2022). Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at https://www.cms.gov/medicare/meaningful-measures-framework/meaningful-measures-20-moving-measure-reduction-modernization. Accessed on February 20, 2023.

quality measure and value-based incentives programs to ensure that quality and safety measures address health equity.

b. Overview of Measure

The Facility Commitment to Health Equity measure will assess IPFs' commitment to health equity using a suite of equity-focused organizational competencies aimed at achieving health equity for populations that have been disadvantaged, marginalized, and underserved by the healthcare system. As previously noted, these populations include, but are not limited to, racial and ethnic minority groups, people with disabilities, members of the LGBTQ+ community, individuals with limited English proficiency, rural populations, religious minorities, and people facing socioeconomic challenges. Table 17 sets forth the five attestation domains, and the elements within each of those domains, to which an IPF will affirmatively attest for the IPF to receive credit for that domain within the Facility Commitment to Health Equity measure.

TABLE 17: THE FACILITY COMMITMENT TO HEALTH EQUITY MEASURE FIVE

Attestation	Elements: Select all that apply
	(Note: Affirmative attestation of all elements within a
	domain will be required for the facility to receive a
	point for the domain in the numerator).
D 11 E 11 C 1 D 11	point for the domain in the numerator).
Domain 1: Equity is a Strategic Priority	
Facility commitment to reducing healthcare disparities	(A) Our facility strategic plan identifies priority
is strengthened when equity is a key organizational	populations who currently experience health
priority. Please attest that your facility has a strategic	disparities.
plan for advancing health equity* and that it includes	(B) Our facility strategic plan identifies health equity
all the following elements.	goals and discrete action steps to achieving these goals.*
	(C) Our facility strategic plan outlines specific
	resources which have been dedicated to achieving our
	equity goals.
	(D) Our facility strategic plan describes our approach
	for engaging key stakeholders, such as community-
	based organizations.
Domain 2: Data Collection	
Collecting valid and reliable demographic and SDOH	(A) Our facility collects demographic information
data on patients served in a facility is an important step	(such as self-reported race, national origin, primary
in identifying and eliminating health disparities. Please	language, and ethnicity data) and/or social determinant
attest that your facility engages in the following	of health information on the majority of our patients.**
activities.	(B) Our facility has training for staff in culturally
	sensitive collection of demographic and/or SDOH
	information.
	(C) Our facility inputs demographic and/or SDOH
	information collected from patients into structured,
	interoperable data elements using a certified electronic
	health record (EHR) technology.
Domain 3: Data Analysis	
•	

Attestation	Elements: Select all that apply
	(Note: Affirmative attestation of all elements within a
	domain will be required for the facility to receive a
	point for the domain in the numerator).
Effective data analysis can provide insights into which	(A) Our facility stratifies key performance indicators
factors contribute to health disparities and how to	by demographic and/or SDOH variables to identify
respond. Please attest that your facility engages in the	equity gaps and includes this information on facility
following activities.	performance dashboards.
Domain 4: Quality Improvement	
Health disparities are evidence that high-quality care	(A) Our facility participates in local, regional, or
has not been delivered equitably*** to all patients.	national quality improvement activities focused on
Engagement in quality improvement activities can	reducing health disparities.
improve quality of care for all patients.	
Domain 5: Leadership Engagement	
Leaders and staff can improve their capacity to address	(A) Our facility senior leadership, including chief
disparities by demonstrating routine and thorough	executives and the entire facility**** board of trustees,
attention to equity and setting an organizational culture	annually reviews our strategic plan for achieving health
of equity. Please attest that your facility engages in the	equity.
following activities.	(B) Our facility senior leadership, including chief
	executives and the entire facility board of trustees,
	annually reviews key performance indicators stratified
	by demographic and/or social factors.

^{*} After publication of the 2022 MUC List, we clarified the language in Domain 1 to refer to "health equity" instead of "healthcare equity."

(1) Measure Calculation

The Facility Commitment to Health Equity measure consists of five attestation-based questions, each representing a separate domain of the IPF's commitment to addressing health equity. Some of these domains have multiple elements to which an IPF will be required to attest. For an IPF to affirmatively attest "yes" to a domain, and receive credit for that domain, the IPF would evaluate and determine whether it engages in each of the elements that comprise that domain. Each of the domains will be represented in the denominator as a point, for a total of five points (that is, one point per domain).

The numerator of the Facility Commitment to Health Equity measure will capture the total number of domain attestations that the IPF is able to affirm. An IPF that affirmatively attests to each element within the five domains will receive the maximum five points.

An IPF will only receive a point for a domain if it attests "yes" to all related elements within that domain. There is no "partial credit" for elements. For example, for Domain 1

^{**} After publication of the 2022 MUC List, we clarified the language in Domain 2 to refer to example demographic information.

^{***} After publication of the 2022 MUC List, we clarified the language in Domain 4: "Health disparities are evidence that high quality care has not been delivered *equitably* to all patients."

^{****} After publication of the 2022 MUC List, we identified that Domain 5 incorrectly referred to the "hospital board of trustees" instead of the "facility board of trustees."

("Facility commitment to reducing healthcare disparities is strengthened when equity is a key organizational priority"), an IPF will evaluate and determine whether its strategic plan meets each of the elements described in (A) through (D) (see Table 17 in section VI.D.2.b of this final rule). If the IPF's strategic plan meets all four of these elements, the IPF would affirmatively attest "yes" to Domain 1 and would receive one (1) point for that attestation. An IPF will not be able to receive partial credit for a domain. For example, if the IPF's strategic plan meets elements (A) and (B), but not (C) and (D), of Domain 1, then the IPF would not be able to affirmatively attest "yes" to Domain 1 and would not receive a point for that attestation, and instead would receive zero points for Domain 1.

In response to our RFI on the potential for a structural measure assessing an IPF's commitment to health equity, several commenters expressed concern that such a measure would be difficult for IPFs to report because of the requirement to use certified electronic health record (EHR) technology for Domain 2 (87 FR 46972 through 46873). We believe that use of certified EHR technology is an important element of collecting valid and reliable demographic and social drivers of health data on patients served in an IPF and that use of this technology facilitates data analytics to ensure consistent, high-quality, equitable care. However, we recognize that some IPFs may face challenges to adopting certified EHR technology. We note that the IPFQR Program is a pay-for-reporting program, not a pay-for-performance program, and therefore IPFs that do not have certified EHR technology can attest that they satisfy the other domains, as applicable, and receive a score of 0-4 out of 5 without any penalties.

(2) Review by the Measure Applications Partnership (MAP)53

We included the Facility Commitment to Health Equity measure on the publicly available MUC List, a list of measures under consideration for use in various Medicare programs.⁵⁴ The

⁵³ Interested parties convened by the consensus-based entity provide input and recommendations on the Measures under Consideration (MUC) list as part of the pre-rulemaking process required by section 1890A of the Act. We refer readers to https://p4qm.org/PRMR-MSR for more information.

⁵⁴ Centers for Medicare & Medicaid Services. List of Measures Under Consideration for December 1, 2022. Available at: https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.

specifications for the Facility Commitment to Health Equity measure, which were available during the review of the MUC List, are available on the CMS website at: https://mmshub.cms.gov/sites/default/files/map-hospital-measure-specifications-manual-2022.pdf.

The CBE-convened MAP Health Equity Advisory Group reviewed the MUC List and the Facility Commitment to Health Equity measure (MUC 2022– 027) in detail on December 6 through 7, 2022.⁵⁵ The MAP Health Equity Advisory Group raised concerns that this measure does not evaluate outcomes and may not directly address health inequities at a systemic level, but generally agreed that a structural measure such as this one represents progress toward improving equitable care.⁵⁶

In addition, on December 8 through 9, 2022, the MAP Rural Health Advisory Group reviewed the 2022 MUC List and expressed support for this measure as a step towards advancing access to and quality of care with the caveat that resource challenges exist in rural communities.⁵⁷

The MAP Hospital Workgroup reviewed the 2022 MUC List on December 13 through 14, 2022.⁵⁸ The MAP Hospital Workgroup recognized that reducing health care disparities would represent a substantial benefit to overall quality of care but expressed reservations about the measure's link to clinical outcomes. As stated in the MAP recommendations document, the MAP Hospital Workgroup members voted to conditionally support the Facility Commitment to Health Equity measure for rulemaking pending: (1) endorsement by the CBE; (2) commitment to consideration of equity related outcome measures in the future; (3) provision of more clarity on the Facility Commitment to Health Equity measure and supplementing interpretation with

⁵⁵ Centers for Medicare & Medicaid Services. 2022-2023 MAP Final Recommendations. Available at: https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.

⁵⁶ Centers for Medicare & Medicaid Services. 2022-2023 MAP Final Recommendations. Available at: https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.

⁵⁷ Centers for Medicare & Medicaid Services. 2022-2023 MAP Final Recommendations. Available at: https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.

⁵⁸ Centers for Medicare & Medicaid Services. 2022-2023 MAP Final Recommendations. Available at: https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.

results; and (4) verification of accurate attestation by IPFs.⁵⁹ Thereafter, the MAP Coordinating Committee deliberated on January 24 through 25, 2023 and ultimately voted to uphold the MAP Hospital Workgroup's recommendation to conditionally support the measure for rulemaking.⁶⁰

We believe that the Facility Commitment to Health Equity measure establishes an important foundation for prioritizing the achievement of health equity among IPFs participating in the IPFQR Program. Our approach to developing health equity measures has been incremental to date, but we see inclusion of such measures in the IPFQR Program as informing efforts to advance and achieve health equity not only among IPFs, but also other acute care settings. We believe this measure to be a building block that lays the groundwork for a future meaningful suite of measures that would assess IPF progress in providing high-quality healthcare for all patients regardless of social risk factors or demographic characteristics.

(3) CBE Endorsement

We have not submitted this measure for CBE endorsement at this time. Although section 1886(s)(4)(D)(i) of the Act generally requires that measures specified by the Secretary must be endorsed by the entity with a contract under section 1890(a) of the Act, section 1886(s)(4)(D)(ii) of the Act states that, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed measures endorsed by consensus organizations and were unable to identify any other measures on this topic endorsed by a consensus organization, and therefore, we believe the exception in section 1886(s)(4)(D)(ii) of the Act applies.

⁵⁹ Centers for Medicare & Medicaid Services. 2022-2023 MAP Final Recommendations. Available at: https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.

⁶⁰ Centers for Medicare & Medicaid Services. 2022-2023 MAP Final Recommendations. Available at: https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.

c. Data Collection, Submission, and Reporting

IPFs are required to submit information for structural measures once annually using a CMS-approved web-based data collection tool available within the Hospital Quality Reporting (HQR) System. For more information about our previously finalized policies related to reporting of structural measures, we refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50890 through 50901) and the FY 2015 IPF PPS final rule (79 FR 45963 through 45964 and 45976). Given the role of committed leadership in improving health outcomes for all patients, we proposed to adopt this measure beginning with attestations submitted to CMS in CY 2025 reflecting the CY 2024 reporting period and affecting the FY 2026 payment determination.

We invited comments on our proposed adoption of the Facility Commitment to Health Equity Measure beginning with the FY 2026 payment determination.

Comment: Many commenters supported adoption of the Facility Commitment to Health Equity measure. One commenter stated that alignment with other programs will support consistent measurement across the continuum of patient care. Several commenters stated that facilities' commitment to health equity is particularly important for IPFs because of health disparities experienced by patients with mental health conditions. Several commenters stated that the Facility Commitment to Health Equity measure is consistent with new standards from The Joint Commission. One commenter stated that facilities attesting to their commitment to health equity will help empower the healthcare workforce to recognize and eliminate health disparities.

Response: We thank commenters for their support of our proposal to adopt the Facility Commitment to Health Equity measure and agree that this measure addresses a topic that is important for IPF patients and this setting.

<u>Comment</u>: Other commenters recommended additional testing, specifically in the IPF setting, to ensure that this measure addresses unique challenges associated with treating the psychiatric patient population prior to adoption of this measure. Some of these commenters also

recommended engaging IPFs to voluntarily test the measure to ensure usability, acceptability, and face validity are met for this setting.

Response: We acknowledge that this measure was initially developed for the general acute care setting. While we recognize the value of measures undergoing testing and evaluation of validity and feasibility in the setting for which they are being adopted, given the urgency of achieving health equity and, as there are currently no other existing measures that address facility commitment to health equity, we believe it is important to implement this measure as soon as feasible. Strong and consistent facility leadership can be instrumental in establishing specific, measurable, and attainable goals to advance equity priorities and improve care for all patients in any care setting, including patients who receive care in inpatient psychiatric facilities. We believe that this measure is equally applicable to freestanding IPFs and psychiatric units within acute care facilities as it is to general acute care settings. Leaders of health services organizations across the health care system, including both IPFs and acute care hospitals, are likely to encounter the same challenges and use the same types of strategies to achieve organizational goals related to improving health equity within their respective organizations. We note that health equity is a critical topic for patients treated in IPFs and that there are high levels of health disparities experienced by this patient population. CMS will monitor measure implementation and data reporting as part of standard program and measure review and will consider updates to the measure if improvements are identified through this process.

<u>Comment</u>: Many commenters expressed concern that this measure has not received endorsement by the CBE.

Response: While we recognize the value of measures undergoing review for potential CBE endorsement, given the urgency of achieving health equity, we believe it is important to implement this measure beginning with the CY 2024 reporting period. We note that, in accordance with section 1886(s)(4)(D)(ii) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or

adopted by a consensus organization identified by the Secretary. We reviewed measures endorsed by consensus organizations and were unable to identify any other measures on this topic endorsed by a consensus organization, and therefore, we believe the exception in section 1886(s)(4)(D)(ii) of the Act applies.

<u>Comment</u>: Some commenters recommended that CMS defer adoption of this measure until CMS and IPFs have reviewed the Hospital IQR Program's implementation of this measure to identify potential improvements to data collection processes that would reduce burden for IPFs. These commenters stated that IPFs often have fewer resources available for data collection relative to acute care hospitals.

Response: We acknowledge commenters' desire to be able to learn from the experiences of acute care hospitals reporting this measure. We note that hospitals participating in the Hospital IQR Program will have already reported data on the similar Hospital Commitment to Health Equity measure for the FY 2025 payment determination (that is, data submitted in CY 2024 representing the CY 2023 performance period) (87 FR 49201) before the reporting of the Facility Commitment to Health Equity Measure for the IPFQR Program begins with the FY 2026 payment determination. Given the timing of this similar measure in the Hospital IQR Program, we believe IPFs will have had the opportunity to learn from the experiences of acute care hospitals, including best practices for minimally burdensome assessment of performance on the required domains.

<u>Comment</u>: Many commenters supported adoption of this measure on the condition that CMS commit to development and adoption of health equity related outcome measures in the future.

Response: We believe this measure to be a building block that lays the groundwork for a more comprehensive suite of measures that would assess progress in providing high-quality healthcare for all patients regardless of social risk factors or demographic characteristics. This more comprehensive suite of measures could eventually include health equity related outcome

measures.

<u>Comment</u>: Many commenters recommended that CMS establish a process to ensure that results are publicly reported in a way that helps patients interpret IPF scores on the Facility Commitment to Health Equity measure.

Response: We believe this measure will provide insightful information to healthcare providers and the public on the number of IPFs currently participating in health equity strategic planning, collecting data, using these data to identify equity gaps, establishing key performance indicators, and reviewing them with hospital senior leaders. We intend to provide educational materials as part of our outreach and public reporting of this measure to ensure understanding and interpretation of publicly reported data.

<u>Comment</u>: Many commenters recommended that prior to adoption of the Facility

Commitment to Health Equity measure CMS identify a means to verify accurate attestation of commitment by IPFs.

Response: We understand commenters' concerns regarding the accuracy of provider self-reported data. While we do not have a specific means to validate IPFs' attestation to this measure, we do require all IPFs participating in the IPFQR Program to complete the Data Accuracy and Completeness Acknowledgement (DACA) each year, which requires attestation that all of the information reported to CMS for the IPFQR Program is accurate and complete. For more information on the IPFQR Program's DACA requirements, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53658).

<u>Comment</u>: Several commenters recommended that CMS update the measure specifications so that IPFs without certified EHR technology are able to positively attest to all domains. These commenters expressed concern that public reporting of measure results for IPFs that do not positively attest to all domains because they are without access to certified EHR technology could lead the public to misinterpret the results as a lack of commitment to health equity when it is actually a resource limitation which, the commenters believed, is due to a lack

of federal funding for EHR implementation.

Response: We acknowledge that some IPFs may face challenges to adopting certified EHR technology. We note that the IPFQR Program is a pay-for-reporting program, not a pay-for-performance program, and therefore IPFs that do not have certified EHR technology can attest that they satisfy the other domains, as applicable, and receive a score of 0-4 out of 5 without any penalties. We understand the commenters' concern that the public may misinterpret IPFs' reported results that are due to resource limitations as a lack of commitment to health equity. To reduce the likelihood of misinterpretation, we intend to provide educational materials as part of our outreach and public reporting of this measure to ensure understanding and appropriate interpretation of publicly reported data.

Comment: Some commenters recommended respecifying the measure so that IPFs are scored on a zero to eleven scale (one point for each element within a domain) as opposed to a zero to five scale (one point for each domain). Other commenters recommended only requiring attestation for 3 out of 5 domains. Some of these commenters stated that some domains are harder to achieve or have more required elements for attestation than others and expressed the belief that reducing the number of required domains would address this concern.

Response: We believe the five domains of this measure are actionable focus areas, and assessment of facility leadership commitment to them is foundational. We also believe this measure will incentivize providers to collect and utilize data to identify critical equity gaps, implement plans to address any identified gaps, and ensure that resources are dedicated toward addressing health equity initiatives. The five questions of the proposed structural measure are adapted from the CMS Office of Minority Health's Building an Organizational Response to Health Disparities framework, which focuses on data collection, data analysis, culture of equity, and quality improvement.⁶¹ We believe that accomplishing each element within a domain is

[Fact Sheet]. U.S. Department of Health and Human Services. Available at: https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Health-Disparities-Guide.pdf.

⁶¹ Centers for Medicare & Medicaid Services. (2021). Building an Organizational Response to Health Disparities
[Fact Short] J. S. Deportment of Health and Hyman Services. Available at https://www.eres.gov/About

important together with the other elements to help hospitals identify, prioritize, and take action on health disparities. Additionally, as discussed previously, we note that the IPFQR Program is a pay-for-reporting program, and IPFs are not scored based on their performance on measures.

<u>Comment</u>: Several commenters expressed concern that IPFs may not report the measure consistently, and one commenter recommended that CMS provide clarification of key terms (such as "strategic plan") to mitigate the risk of inconsistent reporting.

Response: We note that Attestation Guidance for the similar measure adopted in the Hospital IQR Program (the Hospital Commitment to Health Equity measure), includes definitions of key terms including "strategic plan," which we define as "a written plan to address health equity that is shared across the hospital" (or facility in the case of IPFs).⁶² To help with consistent implementation, we will develop a similar Attestation Guidance document for IPFs as part of providing educational and training materials, and which will be conveyed through routine communication channels to IPFs, vendors, and QIOs, including, but not limited to, issuing memos, emails, and notices on a CMS website.

<u>Comment</u>: One commenter did not support adoption of the Facility Commitment to Health Equity measure and expressed their belief that there is insufficient evidence that this measure leads to improved patient outcomes.

Response: We believe this measure is an important foundational measure for improving health equity among those that have been disadvantaged or underserved by the healthcare system. Furthermore, as discussed in section VI.D.2.a of the proposed rule, there is substantial research showing differences in care and experiences among these populations (88 FR 21274 through 21275). We also believe adoption of the Facility Commitment to Health Equity measure will incentivize IPFs to collect and utilize data to identify critical equity gaps, implement plans to address these gaps, and ensure that resources are dedicated toward addressing health equity

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⁶² Available at:

initiatives. This measure aims to support IPFs in leveraging available data, pursuing focused quality improvement activities, and promoting efficient and effective use of resources. Through this measure, providers are encouraged to analyze their own data to understand the many factors, including race, ethnicity, and various social drivers of health, such as housing stability and food security, in order to deliver more equitable care. We believe the delivery of more equitable care will, in turn, improve patient outcomes.

<u>Final Decision</u>: After consideration of the public comments we received, we are finalizing adoption of the Facility Commitment to Health Equity measure as proposed.

3. Adoption of the Screening for Social Drivers of Health Measure Beginning with Voluntary Reporting of CY 2024 Data Followed by Mandatory Reporting Beginning with CY 2025 Data/FY 2027 Payment Determination

a. Background

Health-related social needs (HRSNs), which we define as individual-level, adverse social conditions that negatively impact an individual person's health or healthcare, are significant risk factors associated with worse health outcomes as well as increased healthcare utilization.⁶³ We believe that consistently pursuing identification of HRSNs would have two significant benefits. First, HRSNs disproportionately impact people who have historically been underserved by the healthcare system,⁶⁴ and screening helps identify individuals who may have HRSNs. Second, screening for HRSNs could support ongoing IPF quality improvement initiatives by providing data with which to stratify patient risk and organizational performance. Further, we believe that IPFs collecting patient-level HRSN data through screening is essential for the long-term in encouraging meaningful collaboration between healthcare providers and community-based

⁶³ Centers for Medicare & Medicaid Services. (2021). A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool: Promising Practices and Key Insights. June 2021. Available at:

https://innovation.cms.gov/media/document/ahcm-screeningtool-companion. Accessed on February 20, 2023. ⁶⁴ American Hospital Association. (2020). Health Equity, Diversity & Inclusion Measures for Hospitals and Health System Dashboards. December 2020. Available at:

https://ifdhe.aha.org/system/files/media/file/2020/12/ifdhe_inclusion_dashboard.pdf. Accessed on February 20, 2023.

organizations and in implementing and evaluating related innovations in health and social care delivery.

Health disparities manifest primarily as worse health outcomes in population groups where access to care is inequitable. 65 66 67 68 69 Such differences persist across geography and healthcare settings irrespective of improvements in quality of care over time. 70 71 72 Assessment of HRSNs is an essential mechanism for capturing the interaction between social, community, and environmental factors associated with health status and health outcomes. 73 74 75

Growing evidence demonstrates that specific HRSNs are directly associated with patient health outcomes as well as healthcare utilization, costs, and performance in quality-based

⁶⁵ Seligman, H.K., & Berkowitz, S.A. (2019). Aligning Programs and Policies to Support Food Security and Public Health Goals in the United States. Annual Review of Public Health, 40(1), 319–337. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6784838/. Accessed on February 20, 2023.

⁶⁶ The Physicians Foundation. (2020). Survey of America's Patients, Part Three. Available at: https://physiciansfoundation.org/wp-content/uploads/2020/10/2020-Physicians-Foundation-Survey-Part3.pdf. Accessed on February 20, 2023.

⁶⁷ Office of the Assistant Secretary for Planning and Evaluation (ASPE) (2020). Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Program (Second of Two Reports). Available at: https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress. Accessed on February 20, 2023.

⁶⁸ Trivedi AN, Nsa W, Hausmann LRM, et al. (2014). Quality and Equity of Care in U.S. Hospitals. N Engl J Med, 371(24), 2298-2308. Available at: https://www.nejm.org/doi/10.1056/NEJMsa1405003. Accessed on February 13, 2023.

⁶⁹ Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: https://doi.org/10.31478/201705b. Accessed on February 20, 2023.

⁷⁰ Office of the Assistant Secretary for Planning and Evaluation (ASPE) (2020). Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Program (Second of Two Reports). Available at: https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress. Accessed on February 20, 2023.

⁷¹ Hill-Briggs, F. (2021). Social Determinants of Health and Diabetes: A Scientific Review. Diabetes Care. Available at: https://diabetesjournals.org/care/article/44/1/258/33180/Social-Determinants-of-Health-and-Diabetes-A. Accessed on February 20, 2023.

⁷² Khullar, D., MD. (2020). Association Between Patient Social Risk and Physician Performance American academy of Family Physicians. Addressing Social Determinants of Health in Primary Care team-based approach for advancing health equity. Available at:

https://www.aafp.org/dam/AAFP/documents/patient care/everyone project/team-based-approach.pdf. Accessed on February 20, 2023.

⁷³ Institute of Medicine. (2014). Capturing Social and Behavioral Domains and Measures in Electronic Health Records: Phase 2. Washington, DC: The National Academies Press. Available at: https://doi.org/10.17226/18951. Accessed on February 20, 2023.

⁷⁴ Alley, D.E., C.N. Asomugha, P.H. Conway, and D.M. Sanghavi. (2016). Accountable Health Communities— Addressing Social Needs through Medicare and Medicaid. The New England Journal of Medicine 374(1):8-11. Available at: https://doi.org/10.1056/NEJMp1512532. Accessed on February 20, 2023.

⁷⁵ Centers for Disease Control and Prevention. CDC COVID-19 Response Health Equity Strategy: Accelerating Progress Towards Reducing COVID-19 Disparities and Achieving Health Equity. July 2020. Available at: https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/cdc-strategy.html. Accessed on February 2, 2023.

payment programs.^{76 77} While widespread interest in addressing HRSNs exists, action is inconsistent.⁷⁸

While social risk factors account for 50 to 70 percent of health outcomes, the mechanisms by which this connection emerges are complex and multifaceted. ^{79 80 81 82} The persistent interactions among individuals' HRSNs, medical providers' practices and behaviors, and community resources significantly impact healthcare access, quality, and ultimately costs, as described in the CMS Equity Plan for Improving Quality in Medicare. ^{83 84} In their 2018 survey, to which more than 8,500 physicians responded, the Physicians Foundation found that almost 90 percent of these physician respondents reported their patients had a serious health problem linked to poverty or other social conditions. ⁸⁵ Additionally, associations among disproportionate

⁷⁶ Zhang Y, Li J, Yu J, Braun RT, Casalino LP (2021). Social Determinants of Health and Geographic Variation in Medicare per Beneficiary Spending. JAMA Network Open. 2021;4(6):e2113212.

https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2780864. Accessed on February 20, 2023.

⁷⁷ Khullar, D., Schpero, W.L., Bond, A.M., Qian, Y., & Casalino, L.P. (2020). Association Between Patient Social Risk and Physician Performance Scores in the First Year of the Merit-based Incentive Payment System. JAMA, 324(10), 975–983. https://doi.org/10.1001/jama.2020.13129. Accessed on February 20, 2023.

⁷⁸ TK Fraze, AL Brewster, VA Lewis, LB Beidler, GF Murray, CH Colla. Prevalence of screening for food insecurity, housing instability, utility needs, transportation needs, and interpersonal violence by US physician practices and hospitals. JAMA Network Open 2019;

https://jamanetwork.com/journals/jamanetworkopen/fullarticle/10.1001/jamanetworkopen.2019.11514. Accessed on February 20, 2023.

⁷⁹ Kaiser Family Foundation. (2021). Racial and Ethnic Health Inequities and Medicare. Available at: https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/. Accessed February 20, 2023.

⁸⁰ Khullar, D., MD. (2020). Association Between Patient Social Risk and Physician Performance American academy of Family Physicians. Addressing Social Determinants of Health in Primary Care team-based approach for advancing health equity. Available at:

https://www.aafp.org/dam/AAFP/documents/patient_care/everyone_project/team-based-approach.pdf. Accessed on February 20, 2023.

⁸¹ Hammond, G., Johnston, K., Huang, K., Joynt Maddox, K. (2020). Social Determinants of Health Improve Predictive Accuracy of Clinical Risk Models for Cardiovascular Hospitalization, Annual Cost, and Death. Circulation: Cardiovascular Quality and Outcomes, 13 (6) 290–299. Available at: https://doi.org/10.1161/CIRCOUTCOMES.120.006752. Accessed on February 20, 2023.

⁸² The Physicians Foundation. (2021). Viewpoints: Social Determinants of Health. Available at: https://physiciansfoundation.org/wp-content/uploads/2019/08/The-Physicians-Foundation-SDOH-Viewpoints.pdf. Accessed on February 20, 2023.

⁸³ Centers for Medicare & Medicaid Services. (2021). Paving the Way to Equity: A Progress Report. Available at: https://www.cms.gov/files/document/paving-way-equity-cms-omh-progress-report.pdf. Accessed on February 20, 2023.

⁸⁴ Centers for Medicare & Medicaid Services Office of Minority Health. (2021). The CMS Equity Plan for Improving Quality in Medicare. 2015–2021. Available at: https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH Dwnld-

CMS_EquityPlanforMedicare_090615.pdf#:~:text=The%20Centers%20for%20Medicare%20%26%20Medicaid%2 0Services%20%28CMS%29,evidence%20base%2C%20identifying%20opportunities%2C%20and%20gathering%2 0stakeholder%20input. Accessed on February 20, 2023.

⁸⁵ The Physicians Foundation. (2019). Viewpoints: Social Determinants of Health. Available at:

health risk, hospitalization, and adverse health outcomes have been highlighted and magnified by the COVID-19 pandemic.^{86 87}

In 2017, CMS' Center for Medicare and Medicaid Innovation (CMMI) launched the Accountable Health Communities (AHC) Model to test the impact of systematically identifying and addressing the HRSNs of Medicare and Medicaid beneficiaries (that is, through screening, referral, and community navigation) on their health outcomes and related healthcare utilization and costs. 88 89 90 91 The AHC Model is one of the first federal pilots to systematically test whether identifying and addressing core HRSNs improves healthcare costs, utilization, and outcomes with over 600 clinical sites in 21 states. 92 The AHC Model had a 5-year period of performance that began in May 2017 and ended in April 2022, with beneficiary screening beginning in the summer of 2018. 93 94 Evaluation of the AHC Model data is still underway.

Under the AHC Model, the following five core domains were selected to screen for HRSNs among Medicare and Medicaid beneficiaries: (1) food insecurity; (2) housing instability;

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https://physiciansfoundation.org/wp-content/uploads/2019/08/The-Physicians-Foundation-SDOH-Viewpoints.pdf. Accessed on February 20, 2023.

⁸⁶ Centers for Disease Control and Prevention. (2020). CDC COVID–19 Response Health Equity Strategy: Accelerating Progress Towards Reducing COVID–19 Disparities and Achieving Health Equity. July 2020. Available at: https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/cdc-strategy.html. Accessed on February 20, 2023.

⁸⁷ Kaiser Family Foundation. (2021). Racial and Ethnic Health Inequities and Medicare. Available at: https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/. Accessed on February 20, 2023.

⁸⁸ Centers for Medicare & Medicaid Services. (2021). A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool: Promising Practices and Key Insights. June 2021. Accessed: November 23, 2021. Available at: https://innovation.cms.gov/media/document/ahcm-screeningtool-companion. Accessed on February 20, 2023.

⁸⁹ Alley, D.E., Asomugha, C.N., et al. (2016). Accountable Health Communities—Addressing Social Needs through Medicare and Medicaid. The New England Journal of Medicine 374(1):8–11. Available at: https://doi.org/10.1056/NEJMp1512532. Accessed on February 20, 2023.

⁹⁰ Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: https://doi.org/10.31478/201705b. Accessed on February 20, 2023.

⁹¹ Centers for Medicare & Medicaid Services. (2021). Accountable Health Communities Model. Accountable Health Communities Model | CMS Innovation Center Available at: https://innovation.cms.gov/innovation-models/ahcm. Accessed on February 20, 2023.

⁹² RTI International. (2020). Accountable Health Communities (AHC) Model Evaluation. Available at: https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt. Accessed on February 20, 2023.

⁹³ RTI International. (2020). Accountable Health Communities (AHC) Model Evaluation. Available at: https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt. Accessed on February 20, 2023.

⁹⁴ We note that the model officially concluded in April 2022, but many awardees have continued with no-cost extensions to continue utilizing unspent cooperative agreement funding and all awardees will conclude by April 2023.

(3) transportation needs; (4) utility difficulties; and (5) interpersonal safety. These domains were chosen based upon literature review and expert consensus utilizing the following criteria: (1) availability of high-quality scientific evidence linking a given HRSN to adverse health outcomes and increased healthcare utilization, including hospitalizations and associated costs; (2) ability for a given HRSN to be screened and identified in the inpatient setting prior to discharge, addressed by community-based services, and potentially improve healthcare outcomes, including reduced readmissions; and (3) evidence that a given HRSN is not systematically addressed by healthcare providers.⁹⁵ In addition to established evidence of their association with health status, risk, and outcomes, these five domains were selected because they can be assessed across the broadest spectrum of individuals in a variety of settings.⁹⁶ 97 98

These five evidence-based HRSN domains, which informed development of the two Social Drivers of Health measures adopted in the Hospital IQR Program and finalized here for the IPFQR Program, are described in Table 18. We note that while the measures were initially developed by The Health Initiative (THI), CMS has since assumed stewardship.

TABLE 18: THE FIVE CORE HRSN DOMAINS TO SCREEN FOR SOCIAL DRIVERS OF HEALTH

Domain	Description
Food Insecurity	Food insecurity is defined as limited or uncertain
	access to adequate quality and quantity of food at the
	household level. It is associated with diminished
	mental and physical health and increased risk for
	chronic conditions. ^{99 100} Individuals experiencing food

⁹⁵ Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: https://doi.org/10.31478/201705b. Accessed on February 20, 2023.

⁹⁶ Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: https://doi.org/10.31478/201705b. Accessed on February 20, 2023.

⁹⁷ Centers for Medicare & Medicaid Services. (2021). Accountable Health Communities Model. Accountable Health Communities Model | CMS Innovation Center. Available at: https://innovation.cms.gov/innovation-models/ahcm. Accessed on February 20, 2023.

⁹⁸ Kamyck, D., Senior Director of Marketing. (2019). CMS releases standardized screening tool for health-related social needs. Activate Care. Available at: https://blog.activatecare.com/standardized-screening-for-health-related-social-needs-in-clinical-settings-the-accountable-health-communities-screening-tool/. Accessed on February 20, 2023.

 ⁹⁹ Berkowitz SA, Seligman HK, Meigs JB, Basu S. Food insecurity, healthcare utilization, and high cost: a longitudinal cohort study. Am J Managed Care. 2018 Sep;24(9):399–404. PMID: 30222918; PMCID: PMC6426124. Available at https://pubmed.ncbi.nlm.nih.gov/30222918/. Accessed on February 20, 2023.
 ¹⁰⁰ Hill-Briggs, F. (2021). Social Determinants of Health and Diabetes: A Scientific Review. Diabetes Care. Available at: https://diabetesjournals.org/care/article/44/1/258/33180/Social-Determinants-of-Health-and-Diabetes-A. Accessed on February 20, 2023.

Domain	Description
	insecurity often have inadequate access to healthier
	food options which can impede self-management of
	chronic diseases like diabetes and heart disease, and
	require individuals to make personal trade-offs
	between food purchases and medical needs, including
	prescription medication refills and preventive health
	services. 101 102 Food insecurity is associated with high-
	cost healthcare utilization including emergency
	department (ED) visits and hospitalizations. 103 104 105
	Evidence indicates that individuals with serious mental
	illness have a higher prevalence of food insecurity than
	the U.S. population as a whole (specifically 71%
	prevalence among patients with severe mental illness
	versus 14.9% in the population as a whole). 106
Housing Instability	Housing instability encompasses multiple conditions
	ranging from inability to pay rent or mortgage,
	frequent changes in residence including temporary
	stays with friends and relatives, living in crowded
	conditions, and actual lack of sheltered housing in
	which an individual does not have a personal
	residence. 107 108 Population surveys consistently show
	that people from some racial and ethnic minority
	groups constitute the largest proportion of the U.S.
	population experiencing housing instability ¹⁰⁹
	Housing instability is associated with higher rates of
	chronic illnesses, injuries, and complications and more
	frequent utilization of high-cost healthcare services. 110
	111 Additionally, housing instability can exacerbate

...

¹⁰¹ Seligman, H.K., & Berkowitz, S.A. (2019). Aligning Programs and Policies to Support Food Security and Public Health Goals in the United States. Annual Review of Public Health, 40(1), 319–337. Available at: https://pubmed.ncbi.nlm.nih.gov/30444684/. Accessed on February 20, 2023.

¹⁰² National Academies of Sciences, Engineering, and Medicine 2006. Executive Summary: Cost-Benefit Analysis of Providing Non-Emergency Medical Transportation. Washington, DC: The National Academies Press. Available at: https://doi.org/10.17226/23285. Accessed on February 20, 2023.

¹⁰³ Hill-Briggs, F. (2021). Social Determinants of Health and Diabetes: A Scientific Review. Diabetes Care. Available at: https://diabetesjournals.org/care/article/44/1/258/33180/Social-Determinants-of-Health-and-Diabetes-A. Accessed on February 20, 2023.

Berkowitz SA, Seligman HK, Meigs JB, Basu S. Food insecurity, healthcare utilization, and high cost: a longitudinal cohort study. Am J Managed Care. 2018 Sep;24(9):399–404. PMID: 30222918; PMCID: PMC6426124. Available at https://pubmed.ncbi.nlm.nih.gov/30222918/. Accessed on February 20, 2023.

Dean, E.B., French, M.T., & Mortensen, K. (2020a). Food insecurity, health care utilization, and health care expenditures. Health Services Research, 55(S2), 883–893. Available at: https://doi.org/10.1111/1475-6773.13283. Accessed on February 20, 2023.

https://ps.psychiatryonline.org/doi/10.1176/appi.ps.201300022?url_ver=Z39.88-

^{2003&}amp;rfr id=ori:rid:crossref.org&rfr dat=cr pub%20%200pubmed. Accessed on February 20, 2023.

Larimer, M.E. (2009). Health Care and Public Service Use and Costs Before and After Provision of Housing for Chronically Homeless Persons with Severe Alcohol Problems. JAMA, 301(13), 1349. Available at: https://doi.org/10.1001/jama.2009.414.

¹⁰⁸ Hill-Briggs, F. (2021, January 1). Social Determinants of Health and Diabetes: A Scientific Review. Diabetes Care. Available at: https://pubmed.ncbi.nlm.nih.gov/33139407/.

Henry, M., de Sousa, T., Roddey, C., Gayen, S., Bednar, T.; Abt Associates. The 2020 Annual Homeless Assessment Report (AHAR) to Congress; Part 1: Point-in-Time Estimates of Homelessness, January 2021. U.S. Department of Housing and Urban Development. Accessed November 24, 2021. Available at: https://www.huduser.gov/portal/sites/default/files/pdf/2020-AHAR-Part-1.pdf.

Larimer, M.E. (2009). Health Care and Public Service Use and Costs Before and After Provision of Housing for Chronically Homeless Persons with Severe Alcohol Problems. JAMA, 301(13), 1349. Available at: https://doi.org/10.1001/jama.2009.414.

Baxter, A., Tweed, E., Katikireddi, S., Thomson, H. (2019). Effects of Housing First approaches on health and well-being of adults who are homeless or at risk of homelessness: systematic review and meta-analysis of

Domain	Description
	psychiatric conditions and individuals with psychiatric
	conditions are more likely to have housing
	instability. ¹¹²
Transportation Needs	Unmet transportation needs include limitations that impede transportation to destinations required for all aspects of daily living. 113 Groups disproportionately affected include older adults (aged >65 years), people with lower incomes, people with impaired mobility, residents of rural areas, and people from some racial and ethnic minority groups. Transportation needs contribute to postponement of routine medical care and preventive services which ultimately lead to chronic illness exacerbation and more frequent utilization of high-cost healthcare services including emergency medical services, EDs, and hospitalizations. 114 115 116 117 Patients with serious mental illness often lack access to transportation with many Medicaid eligible patients relying on Medicaid's non-emergency medical transportation (NEMT) to access needed healthcare, though this does not provide access to transportation to
	other aspects of daily living. 118
Utility Difficulties	Inconsistent availability of electricity, water, oil, and gas services is directly associated with housing instability and food insecurity. Specifically, interventions that increase or maintain access to such services have been associated with individual and population-level health improvements. 120
Interpersonal Safety	Interpersonal safety affects individuals across the lifespan, from birth to old age, and is directly linked to mental and physical health. Assessment for this domain includes screening for exposure to intimate

randomized controlled trials. Journal of Epidemiology and Community Health, 73; 379–387. Available at: https://jech.bmj.com/content/jech/73/5/379.full.pdf.

health/#:~:text=Mental%20health%20is%20correlated%20with%20housing%20in%20several,homeless%20population%20in%20America%20suffer%20a%20mental%20illness. Accessed on December 7, 2022.

Housing Instability and Mental Health. UNC Greensboro. May 7, 2021. Available at: https://chcs.uncg.edu/housing-instability-mental-

National Academies of Sciences, Engineering, and Medicine 2006. Executive Summary: Cost-Benefit Analysis of Providing Non-Emergency Medical Transportation. Washington, DC: The National Academies Press. Available at: https://doi.org/10.17226/23285.

¹¹⁴ National Academies of Sciences, Engineering, and Medicine 2006. Executive Summary: Cost-Benefit Analysis of Providing Non-Emergency Medical Transportation. Washington, DC: The National Academies Press. Available at: https://doi.org/10.17226/23285.

Hill-Briggs, F. (2021, January 1). Social Determinants of Health and Diabetes: A Scientific Review. Diabetes Care. Available at: https://pubmed.ncbi.nlm.nih.gov/33139407/.

¹¹⁶ Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: https://doi.org/10.31478/201705b.

Shier, G., Ginsburg, M., Howell, J., Volland, P., & Golden, R. (2013). Strong Social Support Services, Such as Transportation And Help For Caregivers, Can Lead To Lower Health Care Use And Costs. Health Affairs, 32(3), 544–551. Available at: https://doi.org/10.1377/hlthaff.2012.0170.

https://www.nami.org/Advocacy/Policy-Priorities/Supporting-Community-Inclusion-and-Non-Discrimination/Medicaid-Non-Emergency-Medical-Transportation.

¹¹⁹ Baxter, A., Tweed, E., Katikireddi, S., Thomson, H. (2019). Effects of Housing First approaches on health and well-being of adults who are homeless or at risk of homelessness: systematic review and meta-analysis of randomized controlled trials. Journal of Epidemiology and Community Health, 73; 379–387. Available at: https://jech.bmj.com/content/jech/73/5/379.full.pdf.

Wright, B.J., Vartanian, K.B., Li, H.F., Royal, N., & Matson, J.K. (2016). Formerly Homeless People Had Lower Overall Health Care Expenditures After Moving into Supportive Housing. Health Affairs, 35(1), 20–27. Available at: https://doi.org/10.1377/hlthaff.2015.0393.

Domain	Description
	partner violence, child abuse, and elder abuse. 121
	Exposure to violence and social isolation are reflective
	of individual-level social relations and living
	conditions that are directly associated with injury,
	psychological distress, and death in all age groups. 122
	Research indicates that adults with mental illness
	are at an increased risk of being victims of violence,
	noting that 30.9 percent were victims of violence
	within a six month period and recommending increased
	public health interventions to reduce violence in this
	vulnerable population. ¹²⁴

As a first step towards leveraging the opportunity to close equity gaps by identifying patients' HRSNs, we finalized the adoption of two evidence-based measures in the Hospital IQR Program – the Screening for Social Drivers of Health measure and the Screen Positive Rate for Social Drivers of Health measure (collectively, Social Drivers of Health measures) – and refer readers to the FY 2023 IPPS/LTCH PPS final rule (87 FR 49191 through 49220).

Through adoption in the IPFQR Program, these two Social Drivers of Health measures (that is, the Screening for Social Drivers of Health measure discussed in this section and the Screen Positive Rate for Social Drivers of Health measure discussed in section VI.D.4 of this final rule) will support identification of specific risk factors for inadequate healthcare access and adverse health outcomes among patients. We note that these measures will enable systematic collection of HRSNs data. This activity aligns with our other efforts beyond the acute care setting, including the CY 2023 Medicare Advantage and Part D final rule in which we finalized the policy requiring that all Special Needs Plans (SNPs) include one or more questions on housing stability, food security, and access to transportation in their health risk assessment using

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¹²¹ Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: https://doi.org/10.31478/201705b.

Henry M., de Sousa, T., Roddey, C., Gayen, S., Bednar, T.; Abt Associates. The 2020 Annual Homeless Assessment Report (AHAR) to Congress; Part 1: Point-in-Time Estimates of Homelessness, January 2021. U.S. Department of Housing and Urban Development. Accessed November 24, 2021. Available at: https://www.huduser.gov/portal/sites/default/files/pdf/2020-AHAR-Part-1.pdf.

Larimer, M.E. (2009). Health Care and Public Service Use and Costs Before and After Provision of Housing for Chronically Homeless Persons with Severe Alcohol Problems. JAMA, 301(13), 1349. Available at: https://doi.org/10.1001/jama.2009.414.

https://ajph.aphapublications.org/doi/abs/10.2105/AJPH.2013.301680

questions from a list of screening instruments specified in sub-regulatory guidance (87 FR 27726 through 27740) as well as the CY 2023 Physician Fee Schedule (PFS) final rule in which we adopted the Screening for Social Drivers of Health measure in the Merit-based Incentive Payment System (MIPS) (87 FR 70054 through 70055).

The Social Drivers of Health measures (as set forth in this section VI.D.3 and section VI.D.4. of this final rule) will encourage IPFs to identify patients with HRSNs, who are known to experience the greatest risk of poor health outcomes, thereby improving the accuracy of high-risk prediction calculations. Improvement in risk prediction has the potential to reduce healthcare access barriers, address the disproportionate expenditures attributed to people with greatest risk, and improve the IPF's quality of care. 125 126 127 128 Further, these data could guide future public and private resource allocation to promote targeted collaboration among IPFs, health systems, community-based organizations, and others in support of improving patient outcomes. We believe that this screening is especially important for IPF patients because patients with psychiatric conditions have an increased risk of having HRSNs. 129

In the FY 2023 IPF PPS final rule, we observed that the Hospital IQR Program had proposed two Social Drivers of Health measures and stated that we would consider these measures for the IPFQR Program in the future (87 FR 46873). The first of these two measures is the Screening for Social Drivers of Health measure, which assesses the percent of patients

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https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2798096. Accessed on December 7, 2022.

¹²⁵ Baker, MC, Alberti, PM, et al. (2021). Social Determinants Matter for Hospital Readmission Policy: Insights From New York City. Health Affairs, 40(4), 645–654. Available at: https://doi.org/10.1377/hlthaff.2020.01742. Accessed on February 20, 2023.

¹²⁶ Hammond, G., Johnston, K., et al. (2020). Social Determinants of Health Improve Predictive Accuracy of Clinical Risk Models for Cardiovascular Hospitalization, Annual Cost, and Death. Circulation: Cardiovascular Quality and Outcomes, 13 (6) 290–299. Available at: https://doi.org/10.1161/CIRCOUTCOMES.120.006752. Accessed on February 20, 2023.

¹²⁷ Hill-Briggs, F. (2021). Social Determinants of Health and Diabetes: A Scientific Review. Diabetes Care. Available at: https://diabetesjournals.org/care/article/44/1/258/33180/Social-Determinants-of-Health-and-Diabetes-A. Accessed on February 20, 2023.

 ¹²⁸ Jaffrey, J.B., Safran, G.B., Addressing Social Risk Factors in Value-Based Payment: Adjusting Payment Not Performance to Optimize Outcomes and Fairness. Health Affairs Blog, April 19, 2021. Available at: https://www.healthaffairs.org/do/10.1377/forefront.20210414.379479/full/. Accessed on February 20, 2023.
 ¹²⁹ Adepoju, OE, Liaw, W, et al. (2022) Assessment of Unmet Health-Related Social Needs Among Patients with Mental Illness Enrolled in Medicare Advantage. Available at:

admitted to the hospital who are 18 years or older at time of admission and are screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.

Utilization of screening tools to identify the burden of unmet HRSNs can be a helpful first step for IPFs in identifying necessary community partners and connecting individuals to resources in their communities. We believe collecting data across the same five HRSN domains that were screened under the AHC Model and adopted for acute care hospitals in the Hospital IQR Program will illuminate their impact on health outcomes and disparities and the healthcare cost burden for IPFs, particularly for IPFs that serve patients with disproportionately high levels of social risk, given that patients with serious mental illness are especially vulnerable to and affected by HRSNs. In addition, data collection in the IPF care setting could inform meaningful and sustainable solutions for provider-types participating in other quality reporting programs to close equity gaps among the communities they serve.¹³⁰ ¹³¹ ¹³² ¹³³ ¹³⁴

For data collection of the Screening for Social Drivers of Health measure, IPFs could use a self-selected screening tool and collect these data in multiple ways, which can vary to accommodate the population they serve and their individual needs. One example of a potential screening tool for IPFs to collect data on the Screening for Social Drivers Health Measure is the AHC Model's standard 10-item AHC Health-Related Social Needs Screening Tool (AHC HRSN Screening Tool), which enables providers to identify HRSNs in the five core domains (described in Table 18) among community-dwelling Medicare, Medicaid, and dually eligible beneficiaries.

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The Physicians Foundation: 2020 Survey of America's Patients, Part Three. Available at: https://physiciansfoundation.org/wp-content/uploads/2020/10/2020-Physicians-Foundation-Survey-Part3.pdf.
 Office of the Assistant Secretary for Planning and Evaluation (ASPE) (2020). Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Program (Second of Two Reports). Available at: https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress.

Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: https://doi.org/10.31478/201705b.

las Baker, M.C., Alberti, P.M., Tsao, T.Y., Fluegge, K., Howland, R.E., & Haberman, M. (2021). Social Determinants Matter for Hospital Readmission Policy: Insights From New York City. Health Affairs, 40(4), 645–654. Available at: https://doi.org/10.1377/hlthaff.2020.01742.

De Marchis, E., Knox, M., Hessler, D., WillardGrace, R., Oliyawola, JN, et al. (2019). Physician Burnout and Higher Clinic Capacity to Address Patients' Social Needs. The Journal of the American Board of Family Medicine, 32 (1), 69–78.

The AHC Model, including its screening tool, was tested across many care delivery sites in diverse geographic locations across the United States. More than one million Medicare and Medicaid beneficiaries have been screened using the AHC HRSN Screening Tool, which was evaluated psychometrically and demonstrated evidence of both reliability and validity, including inter-rater reliability and concurrent and predictive validity. Moreover, the AHC HRSN Screening Tool can be implemented in a variety of places where patients seek healthcare, including inpatient psychiatric facilities.

The intent of the Screening for Social Drivers of Health measure is to promote adoption of HRSN screening by IPFs. We encourage IPFs to use the screening as a basis for developing their own individual action plans (for example, navigation services and subsequent referral), as well as an opportunity to initiate or improve partnerships with community-based service providers. We believe that this measure will yield actionable information to close equity gaps by encouraging IPFs to identify patients with HRSNs, with a reciprocal goal of strengthening linkages between IPFs and local community-based partners to promptly connect patients and families to the support they need.

Both the Screening for Social Drivers of Health measure and the Screen Positive Rate for Social Drivers of Health measure, discussed in VI.D.4. of this final rule, address our Meaningful Measures Framework's 135 quality priority of "Work with Communities to Promote Best Practices of Healthy Living" through the Meaningful Measures Area of "Equity of Care." Additionally, pursuant to our Meaningful Measures 2.0, these Social Drivers of Health measures address the equity priority area and align with our commitment to introduce plans to close health equity gaps and promote equity through quality measures, including to "develop and implement measures that reflect social and economic determinants." Development, proposal, and adoption of these

¹³⁵ Centers for Medicare & Medicaid Services. Meaningful Measures Framework. Available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.

¹³⁶ Centers for Medicare & Medicaid Services. Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at: https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization.

measures also aligns with our strategic pillar to advance health equity by addressing the health disparities that underlie our health system.¹³⁷ Further, inclusion of these measures in the IPFQR Program aligns with these measures' adoption in the Hospital IQR Program in the FY 2023 IPPS/LTCH final rule (87 FR 49202 through 49215).

The Screening for Social Drivers of Health measure (alongside the Screen Positive Rate for Social Drivers of Health measure described in section VI.D.4 of this final rule) will be the first measurement of social drivers of health in the IPFQR Program. We believe these measures are appropriate for measurement of the quality of care furnished by IPFs. Screening patients for HRSNs during inpatient hospitalization in an IPF will allow healthcare providers, including IPFs, to identify and potentially help address HRSNs for this medically underserved patient population as part of discharge planning and contribute to long-term improvements in patient outcomes. Identifying and addressing HRSNs for patients receiving care in IPFs could have a direct and positive impact on IPFs' quality performance because of improvements in patient outcomes that could occur when patients' HRSNs are reduced. Moreover, collecting aggregate data on the HRSNs of IPF patient populations via these measures is crucial in informing design of future measures that could enable us to set appropriate performance targets for IPFs with respect to closing the gap on health equity.

b. Overview of Measure

The Screening for Social Drivers of Health measure assesses whether an IPF implements screening for all patients who are 18 years or older at time of admission for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety. To report on this measure, IPFs will provide: (1) the number of inpatients admitted to the facility who are 18 years or older at time of admission and who are screened for all of the five HRSNs (food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety);

Brooks-LaSure, C. (2021). My First 100 Days and Where We Go From Here: A Strategic Vision for CMS. Available at: https://www.cms.gov/blog/my-first-100-days-and-where-we-go-here-strategic-vision-cms.

and (2) the total number of patients who are admitted to the facility who are 18 years or older on the date they are admitted.

Measure specifications for the Screening for Social Drivers of Health measure, which were available during the review of the MUC List, are available at https://mmshub.cms.gov/sites/default/files/map-hospital-measure-specifications-manual-2022.pdf.

(1) Measure Calculation

(a) Cohort

The Screening for Social Drivers of Health measure assesses the total number of patients aged 18 years and older, screened for HRSNs (specifically, food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety) during an IPF stay.

(b) Numerator

The numerator of the Screening for Social Drivers of Health measure consists of the number of patients admitted to an IPF stay who are 18 years or older on the date of admission and are screened during their IPF stay for all of the following five HRSNs: food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.

(c) Denominator

The denominator of the Screening for Social Drivers of Health measure consists of the number of patients who are admitted to an IPF stay and who are 18 years or older on the date of admission. The following patients are excluded from the denominator: (1) patients who opt-out of screening; and (2) patients who are themselves unable to complete the screening during their inpatient stay and have no legal guardian or caregiver able to do so on the patient's behalf during their IPF stay.

(d) Calculation

The Screening for Social Drivers of Health measure is calculated as the number of patients admitted to an IPF stay who are 18 years or older on the date of admission screened for

all five HRSNs (food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety) divided by the number of patients 18 years or older on the date of admission admitted to the IPF.

(2) Review by the Measure Applications Partnership

We included the Screening for Social Drivers of Health measure on the publicly available "List of Measures Under Consideration for December 1, 2022" (MUC List), a list of measures under consideration for use in various Medicare programs.¹³⁸ The CBE-convened MAP Health Equity Advisory Group reviewed the MUC List including the Screening for Social Drivers of Health measure (MUC 2022–053) in detail on December 6 through 7, 2022.¹³⁹ The MAP Health Equity Advisory Group expressed support for the collection of data related to social drivers of health, but raised concerns regarding public reporting of these data and potential repetition of asking patients the same questions across settings.¹⁴⁰

In addition, on December 8 through 9, 2022, the MAP Rural Health Advisory Group reviewed the 2022 MUC List and the MAP Hospital Workgroup did so on December 13 through 14, 2022.¹⁴¹ The MAP Rural Health Advisory Group noted some potential reporting challenges including the potential masking of health disparities that are underrepresented in some areas and that sample size and populations served may be an issue, but expressed that the Screening for Social Drivers of Health measure serves as a starting point to determine where screening is occurring. The MAP Hospital Workgroup expressed strong support for the measure but noted that interoperability will be important and cautioned about survey fatigue. The MAP Hospital Workgroup members conditionally supported the measure pending: (1) testing of the measure's reliability and validity; (2) endorsement by the CBE; (3) additional details on how potential tools

¹³⁸ Centers for Medicare & Medicaid Services. List of Measures Under Consideration for December 1, 2022.

Available at: https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.

139 Centers for Medicare & Medicard Services 2022 2023 MAP Final Recommendations. Available at:

¹³⁹ Centers for Medicare & Medicaid Services. 2022-2023 MAP Final Recommendations. Available at: https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.

¹⁴⁰ Centers for Medicare & Medicaid Services. 2022-2023 MAP Final Recommendations. Available at: https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.

¹⁴¹ Centers for Medicare & Medicaid Services. 2022-2023 MAP Final Recommendations. Available at: https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.

map to the individual HRSNs, as well as best practices; (4) identification of resources that may be available to assist patients with identified HRSNs; and (5) the measure's alignment with data standards, particularly the GRAVITY project.¹⁴² The GRAVITY project's mission statement is "to serve as the open public collaborative advancing health and social data standardization for health equity."¹⁴³ Thereafter, the MAP Coordinating Committee deliberated on January 24 through 25, 2023, and ultimately voted to uphold the MAP Hospital Workgroup's recommendation to conditionally support for rulemaking with the same conditions.¹⁴⁴

We believe this measure establishes an important foundation for prioritizing the achievement of health equity among IPFs. Our approach to developing health equity measures is incremental, and we believe that health care equity outcomes in the IPFQR Program will inform future efforts to advance and achieve health care equity by IPFs. We additionally believe this measure to be a building block that lays the groundwork for a future meaningful suite of measures that would assess IPF progress in providing high-quality healthcare for all patients, regardless of social risk factors or demographic characteristics.

(3) CBE Endorsement

We have not submitted this measure for CBE endorsement at this time. Although section 1886(s)(4)(D)(i) of the Act generally requires that measures specified by the Secretary must be endorsed by the entity with a contract under section 1890(a) of the Act, section 1886(s)(4)(D)(ii) of the Act, states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to a measure that has been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed measures endorsed by

Centers for Medicare & Medicaid Services. 2022-2023 MAP Final Recommendations. Available at: https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.
 https://thegravityproject.net/

¹⁴⁴ Centers for Medicare & Medicaid Services. 2022-2023 MAP Final Recommendations. Available at: https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.

consensus organizations and were unable to identify any other measures on this topic endorsed by a consensus organization and therefore, we believe the exception in section 1886(s)(4)(D)(ii) of the Act applies.

c. Data Collection, Submission and Reporting

We believe incremental implementation of the Screening for Social Drivers of Health measure, by permitting one year of voluntary reporting prior to mandatory reporting, will allow IPFs who are not yet screening patients for HRSNs to get experience with collecting data for this measure and equally allow IPFs who already undertake screening efforts to report data already being collected. Therefore, we proposed voluntary reporting of this measure beginning with the data collected in CY 2024, which would be reported to CMS in CY 2025, followed by mandatory reporting beginning with data collected in CY 2025, which would be reported to CMS in CY 2026 for the FY 2027 payment determination.

Due to variability across IPFs and the populations they serve, and in alignment with the Hospital IQR Program, we will allow IPFs flexibility with the selection of tools to screen patients for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety. Potential sources of these data could include, for example, administrative claims data, electronic clinical data, standardized patient assessments, or patient-reported data and surveys.

Multiple screening tools for health-related social needs (HRSNs) already exist. For additional information on resources, we refer readers to evidence-based resources like the Social Interventions Research and Evaluation Network (SIREN) website, for example, for comprehensive information about the most widely used HRSN screening tools. 145 146 SIREN

¹⁴⁵ Social Interventions Research & Evaluation Network. (2019). Social Needs Screening Tool Comparison Table. Available at: https://sirenetwork.ucsf.edu/tools-resources/resources/screening-tools-comparison. Accessed January 18, 2021.

¹⁴⁶ The Social Interventions Research and Evaluation Network (SIREN) at University of California San Francisco was launched in the spring of 2016 to synthesize, disseminate, and catalyze research on SDOH and healthcare delivery.

contains descriptions of the content and characteristics of various tools, including information about intended populations, completion time, and number of questions.

We encourage IPFs to consider digital standardized screening tools and refer readers to the FY 2023 IPPS/LTCH PPS final rule (87 FR 49207 through 49208) where we discuss how the use of certified health information technology (IT), including but not limited to certified EHR technology, can support capture of HRSN information in an interoperable fashion so that these data can be shared across the care continuum to support coordinated care. We also encourage readers to learn about the United States Core Data for Interoperability (USCDI) standard used in certified health IT and how this standard can support interoperable exchange of health and HRSN assessment data.¹⁴⁷

We proposed that IPFs would report aggregate data on this measure, that is IPFs would report aggregated data for the numerator and the denominator to CMS (as described in section VI.D.3.b.(1). of this final rule) but would not be required to report patient-level data. IPFs are required to submit information for chart-abstracted measures once annually using a CMS-approved web-based data collection tool available within the HQR System (previously referred to as the QualityNet Secure Portal). We refer readers to section VI.I of this final rule (Form, Manner, and Timing of Quality Data Submission) for more details on our previously finalized data submission and deadline requirements across measure types.

We invited public comment on this proposal.

<u>Comment</u>: Many commenters supported adoption of the Screening for Social Drivers of Health measure. Some commenters stated that screening for these HRSNs will help IPFs better understand patients' needs, improve care coordination with outpatient and community resources, increase the dignity and respect with which patients are treated, and support development of patient-centered treatment plans. One commenter stated that the data collected through these

Office of the National Coordinator for Health IT (ONC). United States Core Data for Interoperability. Accessed at: https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi.

screenings could help IPFs shape facility level goals associated with health equity and empower the workforce to recognize and eliminate health disparities. One commenter specifically supported the flexibility with respect to tool selection and stated that this will help IPFs select the standardized screening instruments most applicable for their individual patient populations.

Another commenter stated that discharge will not lead to positive patient outcomes if the patient is discharged to unstable conditions or without the transportation necessary to access support services.

Response: We thank commenters for their support of the Screening for Social Drivers of Health measure. We agree that HRSNs are critical factors that impact patient outcomes, and increased knowledge about patients' HRSNs will help IPFs shape goals associated with health equity. Further, we agree that collecting these data will help IPFs improve coordination with outpatient and community resources to better deliver patient-centered care. Finally, we note that these activities would support IPFs' execution of responsibilities related to the required standard for social services under 42 CFR 482.62(f).

<u>Comment</u>: Several commenters recommended that CMS conduct additional testing, specifically in the IPF setting, to ensure that the measure addresses the specific needs of the IPF patient population.

Response: We acknowledge that this measure was initially developed for the general acute care setting. While we recognize the value of measures undergoing testing and evaluation of validity and feasibility in the setting for which they are being adopted, given the urgency of identifying and addressing HRSNs described in section VI.D.4.a of this final rule, and, as there are currently no other existing measures that address Screening for Social Drivers of Health, we believe it is important to implement this measure as soon as feasible. We believe that this measure is equally applicable to freestanding IPFs and psychiatric units within acute care facilities as to general acute care settings, because we believe that identifying the HRSNs of IPF patients will be equally valuable in understanding patients' needs, improving care coordination

with outpatient and community resources, increasing the dignity and respect with which patients are treated, and supporting development of patient-centered treatment plans as identifying the HRSNs of acute care hospital patients. We note that identifying and addressing HRSNs is a critical topic for patients treated in IPFs and that there are high levels of health disparities experienced by this patient population. CMS will monitor measure implementation and data reporting as part of standard program and measure review and will consider updates to the measure if improvements are identified through this process.

<u>Comment</u>: Many commenters expressed concern that this measure has not received endorsement by the CBE.

Response: While we recognize the value of measures undergoing review for potential CBE endorsement, given the urgency of achieving health equity, we believe it is important to implement this measure with voluntary reporting beginning with the CY 2024 reporting period followed by mandatory reporting beginning with the CY 2025 reporting period/FY 2027 payment determination. We note that, under section 1886(s)(4)(D)(ii) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed measures endorsed by consensus organizations and were unable to identify any other measures on this topic endorsed by a consensus organization, and therefore, we believe the exception in section 1886(s)(4)(D)(ii) of the Act applies.

<u>Comment</u>: Many commenters recommended extending the voluntary reporting phase for this measure.

Response: Beginning to collect the data remains imperative as we continue to build on our strategic pillar to advance health equity by addressing the health disparities that underlie our health system. We therefore have determined that the proposed voluntary and mandatory reporting periods prioritize the urgency of capturing social drivers of health data and taking actionable steps towards closing the health equity gap.

Comment: Some commenters recommended that CMS defer adoption of this measure until the Hospital IQR Program's voluntary reporting period for its version of this measure concludes to allow CMS and IPFs to identify best practices for screening patients and collecting HRSNs data in a minimally burdensome way. Some of these commenters stated that IPFs often have fewer resources available for such data collection relative to acute care hospitals. Other commenters recommended engaging IPFs to voluntarily test the measure to ensure usability, acceptability, and face validity are met for this setting.

Response: We acknowledge commenters' desire to be able to learn from the experiences of acute care hospitals reporting this measure. Hospitals participating in the Hospital IOR Program that choose to voluntarily report this measure will have already reported data in CY 2024 (87 FR 49207). Furthermore, the Hospital IQR Program finalized mandatory reporting of this measure for the FY 2026 payment determination (that is data submitted in CY 2025 representing the CY 2024 performance period) (87 FR 49207). Given the timing of reporting this measure in the Hospital IOR Program, we believe that IPFs will have the opportunity to learn from the experiences of acute care hospitals, including best practices for collecting HRSNs data, prior to mandatory reporting for the IPFQR Program for the FY 2027 payment determination. Furthermore, we believe that the voluntary reporting of CY 2024 data submitted to CMS in CY 2025 for the IPFOR Program will provide additional opportunities to identify minimally burdensome screening instruments and data collection practices. Finally, we note that we will monitor measure implementation and data reporting as part of standard program and measure review and will consider updates to the measure if improvements are identified through this process. Therefore, we do not believe that the benefits of extending voluntary reporting of this measure in the IPFQR Program for more than one year outweigh the potential detriments associated with delay in measure adoption that extending the voluntary reporting period would require.

Comment: Several commenters had recommendations related to the specifications for the Screening for Social Drivers of Health measure regarding the frequency and timing of administering these screenings. One commenter recommended not requiring individual patients to be screened more frequently than once per quarter so that patients who are readmitted or admitted to other settings over a short duration are not repeatedly screened when their HRSNs are unlikely to have changed. Another commenter recommended that for patients who have long stays (sometimes greater than one year) the measure should be updated to require an annual screening and screening at discharge. This commenter stated that for these patients screening at discharge would provide data which would inform discharge planning.

Response: We understand the commenters' concerns, especially given the frequency of unmet HRSNs among psychiatric patients, regarding patients who may be screened frequently, or whose screening results may change significantly during their inpatient stay (such as those patients with long duration stays). We note that screening can occur any time during the hospital admission prior to discharge. Further, for patients frequently admitted to inpatient facilities, the IPF could confirm the current status of any previously reported HRSNs and inquire about other HRSNs not previously reported or that may have changed in the intervening period. For additional information on how to apply and report these screenings, we refer readers to the Hospital IQR Program's Frequently Asked Questions document regarding this measure in the Hospital IQR Program, available at: Errort Bookmark not defined. We will develop a similar Frequently Asked Questions document for IPFs as part of providing educational and training materials; this document will be conveyed through routine communication channels to hospitals, vendors, and QIOs, including, but not limited to, issuing memos, emails, and notices on a CMS website.

<u>Comment</u>: Several commenters recommended additional changes to the measure specifications. Due to the sensitive nature of screening for risk of interpersonal violence, commenters recommended changes that included removing this domain from the measure

specifications, and updating the measure to ensure patient privacy when responding to this screening question, either by excluding patients who could not respond to the question confidentially, or by ensuring responses remain hidden in all records and handouts accessible to patients. One commenter recommended removing the exclusion language "and lack of a guardian or caregiver available to do so on the patient's behalf" because such a guardian or caregiver may provide inaccurate information about the patient's risk of interpersonal violence. One commenter recommended excluding patients coming from or being discharged to long-term care settings because these patients would be at lower risk for these five HRSNs. Another commenter recommended expanding the measure to include screening for lack of financial resources.

Response: We have prioritized selection of the proposed five HRSN domains based on existing evidence from both the AHC Model, including recommendations from a technical expert panel (TEP) that informed the initial selection, and emerging evidence of correlations between given social drivers of health and worse health outcomes and social drivers of health for which interventions have shown marked improvements in health outcomes and healthcare utilization (88 FR 21280). Through this process we did not identify lack of financial resources as being one of the social drivers of health that met our criteria for selection (these criteria are set forth in section V.D.3.a. of the proposed rule and in section VI.D.3 of this final rule); therefore, we did not include it in the Screening for Social Drivers of Health measure. We note that while the Screening for Social Drivers of Health measure requires screening for the five identified HRSNs, IPFs may screen for additional HRSNs that they believe are relevant for their patient population and the community in which they serve, and that standardized screening instruments such as those available for screening for these five HRSNs may also include a screening for lack of financial resources. For example, the Accountable Health Communities screening tool includes questions for eight supplemental domains, including financial strain. Furthermore, we note that this measure is a first step towards development of a long-term strategy to integrate

social drivers of health and HRSN data into quality performance measurement and is part of our broader commitment to health equity.

We believe it is imperative that IPFs screen for all five domains established in this measure. We understand commenters' concerns regarding the sensitive nature of screening for risk of interpersonal violence and agree that patient safety must remain the IPF's principal concern. We recommend that IPFs ensure that patients feel that they are safe answering questions and remind patients that they may opt out of the screening for any reason. We note that, because IPFs likely are covered entities under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Rules (codified at 45 CFR Parts 160 and 164), 148 information provided by patients in response to screening for this measure would be protected health information (PHI). 149 Therefore, IPFs are responsible for adopting reasonable safeguards to ensure that patients' PHI is not impermissibly disclosed contrary to applicable confidentiality, security, and privacy laws.

We do not believe it would be appropriate to remove the exclusion which would allow a caregiver or guardian to provide information on a patient's behalf if the patient is unable to do so. While we agree that the scenario presented by commenters (that is, a guardian or caregiver may provide inaccurate information about the patient's risk of interpersonal violence) is possible, we do not believe that the potential unintended consequence of capturing inaccurate data for this HRSN for a small portion of patients outweighs the potential benefit of capturing accurate data regarding all of these five HRSNs for as many patients as possible, including those who are unable to respond to the screening without the assistance of a caregiver or guardian.

Finally, we believe that it is appropriate to assess the HRSNs of all eligible patients (that is, patients who are over 18 years of age at admission and do not meet the measure's exclusion criteria) including patients being admitted from or discharged to long-term care settings. While

¹⁴⁸ For more information on the three HIPAA rules, we refer readers to the HIPAA for Professionals site at: https://www.hhs.gov/hipaa/for-professionals/index.html.

¹⁴⁹ https://www.hhs.gov/answers/hipaa/what-is-phi/index.html.

these patients are at lower risk during their stay in the long-term care facility, we believe it is appropriate for the IPF to assess the patient's overall risk of unmet HRSNs. We note, for example, that the AHC screening instrument assesses the patient's HRSNs over the past 12 months for the majority of the HRSNs included in this tool. Therefore, screening patients admitted from or being discharged to long-term care settings could help identify unmet HRSNs among this patient population. We will continue to take all concerns, comments, and suggestions into account and will consider them as part of any potential future modifications to these measures or potential new measure development in future notice-and-comment rulemaking.

<u>Comment</u>: One commenter recommended that the Screening for Social Drivers of Health measure be completed by a peer support specialist to engender trust and create a safe environment.

Response: We agree with the commenter that it is important for the screening for HRSNs to be accomplished in a way that engenders trust and creates a safe environment. We recommend that IPFs evaluate the requirements for administration (such as whether the screening instrument can be administered by peer support specialists) as part of their instrument selection process. We note that the AHC instrument described in section VI.D.3 of this rule allows administration by clinicians and staff¹⁵⁰ and would allow administration by peer support specialists.

<u>Comment</u>: One commenter recommended aligning SDOH related measures, including this one, across programs including programs for the ambulatory setting (including MIPS).

Response: We agree with the commenter that addressing patients' HRSNs is important in all settings in which patients access care. We note that this measure was adopted into MIPS in the CY 2023 Physician Fee Schedule (PFS) final rule (87 FR 70055) as well as the Hospital IQR

 $^{^{150}\} https://nam.edu/standardized-screening-for-health-related-social-needs-in-clinical-settings-the-accountable-health-communities-screening-tool/$

Program in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49215). In addition, we have proposed to adopt this measure in the PPS-Exempt Cancer Hospital Quality Reporting Program in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27128) and the End-Stage Renal Disease Quality Incentive Program in the CY 2024 ESRD PPS proposed rule (88 FR 42515). We note that only the IPFQR Program is the subject of this final rule, and the commenter's recommendation is therefore beyond the scope of this final rule.

<u>Comment</u>: One commenter recommended against public reporting until a standardized, validated instrument is adopted so the data are collected using a uniform tool. One commenter requested that CMS provide guidance on which available, standardized assessment instruments address each of the domains.

Response: We are sensitive to the concerns raised by commenters about the lack of clarity about which screening instrument IPFs should use in order to screen for HRSNs. We acknowledge the challenges that lack of standardization across screening instruments or data collection practices may introduce in the consistency of the information collected across IPFs. While we acknowledge the potential benefits of a single screening instrument or prescribed set of standards, we also recognize the benefits of providing IPFs with flexibility to customize screening and data collection to their local community contexts and patient populations, especially in the initial stages of implementing screening protocols. We encourage IPFs to prioritize screening tools that have undergone thorough testing to ensure they are accurate and reliable. We believe that this measure should promote high-quality screening practices which, among other things, ensure accurate identification of unmet social needs.

For selecting a screening tool, we suggest that IPFs refer to evidence-based resources for comprehensive information about the most widely used HRSN screening tools. For example, the Social Interventions Research and Evaluation Network (SIREN) website, ¹⁵¹ housed at the Center for Health and Community at the University of California, San Francisco, contains descriptions

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¹⁵¹ https://chc.ucsf.edu/siren

of the content and characteristics of various tools, including information about intended populations, completion time, and number of questions.

Comment: Several commenters stated that a measurement of whether a screening occurred does not indicate whether the needs have been met nor the impact of these specific HRSNs on the patient's health outcomes. Some of these commenters also stated that the lack of resources faced by IPFs may lead IPFs to screen for SDOH for which they are unable to assist patients. These commenters expressed concern that this may be frustrating for patients who would expect the IPF to address these needs after the screening.

Response: During the development of both Social Drivers of Health measures, we gave this topic significant consideration. The intent of the two measures is to promote adoption of screening patients for HRSNs by healthcare providers as well as taking action to connect patients who identify one or more HRSNs with available resources. Evaluation of the AHC Model concluded that universal screening may identify needs that would otherwise remain undetected. While broad availability of community-based resources that address patients' health-related social needs would be ideal, we believe that one of the benefits of collecting data from screening for HRSNs will be identification of opportunities to enable meaningful action, including prioritizing and investing in such resources. Beginning to collect the data on patients' HRSNs remains imperative and a crucial step in developing resources for advancing health equity. Such data collection has already allowed some entities to reallocate resources to address particular HRSNs that disproportionately affect a given patient population or geographic region, as noted in the FY 2023 IPPS/LTCH PPS final rule, in which the Hospital IQR Program adopted these measures (87 FR 49213).

<u>Comment</u>: One commenter requested clarification of whether the measure will represent the "total number" of patients screened for SDOH or the proportion of patients screened for

¹⁵² RTI International. (2020). Accountable Health Communities (AHC) Model Evaluation. Available at: https://innovation.cms.gov/data-and-reports/ 2020/ahc-first-eval-rpt.

Response: IPFs will report the aggregate numerator for this measure (that is, the total number of patients admitted to an IPF stay who are 18 years or older on the date of admission and screened for all five HRSNs), and the aggregate denominator (that is, number of patients who are admitted to an IPF stay and who are 18 years or older on the date of admission). Using these data and the denominator exclusions (that is, patients who opt-out of screening and patients who are themselves unable to complete the screening during their inpatient stay and have no legal guardian or caregiver able to do so on their behalf during their IPF stay), we will calculate the screening rate (that is, the proportion of patients screened for all five SDOH) for this measure.

<u>Comment</u>: One commenter did not support this measure because of their concern that the specific HRSNs in the Screening for Social Drivers of Health measure are not completely aligned with the HL7 Gravity Project.

Response: We have prioritized the five HRSN domains in this measure based on existing evidence from the AHC Model including recommendations from a TEP that informed the initial selection. We commend additional initiatives currently underway to expand capabilities to capture additional social drivers of health data elements, including the Gravity Project. We note that the five domains covered by the Screening for Social Drivers of Health measure are included within the "social risk domains" of the Gravity Project. We support harmonization of data regarding HRSNs for interoperable electronic health information exchange that will meet information exchange standards.

<u>Comment</u>: One commenter did not support this measure stating their belief that there is a lack of evidence that screening impacts quality of care provided by IPFs.

Response: We note that the two Social Drivers of Health measures are derived from existing evidence from both the AHC Model and emerging evidence of correlations between the designated social drivers of health and higher healthcare utilization of emergency departments

and hospitals, worse health outcomes and/or drivers of health for which interventions have shown marked improvements in health outcomes and health care utilization (88 FR 21280).

Comment: One commenter did not support required reporting of these data because, while the commenter agreed that screening for SDOH is important and should be occurring in the IPF setting, the commenter expressed concern that reporting these data is too burdensome and takes away from patient care. Another commenter did not support the Screening for Social Drivers of Health measure because IPF stays are typically only a few days, and the commenter stated their belief that there is therefore insufficient time to complete these screenings during the stay.

Response: While we understand implementation of HRSN screening processes and reporting of the SDOH measures is associated with some burden, as discussed in sections VII.B. and VIII.A of this final rule, we believe the benefits outweigh the burden, as screening for and identifying patients' HRSNs is a critical step towards treating the whole patient, improving clinical outcomes, improving equitable care, and ultimately eliminating disparities in health outcomes among populations that have been historically underserved by the healthcare system.

We note that screening can occur any time during the IPF admission prior to discharge and that, for example, the AHC Screening Tool addresses these 5 HRSNs using a total of 10 questions. Therefore, we believe that IPFs will be able to find sufficient time during the patient's IPF stay to administer this or a similar screening tool for SDOH.

<u>Final Decision</u>: After consideration of the public comments we received, we are finalizing adoption of the Screening for Social Drivers of Health measure as proposed.

- 4. Adoption of the Screen Positive Rate for Social Drivers of Health Measure Beginning with Voluntary Reporting of CY 2024 Data and Followed by Mandatory Reporting Beginning with CY 2025 Data/FY 2027 Payment Determination
- a. Background

The impact of social risk factors on health outcomes has been well-established in the literature. 153 154 155 156 157 The Physicians Foundation reported that 73 percent of the physician respondents to the 2021 iteration of their annual survey agreed that social risk factors like housing instability and food insecurity would drive health services demand. 158 Recognizing the need for a more comprehensive approach to eliminating the health equity gap, we have prioritized quality measures that would capture social risk factors and facilitate assessment of their impact on health outcomes and disparities and healthcare utilization and costs. 159 160 161 Specifically, in the inpatient setting, we aim to encourage systematic identification of patients' HRSNs (as defined in section VI.D.3.a. of this final rule) as part of discharge planning with the intention of promoting linkages with relevant community-based services that address those needs and support improvements in health outcomes following discharge from the IPF.

While the Screening for Social Drivers of Health measure (discussed previously in section VI.D.3. of this final rule) enables identification of individuals with HRSNs, use of the Screen Positive Rate for Social Drivers of Health measure would allow IPFs to capture the

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 ¹⁵³ Institute of Medicine 2014. Capturing Social and Behavioral Domains and Measures in Electronic Health Records: Phase 2. Washington, DC: The National Academies Press. Available at: https://doi.org/10.17226/18951.
 ¹⁵⁴ Centers for Medicare & Medicaid Services. (2021). Accountable Health Communities Model. Accountable Health Communities Model | CMS Innovation Center. Available at: https://innovation.cms.gov/innovation-models/ahcm. Accessed November 23, 2021.

¹⁵⁵ Kaiser Family Foundation. (2021). Racial and Ethnic Health Inequities and Medicare. Available at: https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/. Accessed November 23, 2021.

¹⁵⁶ Milkie Vu et al. Predictors of Delayed Healthcare Seeking Among American Muslim Women, Journal of Women's Health 26(6) (2016) at 58; Nadimpalli SB, Cleland CM, Hutchinson MK, Islam N, Barnes LL, Van Devanter N. (2016) The Association between Discrimination and the Health of Sikh Asian Indians. Health Psychology, 35(4), 351–355. https://doi.org/10.1037/hea0000268.

¹⁵⁷ Office of the Assistant Secretary for Planning and Evaluation (ASPE). (2020). Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Program (Second of Two Reports). Available at: https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress.

¹⁵⁸ The Physicians Foundation. (2020) 2020 Survey of America's Patients, Part Three. Available at: https://physiciansfoundation.org/wp-content/uploads/2020/10/2020-Physicians-Foundation-Survey-Part3.pdf. ¹⁵⁹ Alley, D.E., C.N. Asomugha, P.H. Conway, and D.M. Sanghavi. 2016. Accountable Health Communities—Addressing Social Needs through Medicare and Medicaid. The New England Journal of Medicine 374(1):8–11. Available at: https://doi.org/10.1056/NEJMp1512532.

¹⁶⁰ Centers for Medicare & Medicaid Services. (2021). Accountable Health Communities Model. Accountable Health Communities Model | CMS Innovation Center. Available at: https://innovation.cms.gov/innovation-models/ahcm. Accessed November 23, 2021.

Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: https://doi.org/10.31478/201705b.

magnitude of these needs and even estimate the impact of individual-level HRSNs on healthcare utilization when evaluating quality of care. 162 163 164 The Screen Positive Rate for Social Drivers of Health measure will require IPFs to report the rates of patients who screened positive for each of the five core HRSNs. Reporting the screen positive rate for each of the five core HRSNs will inform actionable planning by IPFs towards closing health equity gaps unique to the populations they serve and enable the development of individual patient action plans (including navigation and referral services).

In the FY 2022 IPF PPS final rule (86 FR 42625 through 42632) and the FY 2023 IPF PPS final rule (87 FR 46865 through 46873), we discussed our ongoing consideration of potential approaches that could be implemented to address health equity through the IPFQR Program. As a result of the feedback we received, we identified the Screen Positive Rate for Social Drivers of Health measure to help inform efforts to address health equity.

This measure assesses the percent of patients admitted to the IPF who are 18 years or older at time of admission who were screened for HRSNs and who screen positive for one or more of the five HRSNs, including food insecurity, housing instability, transportation needs, utility difficulties, or interpersonal safety (reported as five separate rates). 165

We refer readers to section VI.D.3 of this final rule where we previously discussed the screening and identification process resulting in the selection of these five domains associated with the Screen for Social Drivers of Health measure. The Screening for Social Drivers of Health measure forms the basis of this Screen Positive Rate for Social Drivers of Health

Baker, M.C., Alberti, P.M., Tsao, T.Y., Fluegge, K., Howland, R.E., & Haberman, M. (2021). Social Determinants Matter for Hospital Readmission Policy: Insights From New York City. Health Affairs, 40(4), 645–654. Available at: https://doi.org/10.1377/hlthaff.2020.01742.

 ¹⁶³ CMS. Accountable Health Communities Model. Accountable Health Communities Model | CMS Innovation Center. Available at: https://innovation.cms.gov/innovation-models/ahcm. Accessed November 23, 2021.
 ¹⁶⁴ Hammond, G., Johnston, K., Huang, K., Joynt Maddox, K. (2020). Social Determinants of Health Improve Predictive Accuracy of Clinical Risk Models for Cardiovascular Hospitalization, Annual Cost, and Death. Circulation: Cardiovascular Quality and Outcomes, 13 (6) 290–299. Available at: https://doi.org/10.1161/CIRCOUTCOMES.120.006752.

¹⁶⁵ Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: https://doi.org/10.31478/201705b.

measure. That is, the number of patients screened for all five HRSNs in the Screening for Social Drivers of Health measure is the denominator of the Screen Positive Rate for Social Drivers of Health measure described here.

The COVID-19 pandemic underscored the overwhelming impact that these five core domains of HRSNs have on disparities, health risk, healthcare access, and health outcomes, including premature mortality. 166 167 Adoption of the Screen Positive Rate for Social Drivers of Health measure will encourage IPFs to track prevalence of specific HRSNs among patients over time and use the data to stratify risk as part of quality performance improvement efforts. This measure may also prove useful for patients by providing data transparency and signifying IPFs' familiarity, expertise, and commitment regarding these health equity issues. This measure also has the potential to reduce healthcare provider burden and burnout, including among IPFs and their staff, by both acknowledging patients' non-clinical needs that nevertheless greatly contribute to adverse clinical outcomes and linking providers with community-based organizations to enhance patient-centered treatment and discharge planning. 168 169 170 Finally, we believe the Screen Positive Rate for Social Drivers of Health measure has the potential to facilitate data-informed collaboration with community-based services and focused community investments, including the development of pathways and infrastructure to connect patients to local community resources.

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¹⁶⁶ Kaiser Family Foundation. (2021). Racial and Ethnic Health Inequities and Medicare. Available at: https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/. Accessed November 23, 2021.

¹⁶⁷ Centers for Disease Control and Prevention. (2019). CDC COVID–19 Response Health Equity Strategy: Accelerating Progress Towards Reducing COVID–19 Disparities and Achieving Health Equity. July 2020. Available at: https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/cdc-strategy.html. Accessed November 17, 2021.

¹⁶⁸ The Physicians Foundation. (2020). Survey of America's Patients, Part Three. Available at: https://physiciansfoundation.org/wp-content/uploads/2020/10/2020-Physicians-Foundation-Survey-Part3.pdf. ¹⁶⁹ De Marchis, E., Knox, M., Hessler, D., WillardGrace, R., Oliyawola, JN, et al. (2019). Physician Burnout and Higher Clinic Capacity to Address Patients' Social Needs. The Journal of the American Board of Family Medicine, 32 (1), 69–78.

¹⁷⁰ Kung, A., Cheung, T., Knox, M., Willard-Grace, R., Halpern, J., et.al, (2019). Capacity to Address Social Needs Affect Primary Care Clinician Burnout. Annals of Family Medicine. 17 (6), 487–494. Available at: https://doi.org/10.1370/afm.2470.

Ultimately, we are focused on supporting effective and sustainable collaboration between healthcare delivery and local community-based services organizations to meet the unmet needs of people they serve. Reporting data from both the Screening for Social Drivers of Health and the Screen Positive Rate for Social Drivers of Health measures will enable both identification and quantification of the levels of unmet HRSNs among communities served by IPFs. These two Social Drivers of Health measures harmonize, as it is important to know both whether screening occurred and the results from the screening in order to develop sustainable solutions. We believe that there are multiple benefits to increasing IPFs' understanding of their patients' HRSNs. First, we believe that this could lead to increased clinical-community collaborations and an associated increase in system capacity and community investments. Second, we believe this in turn could yield a net reduction in costly healthcare utilization by promoting more appropriate healthcare service consumption.¹⁷¹

Pursuant to our Meaningful Measures 2.0 Framework and in alignment with the measures previously adopted for hospitals participating in the Hospital IQR Program, the Screen Positive Rate for Social Drivers of Health measure will address the equity priority area and align with our commitment to introduce plans to close health equity gaps and promote equity through quality measures, including to "develop and implement measures that reflect social and economic determinants." Under our Meaningful Measures Framework, the Screen Positive Rate for Social Drivers of Health measure will address the quality priority of "Work with Communities to Promote Best Practices of Healthy Living" through the Meaningful Measures Area of "Equity of

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¹⁷¹ Centers for Medicare & Medicaid Services. (2021). Accountable Health Communities Model. Accountable Health Communities Model | CMS Innovation Center. Available at: https://innovation.cms.gov/innovation-models/ahcm. Accessed November 23, 2021.

¹⁷² Centers for Medicare & Medicaid Services. Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at: https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization.

Care."¹⁷³ Adoption of this measure will also align with our strategic pillar to advance health equity by addressing the health disparities that underlie our health system.¹⁷⁴

b. Overview of Measure

The Screen Positive Rate for Social Drivers of Health measure is intended to enhance standardized data collection that can identify individuals who are at higher risk for poor health outcomes related to HRSNs who would benefit from connection via the IPF to targeted community-based services.¹⁷⁵ The measure identifies the proportion of patients admitted to an IPF stay who are 18 years or older on the date of admission to the IPF who screened positive for one or more of the following five HRSNs: food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.

Consistent with the Hospital IQR Program, which adopted this measure in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49215 through 49220), we will require IPFs to report this measure as five separate rates. Specifically, IPFs will report the number of patients who screened positive for food insecurity, the number of patients who screened positive for housing instability, the number of patients who screened positive for transportation needs, the number of patients who screened positive for utility difficulties, and the number of patients who screened positive for interpersonal safety. We note that this measure is intended to provide information to IPFs on the level of unmet HRSNs among patients served, and not for comparison between IPFs.

The specifications for the Screen Positive Rate for Social Drivers of Health measure, which were available during the review of the MUC List, are available at: https://mmshub.cms.gov/sites/default/files/map-hospital-measure-specifications-manual-2022.pdf.

¹⁷³ Centers for Medicare & Medicaid Services. (2021). CMS Measures Management System Blueprint (Blueprint v 17.0). Available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/MMS-Blueprint.

Brooks-LaSure, C. (2021). My First 100 Days and Where We Go From Here: A Strategic Vision for CMS.
 Available at: https://www.cms.gov/blog/my-first-100-days-and-where-we-go-here-strategic-vision-cms.
 Centers for Medicare & Medicaid Services. (2021). A Guide to Using the Accountable Health Communities
 Health-Related Social Needs Screening Tool: Promising Practices and Key Insights (June 2021). Available at: https://innovation.cms.gov/media/document/ahcm-screeningtool-companion. Accessed November 23, 2021.

(1) Measure Calculation

(a) Cohort

The Screen Positive Rate for Social Drivers of Health measure is a process measure that provides information on the percent of patients, 18 years or older on the date of admission for an IPF stay, who were screened for all five HRSNs,¹⁷⁶ and who screen positive for one or more of the following five HRSNs: food insecurity; housing instability; transportation needs; utility difficulties; or interpersonal safety.

(b) Numerator

The numerator consists of the number of patients admitted for an IPF stay who are 18 years or older on the date of admission, who were screened for an HRSN, and who screen positive for having an unmet need in one or more of the following five HRSNs (calculated separately): The number of patients who screened positive for food insecurity, the number of patients who screened positive for housing instability, the number of patients who screened positive for transportation needs, the number of patients who screened positive for utility difficulties, and the number of patients who screened positive for interpersonal safety. IPFs will report the number of patients who screened positive for having unmet needs in each of the five HRSNs as a separate numerator. A patient who screened positive for more than one unmet HRSN will be included in the numerator for each of those HRSNs. For example, a patient who screened positive for food insecurity, housing instability, and transportation needs would be included in each of these numerators.

(c) Denominator

The denominator consists of the number of patients admitted for an IPF stay who are 18 years or older on the date of admission and are screened for all five HRSNs (food insecurity,

 $^{^{176}}$ We have updated this language to read "all five HRSNs" as opposed to "an HRSN" to update the language on the 2022 MUC List: https://mmshub.cms.gov/sites/default/files/2022-MUC-List.xlsx

housing instability, transportation needs, utility difficulties and interpersonal safety)¹⁷⁷ during their IPF stay. The following patients are excluded from the denominator: (1) patients who opt out of screening; and (2) patients who are themselves unable to complete the screening during their inpatient stay and have no caregiver able to do so on the patient's behalf during their inpatient stay.

(d) Calculation

The results of this measure are calculated as five separate rates. Each rate is derived from the number of patients admitted for an IPF stay and who are 18 years or older on the date of admission, screened for an HRSN, and who screen positive for each of the five HRSNs (that is, the number of patients who screened positive for food insecurity, the number of patients who screened positive for housing instability, the number of patients who screened positive for transportation needs, the number of patients who screened positive for utility difficulties, and the number of patients who screened positive for interpersonal safety) divided by the number of patients 18 years or older on the date of admission screened for all five HRSNs. The measure is reported as five separate rates – one for each HRSN, each calculated with the same denominator.

(2) Review by the Measure Applications Partnership

We included the Screen Positive Rate for Social Drivers of Health measure on the publicly available MUC List, a list of measures under consideration for use in various Medicare programs.¹⁷⁸ The CBE-convened MAP Health Equity Advisory Group reviewed the MUC List and the Screen Positive Rate for Social Drivers of Health measure (MUC 2022–050) in detail on December 6 through 7, 2022.¹⁷⁹ The MAP Health Equity Advisory Group expressed support for the collection of data related to social drivers of health, but raised concerns regarding public reporting of these data and potential repetition of asking patients the same questions across

We have updated this language to read "all five HRSNs" as opposed to "an HRSN" to update the language on the 2022 MUC List: https://mmshub.cms.gov/sites/default/files/2022-MUC-List.xlsx

 ¹⁷⁸ Centers for Medicare & Medicaid Services. List of Measures Under Consideration for December 1, 2022.
 Available at: https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.
 179 Centers for Medicare & Medicaid Services. 2022-2023 MAP Final Recommendations. Available at: https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.

In addition, on December 8 through 9, 2022, the MAP Rural Health Advisory Group reviewed the 2022 MUC List, which was also reviewed by the MAP Hospital Workgroup on December 13 through 14, 2022.¹⁸¹ The MAP Rural Health Advisory Group noted potential reporting challenges including the potential masking of health disparities that are underrepresented in some areas and that sample size and populations served may be an issue but also expressed support that the measure seeks to advance the drivers of health and serves as a starting point to determine where screening is occurring. The MAP Hospital Workgroup recommended conditional support of the measure for rulemaking pending: (1) endorsement by the CBE to address reliability and validity concerns; (2) attentiveness to how results are shared and contextualized for public reporting; and (3) examination of any differences in reported rates by reporting process (that is, to assess whether reported rates are the same or different across IPFs and other facilities that may use different processes to report their data).¹⁸² Thereafter, the MAP Coordinating Committee deliberated on January 24 through 25, 2023, and ultimately voted to conditionally support the Screen Positive Rate for Social Drivers of Health measure for rulemaking with the same conditions.¹⁸³

We agree with the MAP Coordinating Committee's support for the proposed Screen Positive Rate for Social Drivers of Health measure. We believe this measure, alongside the Screening for Social Drivers of Health measure, establishes an important foundation to prioritizing the achievement of health equity among IPFs participating in the IPFQR Program. Our approach to developing health equity measures is incremental, and we believe that health equity outcomes in the IPFQR Program will inform future efforts to advance and achieve health

¹⁸⁰ Centers for Medicare & Medicaid Services. 2022-2023 MAP Final Recommendations. Available at: https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.

¹⁸¹ Centers for Medicare & Medicaid Services. 2022-2023 MAP Final Recommendations. Available at: https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.

¹⁸² Centers for Medicare & Medicaid Services. 2022-2023 MAP Final Recommendations. Available at: https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.

¹⁸³ Centers for Medicare & Medicaid Services. 2022-2023 MAP Final Recommendations. Available at: https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.

equity by IPFs. We believe this measure to be a building block that lays the groundwork for a future meaningful suite of measures that would assess IPF progress in providing high-quality healthcare for all patients, regardless of social risk factors or demographic characteristics.

(3) CBE Endorsement

We have not submitted this measure for CBE endorsement at this time. Although section 1886(s)(4)(D)(i) of the Act generally requires that measures specified by the Secretary must be endorsed by the entity with a contract under section 1890(a) of the Act, section 1886(s)(4)(D)(ii) of the Act states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to a measure that has been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed measures endorsed by consensus organizations and were unable to identify any other measures on this topic endorsed by a consensus organization; therefore, we believe the exception in section 1886(s)(4)(D)(ii) of the Act applies.

c. Data Collection, Submission, and Reporting

We believe incremental implementation of the Screen Positive Rate for Social Drivers of Health measure, by permitting one year of voluntary reporting prior to mandatory reporting, will allow IPFs who are not yet screening patients for HRSNs to get experience with the measure and equally allow IPFs who already undertake screening efforts to report data already being collected. Therefore, we proposed voluntary reporting of this measure, along with the Screening for Social Drivers of Health measure described in section VI.D.3 of this final rule, beginning with the data collected in CY 2024, which will be reported to CMS in CY 2025 followed by mandatory reporting beginning with data collected in CY 2025, which will be reported to CMS in CY 2026 and affect FY 2027 payment determination.

While this measure will require IPFs to collect patient-level data on their patients' social

drivers of health screening results, we proposed to adopt this measure as an aggregate measure (that is, IPFs would be required to submit only numerator results for each of the five screening areas and the number of patients screened for all five of the HRSNs). IPFs are required to submit information for aggregate chart-abstracted measures once annually using a CMS-approved web-based data collection tool available within the HQR System (previously referred to as the QualityNet Secure Portal). We refer readers to section VI.I of this final rule (Form, Manner, and Timing of Quality Data Submission) for more details on our previously finalized data submission and deadline requirements across measure types.

We invited public comment on our proposal.

We note that we have addressed comments that broadly referred to both the Screening for Social Drivers of Health measure and the Screen Positive Rate for Social Drivers of Health measure in the previous section of this final rule (VI.D.3.).

<u>Comment</u>: Many commenters supported adoption of the Screen Positive Rate for Social Drivers of Health measure. Some commenters stated that knowing which patients have each of these HRSNs will help IPFs better understand patients' needs, improve care coordination with outpatient and community resources, increase the dignity and respect with which patients are treated, and support development of patient-centered treatment plans.

Response: We thank commenters for their support of the Screen Positive Rate for Social Drivers of Health measure. We agree that HRSNs are critical factors that impact patient outcomes, and increased knowledge about patients' HRSNs will help IPFs shape goals associated with health equity. Further, we agree that collecting these data will help IPFs improve coordination with outpatient and community resources to better deliver patient-centered care.

<u>Comment</u>: One commenter stated that access to these data will be useful for patient advocates to be able to identify IPFs that are more experienced with treating patients with more intensive resource needs.

Response: We agree with the commenter that publicly reporting these data might help patients with more intensive resource needs select IPFs that are more familiar with treating patients with that level of need. We note, however, that the measure is intended to provide information to IPFs on the level of unmet need among their patients and potentially in the community, and not for comparison between IPFs (88 FR 21286).

<u>Comment</u>: Some commenters expressed concern that publicly reporting these data may lead to inaccurate perceptions of the quality of care at IPFs that treat high volumes of patients who screen positive for one or more HRSNs. Several of these commenters stated that IPF patients may also have more unmet HRSNs than those at acute care hospitals so the data may be further misleading if the two settings are compared.

Response: We appreciate the commenters' concerns. The measure is intended to provide information to IPFs on the level of unmet need among their patients and potentially in the community, and not for comparison between IPFs (88 FR 21286). We believe public reporting of healthcare quality data promotes transparency in the delivery of care by increasing the involvement of leadership in healthcare quality improvement, creating a sense of accountability, helping to focus organizational priorities, and providing a means of delivering important healthcare information to consumers and patient advocates. We intend to conduct outreach and education with providers and patients to share information about the two Social Drivers of Health measures in conjunction with public reporting.

Comment: One commenter expressed the belief that reporting five separate rates, individually reflecting the proportion of patients who screened positive for each of the five HRSNs, is a flawed methodology because it may not yield reliable and valid comparisons.

Another commenter expressly supported reporting five separate rates for this measure to improve transparency.

Response: We believe that reporting a separate screen positive rate for each of the five HRSNs will provide important information to IPFs, the communities that they serve, and policy

makers. Because different community-based resources are appropriate to address each of the five HRSNs, we believe that reporting each of these rates separately will provide reliable and valid information to identify which communities are most in need of which resources to better enable support in addressing the most prevalent HRSNs.

<u>Comment</u>: Several commenters recommended that we develop outcome measures related to each of the five HRSNs for future adoption in this and other quality reporting programs.

Response: We thank commenters for their feedback. We view the two Social Drivers of Health measures as a first step towards development of a long-term strategy to integrate social drivers of health data into IPF quality performance measurement as part of our broader commitment to health equity. We will continue to take all comments, concerns, and suggestions into account and will consider them as part of any potential new measure development in future notice-and-comment rulemaking.

<u>Comment</u>: One commenter requested clarification on how to define a positive screening on a tool with a reporting scale.

Response: Because the reported value of screening results could vary among different screening tools or instruments, we recommend that IPFs carefully review the supporting materials that accompany each tool to understand how to properly administer the instrument and interpret results when selecting a screening instrument for their patient population.

<u>Comment</u>: One commenter did not support adoption of the Screen Positive Rate for Social Drivers of Health measure because the commenter expressed their belief that only IPFs would be able to use the data regarding their patient population and that they will already have the data from performing the screening.

Response: We respectfully disagree and believe that there are multiple interested parties who will be able to use data regarding IPFs' patient populations, including patients and their caregivers, patient advocacy organizations, local community services organizations, and federal, state, and local policy makers. We also believe that the measure will facilitate systematic

gathering of such data in a manner that provides information to IPFs on the level of unmet need among their patients that many IPFs do not compile currently.

<u>Final Decision</u>: After consideration of the public comments we received, we are finalizing adoption of the Screen Positive Rate for Social Drivers of Health measure as proposed.

5. Adoption of the Psychiatric Inpatient Experience (PIX) Survey Beginning with Voluntary Reporting of CY 2025 Data Followed by Mandatory Reporting Beginning with CY 2026 Data/FY 2028 Payment Determination

a. Background

We believe that a comprehensive approach to quality must include directly reported feedback regarding facility, provider, and payer performance. Therefore, we have consistently stated our commitment to identifying an appropriate patient experience of care measure for the IPF setting and adopting this measure in the IPFQR Program at the first opportunity (77 FR 53646, 78 FR 50897, 79 FR 45964 through 45965, 80 FR 46714 through 46715, 82 FR 38470 through 38471, 83 FR 38596, 84 FR 38467, 85 FR 47043, 86 FR 42654 through 42656, and 87 FR 46846).

In the FY 2014 IPPS/LTCH PPS final rule, we adopted a voluntary information collection regarding whether IPFs participating in the IPFQR Program assess patient experience of inpatient behavioral health services using a standardized instrument and for IPFs that answer "Yes" to indicate the name of the survey that they administer (78 FR 50896 through 50897). In the FY 2015 IPF PPS final rule, we adopted this information collection as the Assessment of Patient Experience of Care measure beginning with the FY 2016 payment determination (79 FR 45964 through 45965). Data collected for the FY 2018 payment determination (that is, data collected in CY 2016) showed that while the majority of IPFs (approximately 76 percent) were collecting patient experience of care data through a standardized instrument, there was a wide variation in the instrument being used. The data for CY 2016 indicated that the most widely used survey instrument was not in the public domain and was used by less than 30

percent of the IPFs that used a patient experience survey. In the FY 2015 IPF PPS final rule, we indicated our intention to adopt a standardized measure of patient experience of care for the IPFQR Program (79 FR 45964 through 45965).

In the FY 2019 IPF PPS final rule, we removed the Assessment of Patient Experience of Care measure from the IPFQR Program, because we believed that we had collected sufficient information to inform development of a patient experience of care measure (83 FR 38596 through 38597). In the FY 2020 IPF PPS final rule, we summarized our analysis of the results of the Assessment of Patient Experience of Care measure and requested feedback on potential adoption of the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey for the IPFQR Program (84 FR 38467). In response to our request, many commenters expressed concern that the HCAHPS survey was not specified for the IPF setting and recommended that CMS identify a survey that has been developed for and tested in the IPF setting. Furthermore, in the FY 2021 IPF PPS proposed rule, we did not propose any updates to the IPFOR Program; however, we received many comments requesting that we adopt a patient experience of care measure in the IPFQR Program, which we summarized in the FY 2021 IPF PPS final rule (85 FR 47043). We received similar input strongly advocating for a patient experience of care measure for the IPFOR Program in response to a solicitation of comments on potential measures for the IPFOR Program in the FY 2022 IPF PPS proposed rule (86 FR 19511 through 19512), which we summarized in the FY 2022 IPF PPS final rule (86 FR 42654 through 42656). Many of these comments were from patients and their families and described how meaningful such a measure would be for individuals who receive services from IPFs. Though we did not solicit input on a patient experience of care measure in the FY 2023 IPF PPS proposed rule, we received many comments strongly recommending that we adopt such a measure, which we summarized in the FY 2023 IPF PPS final rule (87 FR 46846). Since publication of the FY 2023 IPF PPS final rule, section 4125(c) of the Consolidated Appropriations Act, 2023 (Pub. Law 117-328) was enacted, which amends section 1886(s)(4) of

the Act to require that the quality measures specified for the IPFQR Program must include a quality measure of patients' perspective on care not later than the FY 2031 payment determination.

We have continued to review publicly available patient experience of care instruments to identify such an instrument specified for, and tested in, the IPF setting. In our review, we identified the Psychiatric Inpatient Experience (PIX) survey as a publicly available survey instrument developed for and tested in the IPF setting. Pursuant to the Meaningful Measures 2.0 Framework, this measure addresses the "Person-Centered" priority area, as well as the "Individual and Caregiver Voice" foundation and aligns with our commitment to prioritize outcome and patient-reported measures.¹⁸⁴ This measure also aligns with the CMS National Quality Strategy Goal 4 "Foster Engagement." It also supports the Behavioral Health Strategy goal of "Strengthen Equity and Quality in Behavioral Health Care." Furthermore, this measure supports the new Universal Foundation domain of "Person-Centered Care." Furthermore, this measure

b. Overview of Measure

The PIX survey was developed by a team at the Yale University, Yale New Haven
Psychiatric Hospital to address the gap in available experience of care surveys, specifically the
lack of publicly available, minimally burdensome, psychometrically validated surveys specified
for the IPF setting.¹⁸⁷ The interdisciplinary team that developed this survey, including researchers
and clinicians, conducted the following steps in developing the survey: (1) literature review; (2)
patient focus groups; (3) solicitation of input from a patient and family advisory council; (4)
review of content validity with an expert panel; (5) development of survey; and (6) survey

¹⁸⁴ Centers for Medicare & Medicaid Services. Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at: https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization.

¹⁸⁵ CMS. (2022). CMS Behavioral Health Strategy. Available at https://www.cms.gov/cms-behavioral-health-strategy. Accessed on February 20, 2023.

https://www.nejm.org/doi/full/10.1056/NEJMp2215539

¹⁸⁷ Klemanski DH, Barnes T, Bautista C, Tancreti C, Klink B, Dix E. Development and Validation of the Psychiatric Inpatient Experience (PIX) Survey: A Novel Measure of Patient Experience Quality Improvement. *Journal of Patient Experience*. 2022;9. doi:10.1177/23743735221105671

testing within the Yale New Haven Psychiatric Hospital system.¹⁸⁸

The resulting survey contains 23 items in four domains. Patients can respond to each of the 23 items using a five-point Likert scale (that is, strongly disagree, somewhat disagree, neutral, somewhat agree, strongly agree) or choose that the item does not apply. The four domains are:

- Relationship with Treatment Team;
- Nursing Presence;
- Treatment Effectiveness; and
- Healing Environment. 189

The PIX survey is distributed to patients by administrative staff at a time beginning 24 hours prior to planned discharge. The survey, which is available in both English and Spanish and in accessible formats can be completed prior to discharge using either a paper copy of the survey or an electronic version of the survey via tablet computer. For a complete list of survey questions, including which questions are elements of each domain, we refer readers to the description of the survey in the Journal of Patient Experience: .

(1) Measure Calculation

(a) Cohort

The cohort for this measure is all patients discharged from an IPF during the reporting period who do not meet one of the following exclusions: (1) patients who are under 13 years of age at time of discharge, and (2) patients who are unable to complete the survey due to cognitive or intellectual limitations. The sampling procedures that IPFs can apply to the PIX survey

¹⁸⁸ Klemanski DH, Barnes T, Bautista C, Tancreti C, Klink B, Dix E. Development and Validation of the Psychiatric Inpatient Experience (PIX) Survey: A Novel Measure of Patient Experience Quality Improvement. *Journal of Patient Experience*. 2022;9. doi:10.1177/23743735221105671

¹⁸⁹ Klemanski DH, Barnes T, Bautista C, Tancreti C, Klink B, Dix E. Development and Validation of the Psychiatric Inpatient Experience (PIX) Survey: A Novel Measure of Patient Experience Quality Improvement. *Journal of Patient Experience*. 2022;9. doi:10.1177/23743735221105671

¹⁹⁰ Klemanski DH, Barnes T, Bautista C, Tancreti C, Klink B, Dix E. Development and Validation of the Psychiatric Inpatient Experience (PIX) Survey: A Novel Measure of Patient Experience Quality Improvement. *Journal of Patient Experience*. 2022;9. doi:10.1177/23743735221105671

measure are described in section VI.I.6 of this final rule.

(b) Calculation

The measure will be reported as five separate rates, one for each of the four domains of the PIX survey and one overall rate. Each of these rates will be calculated from patient responses on the PIX survey and then publicly reported on the Care Compare website (or successor CMS website). We will report the mean rates for each domain as well as the overall mean rate on the Care Compare website (or successor CMS website). To calculate the mean scores, we will assign a numerical value ranging from 1 (Strongly Disagree) to 5 (Strongly Agree). We will then calculate the average response by adding the values of all responses and dividing that value by the number of responses, excluding questions that were omitted or to which the patient selected "Does Not Apply."

(2) Review by the Measure Applications Partnership (MAP)

We included the PIX survey measure on the publicly available "List of Measures Under Consideration for December 1, 2022" (MUC List), a list of measures under consideration for use in various Medicare programs.¹⁹¹ The CBE-convened Measure Applications Partnership (MAP) reviewed the MUC List and discussed the potential use of the PIX survey for the IPFQR Program.

The MAP Health Equity Advisory Group agreed that well-constructed patient experience of care measures are an important indicator of quality care. Overall, the MAP Health Equity Advisory Group expressed that this measure is a "step in the right direction for behavioral health."¹⁹²

In addition, on December 8 through 9, 2022, the MAP Rural Health Workgroup reviewed the 2022 MUC List and expressed support for this measure, with patient support being especially

 ¹⁹¹ Centers for Medicare & Medicaid Services. List of Measures Under Consideration for December 1, 2022.
 Available at: https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.
 192 Centers for Medicare & Medicaid Services. 2022-2023 MAP Final Recommendations. Available at: https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.

strong. Some members of the MAP Rural Health Advisory Group were concerned about operational challenges, specifically costs related to implementation and maintenance and potential bias if the surveying occurs prior to discharge.¹⁹³

The MAP Hospital workgroup reviewed the 2022 MUC List on December 13 through 14, 2022. The MAP Hospital workgroup conditionally supported the measure for rulemaking, while emphasizing the importance of including patient reported experience of care data in the IPFQR Program. The MAP Hospital workgroup's conditions for support included endorsement by the CBE and additional testing data for this measure, specifically: (1) data from testing of the measure in a variety of settings (including urban, rural, safety net providers, and others), (2) data regarding survey results depending on the timing of survey administration (pre- versus post-discharge), (3) data regarding patient factors (for example, voluntary versus involuntary admissions), and (4) data regarding of mode of administration (for example, email versus mail) that may affect performance. Thereafter, the MAP Coordinating Committee deliberated on January 24 through 25, 2023 and ultimately voted to uphold the Hospital Workgroup's recommendation to conditionally support the PIX survey measure for rulemaking pending the same conditions as the MAP Hospital workgroup. 195

We believe that the testing that has been conducted on the PIX survey demonstrates that it is a valid and reliable tool for measuring patient experience of care in IPFs, and that the results from this initial testing are generalizable across IPFs. However, we agree with the MAP Hospital workgroup that additional testing of this measure could help better understand measure results, including any differences in measure results that were not analyzed during the PIX survey's initial testing. Therefore, the measure developer intends to conduct additional testing of the PIX survey prior to public reporting of the measure data, and we proposed a voluntary

¹⁹³ Centers for Medicare & Medicaid Services. 2022-2023 MAP Final Recommendations. Available at: https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.

¹⁹⁴ Centers for Medicare & Medicaid Services. 2022-2023 MAP Final Recommendations. Available at: https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.

¹⁹⁵ Centers for Medicare & Medicaid Services. 2022-2023 MAP Final Recommendations. Available at: https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.

reporting period before beginning mandatory reporting of the PIX survey. 196

(3) CBE Endorsement

The measure developer has not submitted this measure for CBE endorsement at this time. The developer does intend to submit this measure for endorsement in the future, following additional testing as recommended by the MAP Hospital workgroup. Although section 1886(s)(4)(D)(i) of the Act generally requires that measures specified by the Secretary must be endorsed by the entity with a contract under section 1890(a) of the Act, section 1886(s)(4)(D)(ii) of the Act states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to a measure that has been endorsed or adopted by a consensus organization identified by the Secretary.

We reviewed measures endorsed by consensus organizations and were unable to identify any other measures on this topic endorsed by a consensus organization. We did identify the Experience of Care and Health Outcomes (ECHO) Survey measure (CBE #008); however, this measure has had its endorsement removed as of the spring 2020 cycle. Additionally, the ECHO Survey was developed and tested for outpatient behavioral health, not the inpatient setting. Additionally, we identified the Patient Experience of Psychiatric Care as Measured by the Inpatient Consumer Survey (ICS) measure (CBE #0726). This measure has also had its endorsement removed as of the spring 2018 cycle. As neither of these two measures is endorsed at this time, we believe the exception in section 1886(s)(4)(D)(ii) of the Act applies.

c Data Collection, Submission and Reporting

IPFs will be responsible for administering the survey and collecting data on survey

would begin with CY 2026 data. We have corrected the above error here.

¹⁹⁶ We note that in the FY 2024 IPF PPS proposed rule we inadvertently stated in section V.5.b.(2) "Review by the MAP" of the proposal that we were providing a two-year voluntary reporting period (88 FR 21289), which was inconsistent with our proposal to provide a one-year voluntary reporting period (88 FR 21290). As noted throughout the proposed rule, we proposed that voluntary reporting would begin with CY 2025 data and mandatory reporting

responses, because the PIX survey is administered beginning 24 hours prior to a patient's planned discharge. Therefore, IPFs will collect the data in a manner similar to the collection of data for chart-abstracted measures or other patient screening measures. That is, the IPFs will collect data in the facility and then report these data to CMS using the methods described in section VI.I.4 of this final rule, "Data Submission Requirements," under "Procedural Requirements."

Because we anticipate that many IPFs, which already administer different patient experience of care survey instruments to their patients, will need to transition to the PIX survey, we proposed a voluntary reporting period beginning with data from CY 2025, which will be reported to CMS in CY 2026. We will then require IPFs to report data for the PIX survey measure beginning with data collected during CY 2026, to be reported to CMS during CY 2027 and affecting the FY 2028 payment determination.

We invited comments on our proposal.

Comment: Many commenters strongly supported the PIX survey measure. These commenters expressed that the measure addresses a long-standing measure gap in the IPFQR Program, which these commenters characterized as discriminatory, and specifically supported the PIX survey instrument because it was developed with input from people with lived experience in the IPF setting. Some of these commenters representing patients and their families provided descriptions of their own and their family members' lived experiences to explain how important such a survey opportunity would be to IPF patients. Some commenters stated that patients are especially vulnerable during inpatient treatment and that psychological distress can be exacerbated in this setting. These commenters expressed that collecting data regarding the patients' experiences of care can improve patient-centered, trauma-informed care in which patients are treated with dignity and respect. Other commenters stated that formal patient feedback motivates improved care. One commenter stated that collection and public reporting of these data would assist community-based providers in identifying IPFs to which to refer patients.

Other commenters stated that surveying IPF patients regarding their experience of care is a form of treating them with dignity and respect, empowering them, and showing that their experiences are important. Several commenters stated that survey data can be tied to other data sets to support research. Another commenter expressed that IPFs will be able to compare themselves to other IPFs, which could motivate quality improvement.

Response: We thank commenters for their support of the PIX survey measure. We agree that adoption of a patient experience of care measure for the IPF setting addresses a long-standing measure gap, encourages patient-centered care, and shows that we believe that the patient's experience is a critical element of providing quality care.

Comment: Some commenters expressed concern regarding measuring patient experience of care prior to discharge. Some of these commenters expressed that patients may feel unsafe responding honestly at any point prior to discharge because of a fear of retaliation for unfavorable responses. These commenters recommended providing an option for patients to respond post-discharge (such as providing a paper copy of the survey with a sealable, addressed envelope to return the survey after completing it). Another commenter stated that the setting in which the survey is administered, and time provided to complete the survey, could lead to variation in results and recommended administering the survey post-discharge. Many commenters recommended allowing vendors to collect and report the data for IPFs. Other commenters were specifically concerned regarding the 24 hours prior to discharge time period for administering the survey. Some of these commenters stated that there are many clinical activities occurring during this phase of the patient's stay and that adding another step may be burdensome for staff and patients. Other commenters concerned about the 24 hour prior to discharge time period expressed that discharge timelines are often uncertain, and therefore it may be difficult to know when the 24 hours prior to discharge window has started, especially for patients with long stays.

Response: We would like to clarify that, if it is not possible for a patient to complete the

survey prior to discharge, the facility should provide a sealable, addressed envelope for the patient to return the survey following discharge. This situation could apply in situations in which the patient would prefer more time or privacy to complete the survey, in situations in which there are competing clinical priorities prior to discharge, or in situations in which there is uncertainty regarding the timing of a patient's discharge. However, we caution IPFs that relying exclusively on the mail-back option may prevent the IPF from meeting the measure's minimum sampling requirements. If the IPF is able to meet the minimum sampling requirements and chooses to use a vendor to receive paper surveys, aggregate and analyze data provided through the surveys, or to report these data to CMS on the IPF's behalf, that would be consistent with the measure methodology and specifications.

Comment: Many commenters expressed support for surveying patients regarding their experience of care, but expressed that they already have tools or vendors in place and that transitioning to the PIX survey would be disruptive. Some commenters specifically stated that this transition would disrupt their historical trend data. One commenter expressed concern that patients complete too many experience surveys and recommended that CMS select one tool based on an evaluation of all current surveys. Some commenters expressed a preference for a CAHPS survey because these surveys are used in other care settings and are the core element of the CMS Foundational Measurement Strategy to address the person-centered care domain. Other commenters stated that patients with primary psychiatric diagnoses continue to be excluded from HCAHPS and that, even if this exclusion were removed, by adopting the PIX survey, data about patient experience in an IPF would not be comparable to data regarding patient experience in general acute care hospitals. Other commenters recommended that CMS allow IPFs to select their own patient experience instrument provided that it addresses the domains addressed by the PIX survey.

Response: We recognize that many IPFs already use patient experience of care survey instruments or vendors to administer and collect survey instruments on behalf of IPFs, and that

there is a burden for these IPFs to transition to a new survey instrument and administration and collection process. We further recognize that historical quality improvement trend data and analytical processes may be impacted for these IPFs who already use other patient experience of care survey instruments. We considered allowing IPFs to select their own patient experience data collection instrument provided that it addresses the domains addressed by the PIX survey. However, we believe that using a single, standardized instrument to assess patient experience of care across both freestanding IPFs and those psychiatric units in acute care hospitals will provide comparability of experience data. We believe that publicly reporting patient experience of care data that allows for comparisons between IPFs will be most meaningful to patients and their caregivers, and will allow IPFs to compare their measure results to similar IPFs as part of their quality improvement initiative. We understand commenters' concern that by adopting a different patient experience of care measure in the IPF setting than that for general acute care hospitals (that is, the HCAHPS survey) measure results will not be comparable across these settings, even if HCAHPS is expanded to patients with primary psychiatric diagnoses in the general acute care setting. However, in response to our previous RFIs about incorporating a patient experience of care measure in the IPFQR Program, many commenters (representing patients, patient advocates, caregivers, IPFs, and provider associations) recommended that we adopt a patient experience of care measure that was developed specifically for patients receiving care in IPFs (84 FR 38467). These commenters stated that there are elements of care, such as group therapy, that are unique to the IPF setting and stated that a survey for this setting should specifically address these elements of care. Because it was developed specifically for this setting, with input from patients and their caregivers, the PIX survey does include questions regarding these unique elements of care, whereas the HCAHPS survey does not.

With respect to concerns regarding loss of trend data, we have proposed to adopt the measure for mandatory reporting beginning with CY 2026 data (which will be submitted to CMS in CY 2027 and affect FY 2028 payment determination) to provide additional time for IPFs to

transition to this new survey. We wish to clarify that IPFs will be permitted to add questions to the survey, so if there are specific metrics that an IPF wishes to continue tracking, they will be able to do so. We believe that IPFs will have sufficient time prior to when mandatory reporting of this measure begins with the FY 2028 payment determination to determine which questions will be most appropriate to add to the survey without overburdening patients, or how to compare results from patient responses to the PIX survey to those of their existing surveys.

We believe that the commenter who referenced the CMS Foundational Measurement Strategy was referring to the CMS Universal Foundation, ¹⁹⁷ which includes setting specific versions of the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey. We considered potential adoption of a CAHPS measure for the IPFQR Program and solicited comment on this in the FY 2020 IPF PPS proposed rule (84 FR 16986 through 16987) and summarized the responses to this request in the FY 2020 IPF PPS final rule (84 FR 38467). Following our review of the HCAHPS survey and responses to that request for information, we determined that the PIX survey is more appropriate for the IPFQR Program since it has been developed and tested specifically for IPFs and with the input of individuals with lived experience with care in this setting. Therefore, while the HCAHPS survey is appropriate for the general acute care setting, we believe that the PIX survey is a more appropriate instrument for measuring patient experience of care in the IPF setting.

Comment: Many commenters expressed concern that the PIX survey has not been sufficiently tested for national implementation. These commenters specifically noted a lack of testing in diverse geographic settings (including testing for differences in performance in urban versus rural settings), lack of testing which compares this survey to other inpatient consumer surveys, lack of information about the correlation coefficients for the proposed domains, lack of reliability coefficients to determine the survey's internal consistency, lack of demographic data regarding patients who respond versus those who do not, lack of testing among the forensically

¹⁹⁷ https://www.cms.gov/aligning-quality-measures-across-cms-universal-foundation

and/or involuntarily admitted populations, lack of longitudinal testing, and lack of testing with facilities which have an average length of stay greater than 10 days. Some commenters recommended additional testing with volunteer IPFs prior to implementation as a mandatory measure. Some of these commenters recommended postponing mandatory adoption to ensure sufficient testing. One commenter expressed concern that the PIX survey does not clearly connect questions to key outcomes, and recommended further research and testing to identify these connections.

Response: We understand commenters' concerns regarding the testing of the PIX survey measure. We recognize that this is a relatively new instrument. We note that the measure developer is continuing to test this instrument to further address these questions and concerns prior to the national implementation of the measure. To increase time for testing and to better identify information that will need to be provided during education and outreach sessions prior to public reporting, we proposed and are adopting mandatory reporting of this measure for the FY 2028 payment determination, which would not require IPFs to begin administering and collecting responses to the PIX survey until CY 2026.

<u>Comment</u>: Some commenters expressed concern that this survey instrument is only available in a limited number of languages and recommended translation into additional languages to improve accessibility for all patients. Some of these commenters recommended adding supportive services to help those with language barriers or limited health literacy complete the survey.

Response: The measure developer has translated the survey from English into Spanish, Mandarin, and Farsi. The measure developer is currently working to translate the survey into other frequently requested languages (including, French, Arabic, and Japanese). For patients who have language barriers, the measure developer is currently developing survey administration guidelines for best practices in survey administration to enhance the accessibility of the PIX survey. These include but are not limited to screen readers, the use of visual cueing (for

example, using simple emojis that correspond with the Likert scale options), and the ability to request assistance in completing the survey. Options for phone surveys and the use of interpreters will also be included in these guidelines. Finally, the measure developer will add a question to the survey to indicate if the survey was completed with assistance. We anticipate that the updated survey will be available during FY 2023 so that IPFs can review it during their implementation planning in advance of the performance period for voluntary reporting (that is CY 2025).

<u>Comment</u>: Some commenters requested clarification regarding whether facilities could add their own elements to the survey to maintain historical trend data regarding questions that are important among their specific patient populations. Other commenters specifically requested the inclusion of a free-text comment section.

Response: Individual facilities can add supplemental items to the survey instrument provided that they do not amend or remove the key elements of the PIX survey in order to collect data for and report on this measure. We note that IPFs may not factor supplemental items into existing scoring procedures as this would affect reliability and validity of this measure.

Furthermore, we encourage facilities to consider the number of supplemental questions so as not to overburden or fatigue patients in completing the survey instrument.

<u>Comment</u>: One commenter recommended allowing patients to complete surveys regularly throughout their stay.

Response: Although we believe that this may be unduly burdensome to patients and create administrative and logistical burden for facilities, this is not inconsistent with reporting data on the PIX survey for this measure if the IPF only includes data for surveys administered according to the PIX survey measure's guidelines (specifically, PIX surveys administered beginning 24 hours prior to discharge) in the measure results reported to CMS.

<u>Comment</u>: Several commenters recommended additional questions, topics, and domains that they believe would be important to include in a patient experience of care survey for the IPF

setting. These topics included: (1) data on racial and ethnic disparities in diagnosing, treating, and providing care; (2) addressing patients' spiritual needs; (3) progress towards remediating life circumstances that precipitated the hospitalization; (4) perceptions of discharge planning and aftercare; (5) follow-up appointment availability (were they offered and scheduled); (6) staff cultural competency; (7) family involvement in treatment; (8) nurses' performance; (9) quantity of food; (10) overall rating; (11) wait time; and (12) family and caregiver perspectives.

Response: We note that the PIX survey was developed by an interdisciplinary team with input from patients and a patient and family advisory council to address items that are important to patients in this setting of care. However, as discussed previously, individual facilities can add supplemental items to the survey to address issues important to their patient populations or that are significant in the historical trend data.

Comment: One commenter stated that frequency measurement (which asks patients to recall how often something happened) versus evaluative measurement (which asks patients to identify how well their needs were met) can influence the magnitude of differences when evaluating patient experience by race and ethnicity. This commenter specifically noted that evaluative measures are typically better at identifying disparities than frequency-based measures and recommended considering this in developing a survey for this setting.

Response: The PIX survey uses an evaluative measurement (which asks patients to evaluate their experience of their care) approach with a Likert Scale (that is, strongly disagree, somewhat disagree, neutral, somewhat agree, strongly agree, and does not apply) versus a frequency style of evaluation (which asks patients to report whether or how frequently something occurred).

We agree with the commenter that one strength of the evaluative measurement approach is the ability to better identify disparities and detect inequities and note that this was a factor in the survey design of the PIX survey.¹⁹⁸

¹⁹⁸ Linacre JM. Optimizing rating scale category effectiveness. J Appl Meas. 2002;3(1):85-106. PMID: 11997586.

<u>Comment</u>: Many commenters recommended that the survey be administered by a peer or advocate to reduce concerns regarding retaliation.

Response: We appreciate this recommendation and believe that peer advocates could assist with survey administration with minimal training. The measure developer is currently developing survey administration guidelines which will incorporate information on the appropriate training for staff (including peer advocates) who will be responsible for survey administration. We anticipate that these guidelines will be available during FY 2023 so that IPFs can review them during their implementation planning in advance of the performance period for voluntary reporting (that is, CY 2025).

<u>Comment</u>: Several commenters had questions regarding public reporting of these data for this measure. One commenter requested clarification regarding whether the data would be publicly reported. Another commenter recommended that the data be accompanied by patient demographic and clinical information to allow for stratification and analysis.

Response: As described in section VI.H of the FY 2024 IPF PPS proposed rule, we have an established policy for publicly displaying the data submitted by IPFs for the IPFQR Program (88 FR 21299 through 21300). Consistent with that policy, we intend to publicly report these data. Specifically, in accordance with section 1886(s)(4)(E) of the Act, data that an IPF submits to CMS for the IPFQR Program will be made publicly available on a CMS website after providing the IPF an opportunity to review the data to be made public. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53653 through 53654), we adopted procedures for making data submitted under the IPFQR Program available to the public, after an IPF has the opportunity to review such data prior to public display, as required by section 1886(s)(4)(E) of the Act. We adopted modifications to these procedural requirements in 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). Specifically, IPFs will have a period of 30 days to review and submit corrections to errors resulting from CMS calculations prior to the data being made public.

We agree that the intersectionality of patient characteristics, including the categorization of clinical populations would provide useful information for researchers and potentially for patients and caregivers in selecting a facility at which to receive care. However, we note that the survey is anonymous and therefore cannot be linked to patients' clinical data. The measure developer specifically omitted clinical characterizations because of patients' concerns regarding discrimination, retaliation, and uncertainty about their suspected versus diagnosed conditions. We will consider the appropriateness and feasibility of including demographic data with publicly reported measure results for future public reporting.

<u>Comment</u>: Several commenters requested clarification on how the data would be collected and reported. Some of these commenters stated that IPFs with limited technological resources would find it hard to implement this survey. Some of these commenters further stated that without sufficient technological resources this survey would be burdensome for IPFs to administer.

Response: IPFs will collect data in the facility and then report these data to CMS using the methods described in section VI.I.4 of this final rule, that is "Data Submission Requirements" under "Procedural Requirements." This aligns with previously finalized policies for submitting data on chart-abstracted measures. We recognize that this may be burdensome for IPFs; however, given the importance of including a patient experience of care measure in the IPFOR Program, we believe that the benefit of adopting this measure outweighs this burden.

<u>Comment</u>: One commenter requested clarification regarding whether IPFs would be required to respond to patients to resolve issues identified in the PIX survey prior to the patient's discharge. Another commenter expressed concern that patients may include a threat to self or others in their survey response which would require IPFs to review responses to ensure that such threats were addressed prior to discharge.

Response: We wish to clarify that the PIX survey is an anonymous survey. Therefore, it would not be possible for IPFs to address input from individual patients, either prior to or after

discharge. We note that there are no questions on the PIX survey, which is a series of 23 items to which patients respond using a five-point Likert scale (that is, strongly disagree, somewhat disagree, neutral, somewhat agree, strongly agree) or choose that the item does not apply, that address a patient's potential threat to self or others. We acknowledge the possibility that, during IPF staff's administration of the survey, the patient may express to the staff member a potential threat to self or others. However, we believe the IPF will be able to train its staff to appropriately respond to and notify clinical and other staff of the patient's potential threat to self or others as with any other situation where IPF staff interact with IPF patients.

<u>Comment</u>: One commenter requested clarification regarding whether completing the survey would be mandatory for patients. Another commenter expressed concern that behavioral health patients often refuse to complete surveys.

Response: We agree that some patients may choose not to complete a survey. We note that, consistent with our proposal in the FY 2024 IPF PPS proposed rule (88 FR 21301), we are requiring IPFs to develop sampling plans that ensure that IPFs are able to submit data for 300 completed PIX surveys per year. IPFs would be required to sample from every month throughout the entire reporting period and not stop sampling or curtail ongoing interview activities once a certain number of completed surveys has been attained. We recommend that in developing sampling plans, IPFs consider the predicted rate of non-completion to ensure that they reach 300 completed PIX surveys.

<u>Comment</u>: Several commenters requested clarification regarding whether patients would be able to have assistance, such as from a family member, friend, or peer support specialist, to complete the survey if the patient is unable to complete the survey. One commenter requested clarification regarding whether a parent or guardian would be required to complete the survey for minors.

Response: The PIX survey is suitable for individuals of all ages within the measure cohort, which includes patients who are 13 or older at time of discharge. The survey was tested

with adolescents aged 13 to 17 and testing found that they were able to complete it without any significant differences in scores compared to adults. Nonetheless, we understand that some individuals may require assistance, and patients must be offered the option to seek help from staff, a caregiver (including parents or guardians), or a peer. Additionally, the measure developer is updating the survey to include a question asking if the patient received any assistance while completing it. We anticipate that the updated survey will be available during FY 2023 so that IPFs can review it during their implementation planning in advance of the performance period for voluntary reporting (that is CY 2025)

<u>Comment</u>: Several commenters expressed concern that the exclusion of patients who are unable to complete the survey due to cognitive or intellectual limitations could lead to subjective exclusions and create bias in the survey administration. Several of these commenters recommended removing this exclusion, and other commenters recommended providing standardized definitions that IPFs could apply.

Response: The measure developer is currently developing guidelines for best practices in survey administration to enhance the accessibility of the PIX survey and sampling integrity. All patients, including people with intellectual and development disabilities, must have an opportunity to participate in or benefit from the survey equal to that afforded to others. We anticipate that these guidelines will be available during FY 2023 so that IPFs can review them during their implementation planning in advance of the performance period for voluntary reporting (that is, CY 2025). We will communicate the availability of these guidelines through regular sub-regulatory communications.

We note that patients who are unable to complete the survey unaided on the basis of a disability must be offered reasonable modifications, such as the use of visual cueing (for example, using simple emojis that correspond with the Likert scale options). We believe that inclusivity is a key priority of adopting a patient experience of care survey and emphasize the importance of maximizing accessibility for all patients.

Comment: Several commenters expressed concern that the data collected by this survey may not be sufficient to improve patient experience. Another commenter requested clarification regarding whether the survey has been shown to improve patient outcomes. One commenter expressed concern about the Healing Environment domain in the PIX survey instrument because regulations and licensing requirements heavily restrict the environment of the IPF. One commenter expressed concern that IPFs do not have the resources to improve care based on the results of the PIX survey.

Response: We believe that a comprehensive approach to quality must include directly reported feedback from patients. We have consistently stated our commitment to identifying a patient experience of care measure for the IPF setting, and in our measure strategies, including the Meaningful Measures 2.0 Framework, the CMS National Quality Strategy, the Behavioral Health Strategy, and the Universal Foundation, we have consistently identified the need for person-centered care and engagement. Furthermore, we note that a review of 55 studies found that within these studies it was more common to find positive associations between patient experience and patient safety and clinical effectiveness than no associations. 199 However, including a measure of patient experience demonstrates that a positive patient experience is an important goal in its own right. This is supported by consistently strong patient and caregiver input requesting such a measure be adopted in the IPFOR Program and emphasizing that such a measure is an important element of showing that we believe that IPF patients should be treated with dignity and respect in an environment in which their voices matter as part of a patientcentered care experience. Additionally, we believe that having a nationally standardized patient experience of care measure will allow IPFs to compare their patient experience results with the results of other IPFs. This will allow IPFs to identify opportunities for improvement, including to their Healing Environment score, within the regulatory and licensure constraints under which

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¹⁹⁹ Doyle, c. Lennox, L, and Bell, D. A systematic review of evidence on the links between patient experience and clinical safety and effectiveness. BMJ Open. Available at: https://bmjopen.bmj.com/content/3/1/e001570

IPFs operate. That is, if other similar IPFs score higher in the Healing Environment domain despite operating within the same regulatory and licensure constraints, this will highlight the opportunity for the IPF to improve its Healing Environment.

<u>Comment</u>: One commenter expressed concern that the domain names do not appear to match the substance of the questions within the domain. This commenter expressed concern that there may be overlap or inconsistencies between the use of "treatment team" and "nursing team."

Response: We appreciate this concern; however, we believe the domain labels have been appropriately applied. Specifically, the four-domain survey aligned with the theoretical basis of patient experience and was chosen through extensive focus group testing. Further, decisions around domains and their labels were based on the degree to which individual items statistically coalesced around central themes. We noted that patients in focus groups rarely distinguished roles among their care teams. Functionally, medical providers and social workers operate in a collaborative framework to guide treatment and coordinate aftercare. Thus, questions about patients' relationships with their treatment team center around their interactions with those who provide medical and therapeutic care. The Nursing Presence domain was identified as a separate domain due to the distinctive nature of nurses' roles in comprehensively caring for all patients on the unit in support of the treatment team. We agree with the measure developer that this important distinction merited a separate domain to represent the unique work of the varying team members with whom patients interact.

<u>Comment</u>: Some commenters expressed concerns that this measure has not been endorsed by the CBE.

Response: We note that following additional testing, the measure developer intends to submit this measure to the CBE for endorsement. While we recognize the value of measures undergoing CBE endorsement review, given the urgency of adopting a patient experience of care measure for this setting, as there are currently no CBE-endorsed measures that address IPF patient experience of care, we believe it is important to implement this measure beginning with

voluntary reporting of CY 2025 data followed by mandatory reporting beginning with CY 2026 data, reported to CMS in CY 2027 and affecting the FY 2028 payment determination. We note that under section 1886(s)(4)(D)(ii) of the Act the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed measures endorsed by consensus organizations and were unable to identify any other measures on this topic endorsed by a consensus organization, and therefore, we believe the exception in section 1886(s)(4)(D)(ii) of the Act applies.

<u>Comment</u>: One commenter requested clarification on who developed the survey, whether it is proprietary, and if so, how IPFs will obtain licenses to use the survey.

Response: As described in the FY 2024 IPF PPS proposed rule (88 FR 21288), the PIX survey was developed by a team at the Yale University, Yale New Haven Psychiatric Hospital and is in the public domain. We note that the measure developer is currently developing guidelines for best practices in survey administration, and we strongly encourage staff who will be responsible for administering the survey to review these guidelines as soon as they become available. Because the measure developer has made the PIX survey available in the public domain, there is no certification or license required to administer the PIX survey.

<u>Comment</u>: One commenter expressed concern that there are too many questions for patients to complete.

Response: We understand the importance of balancing the number of survey questions to improve completion rates with minimal burden to the patient, while including a sufficient range of questions to address the most important aspects of patients' experiences about the care they received. We note that the PIX survey has 23 items, which is comparable to the number of questions in other patient experience of care survey instruments. Specifically, two other surveys which address inpatient care include the HCAHPS survey, which has 29 questions, and the Inpatient Consumer Survey (ICS), which has 28 items.

<u>Comment</u>: One commenter opposed adopting this survey in a pay-for-performance program.

Response: We note that the IPFQR Program is a pay-for-reporting program (that is, IPFs that comply with all requirements and submit required data under the IPFQR Program receive their full payment update) and that there are not currently any Medicare pay-for-performance programs (that is, programs which adjust payment based on the performance on measures) which address the IPF setting.

<u>Comment</u>: Some commenters requested clarification regarding whether the measure would be scored with "top-box" scoring or with mean scores, because the MUC List and the proposed rule described different methods.

Response: We considered "top-box" scoring and mean scores as we identified an approach to adopting and publicly reporting the PIX survey measure in the IPFQR Program.

Specifically, we considered modeling the "top-box" scoring used for reporting performance on the HCAHPS measure in which data are reported based on the percent of respondents who selected the most positive response (that is, the "top-box"). However, we believe that mean scores (that is, the numerical average calculated by assigning each response a numerical value from 1 – the least positive, to 5 the most positive, summing the scores, and dividing that value by the number of responses) provide information that is more meaningful to patients and their caregivers who are more likely to be familiar with mean scores as opposed to "top-box" scores.

Therefore, we decided to propose mean scores, which we described in the FY 2024 IPF PPS proposed rule (88 FR 21289). We note that the MUC list submission acknowledged the possibility that mean scores would be useful for reporting with the statement that "it may be useful for the distribution of total Likert-scale responses to be made available during initial implementation."

<u>Comment</u>: One commenter expressed support for reporting separate rates for each domain in addition to the overall rate. This commenter stated that this level of data will improve

patient choice and support IPFs' quality improvement efforts.

Response: We thank this commenter for the support and agree that the increased level of detail will improve patient choice and support IPF's quality improvement efforts.

<u>Comment</u>: Several commenters requested clarification regarding whether there will be a one-year or two-year voluntary reporting period.

Response: We wish to clarify that, consistent with our proposal in the FY 2024 IPF PPS proposed rule (88 FR 21290), there will be a 1-year voluntary reporting period. IPFs that wish to participate in the voluntary reporting period will be able to report CY 2025 data to CMS in CY 2026. Beginning with CY 2026 data, which will be reported to CMS in CY 2027, all IPFs will be required to report these data to CMS and failure to do so would affect their payment determination for FY 2028.

<u>Comment</u>: Several commenters expressed support for adoption of this measure for voluntary reporting of CY 2025 data in CY 2026 followed by mandatory reporting beginning with CY 2026 data affecting the FY 2028 payment determination to ensure there is a patient experience measure in the IPFQR Program as soon as technically feasible.

Response: We thank these commenters for their support.

<u>Final Decision</u>: After consideration of the public comments we received, we are finalizing adoption of the PIX survey measure as proposed.

E. Modification of the COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP)

Measure Beginning with the Quarter 4 CY 2023 Reporting Period/FY 2025 Payment

Determination

1. Background

On January 31, 2020, the Secretary of the Department of Health and Human Services declared a public health emergency (PHE) for the United States in response to the global outbreak of SARS–COV–2, a novel (new) coronavirus that causes a disease named "coronavirus

disease 2019" (COVID–19).²⁰⁰ Subsequently, multiple quality reporting programs including the Hospital IQR Program (86 FR 45374) and the IPFQR Program (86 FR 42633 through 42640) adopted the COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP) measure. The COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP) measure adopted in the IPFQR Program in the FY 2022 IPF PPS final rule (86 FR 42633 through 42650) requires each IPF to calculate the percentage of HCP eligible to work in the IPF for at least one day during the reporting period, excluding persons with contraindications to the COVID-19 vaccine, who have received a complete vaccination course against SARS-CoV-2 (86 FR 42633 through 42640).

COVID–19 has continued to spread domestically and around the world with more than 103.9 million cases and 1.13 million deaths in the United States as of June 19,2023.²⁰¹ In recognition of the ongoing significance and complexity of COVID–19, the Secretary renewed the PHE on April 21, 2020, July 23, 2020, October 2, 2020, January 7, 2021, April 15, 2021, July 19, 2021, October 15, 2021, January 14, 2022, April 12, 2022, July 15, 2022, October 13, 2022, January 11, 2023, and February 9, 2023.²⁰² While the PHE status ended on May 11, 2023,²⁰³ HHS has stated that the public health response to COVID-19 remains a public health priority with a whole of government approach to combatting the virus, including through vaccination efforts.²⁰⁴

In the FY 2022 IPF PPS final rule (86 FR 42633 through 42635) and in our Revised

²⁰⁰ 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.

²⁰¹ Centers for Disease Control and Prevention. COVID Data Tracker. Accessed February 13, 2023. Available at: https://covid.cdc.gov/covid-data-tracker/#datatracker-home.

²⁰² U.S. Dept. of Health and Human Services. Office of the Assistant Secretary for Preparedness and Response. (2023). Renewal of Determination that a Public Health Emergency Exists. Available at: https://aspr.hhs.gov/legal/PHE/Pages/covid19-11Jan23.aspx.

²⁰³ https://www.whitehouse.gov/wp-content/uploads/2023/01/SAP-H.R.-382-H.J.-Res.-7.pdf

²⁰⁴ U.S. Dept. of Health and Human Services. Fact Sheet: COVID-19 Public Health Emergency Transition Roadmap. February 9, 2023. Available at: https://www.hhs.gov/about/news/2023/02/09/fact-sheet-covid-19-public-health-emergency-transition-roadmap.html.

Guidance for Staff Vaccination Requirements,²⁰⁵ we stated that vaccination is a critical part of the nation's strategy to effectively counter the spread of COVID–19. We continue to believe it is important to incentivize and track HCP vaccination through quality measurement across care settings, including IPFs, in order to protect HCP, patients, and caregivers, and to help sustain the ability of HCP to continue serving their communities throughout the PHE and beyond.

At the time we issued the FY 2022 IPF PPS final rule where we adopted the COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP) measure, the Food and Drug Administration (FDA) had issued emergency use authorizations (EUAs) for initial and primary adult vaccines manufactured by Pfizer-BioNTech,²⁰⁶ Moderna,²⁰⁷ and Janssen.²⁰⁸ On August 23, 2021, the FDA issued an approval for the Pfizer-BioNTech vaccine, now marketed as Comirnaty.²⁰⁹ The FDA issued approval for the Moderna vaccine, marketed as Spikevax, on January 31, 2022²¹⁰ and an EUA for the Novavax adjuvanted vaccine on July 13, 2022.²¹¹ The FDA also issued EUAs for COVID–19 single vaccine booster doses in September 2021²¹² and

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COVID-19 Vaccine for Certain Populations. Available at: https://www.fda.gov/news-events/press-announcements/fda-authorizes-booster-dose-pfizer-biontech-covid-19-vaccine-certain-populations.

²⁰⁵ Centers for Medicare & Medicaid Services. Revised Guidance for Staff Vaccination Requirements QSO-23-02-ALL. October 26, 2022. Available at: https://www.cms.gov/files/document/qs0-23-02-all.pdf.

²⁰⁶ Food and Drug Administration. (December 2020). FDA Takes Key Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for First COVID-19 Vaccine. Available at: https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19.

²⁰⁷ Food and Drug Administration. (December 2020). FDA Takes Additional Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for Second COVID-19 Vaccine. Available at: https://www.fda.gov/news-events/press-announcements/fda-takes-additional-action-fight-against-covid-19-issuing-emergency-use-authorization-second-covid.

²⁰⁸ Food and Drug Administration. (February 2021). FDA Issues Emergency Use Authorization for Third COVID-19 Vaccine. Available at: https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-third-covid-19-vaccine.

²⁰⁹ Food and Drug Administration. (August 2021). FDA Approves First COVID-19 Vaccine. Available at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine.

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

²¹¹ Food and Drug Administration. (July 2022). Coronavirus (COVID-19) Update: FDA Authorizes Emergency Use of Novavax COVID-19 Vaccine, Adjuvanted. Available at: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-emergency-use-novavax-covid-19-vaccine-adjuvanted.

²¹² Food and Drug Administration. (September 2021). FDA Authorizes Booster Dose of Pfizer-BioNTech

October 2021²¹³ for certain populations and in November 2021²¹⁴ for all individuals 18 years of age and older. EUAs were subsequently issued for a second vaccine booster dose in March 2022²¹⁵ and for bivalent or "updated" booster doses in August 2022.²¹⁶

In the FY 2022 IPF PPS final rule, we stated that data demonstrating the effectiveness of COVID–19 vaccines to prevent asymptomatic infection or transmission of SARS–COV–2, the novel (new) coronavirus that causes COVID-19, were limited (86 FR 42634). While the impact of COVID–19 vaccines on asymptomatic infection and transmission was not yet fully known at the time of the FY 2022 IPF PPS final rule, there were robust data available on COVID–19 vaccine effectiveness across multiple populations against symptomatic infection, hospitalization, and death. Two-dose COVID–19 vaccines from Pfizer-BioNTech and Moderna had been found to be 88 percent and 93 percent effective against hospitalization for COVID–19, respectively, over 6 months for adults over age 18 without immunocompromising conditions. ²¹⁷ During a SARS-COV-2 surge in the spring and summer of 2021, 92 percent of COVID–19 hospitalizations and 91 percent of COVID–19-associated deaths were reported among persons not fully vaccinated. ²¹⁸ Real-world studies of population-level vaccine effectiveness indicated similarly high rates of effectiveness in preventing SARS-COV-2 infection among frontline

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²¹³ Food and Drug Administration. (October 2021). Coronavirus (COVID-19) Update: FDA Takes Additional Actions on the Use of a Booster Dose for COVID-19 Vaccines. Available at: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-additional-actions-use-booster-dose-covid-19-vaccines.

²¹⁴ Food and Drug Administration. (November 2021). Coronavirus (COVID-19) Update: FDA Expands Eligibility for COVID-19 Vaccine Boosters. Available at: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-expands-eligibility-covid-19-vaccine-boosters.

²¹⁵ Food and Drug Administration. (March 2022). Coronavirus (COVID-19) Update: FDA Authorizes Second Booster Dose of Two COVID-19 Vaccines for Older and Immunocompromised Individuals. Available at: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-second-booster-dose-two-covid-19-vaccines-older-and.

²¹⁶ Food and Drug Administration. (August 2022). Coronavirus (COVID-19) Update: FDA Authorizes Moderna, Pfizer-BioNTech Bivalent COVID-19 Vaccines for Use as a Booster Dose. Available at: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-pfizer-biontech-bivalent-covid-19-vaccines-use.

²¹⁷ Centers for Disease Control and Prevention. (September 24, 2021). Morbidity and Mortality Weekly Report (MMWR). Comparative Effectiveness of Moderna, Pfizer-BioNTech, and Janssen (Johnson & Johnson) Vaccines in Preventing COVID-19 Hospitalizations Among Adults Without Immunocompromising Conditions – United States, March-August 2021. Available

at: https://cdc.gov/mmwr/volumes/70/wr/mm7038e1.htm?s_cid=mm7038e1_w.

²¹⁸ Centers for Disease Control and Prevention. (September 10, 2021). Morbidity and Mortality Weekly Report (MMWR). Monitoring Incidence of COVID-19 Cases, Hospitalizations, and Deaths, by Vaccination Status – 13 U.S. Jurisdictions, April 4-July 17, 2021. Available at: https://cdc.gov.mmwr/volumes/70/wr/mm7037e1.htm.

workers in multiple industries, with a 90 percent effectiveness in preventing symptomatic and asymptomatic infection from December 2020 through August 2021.²¹⁹ Vaccines have also been highly effective in real-world conditions (that is, vaccines have continued to be highly effective in conditions other than clinical trials) at preventing COVID–19 in HCP with up to 96 percent effectiveness for fully vaccinated HCP, including those at risk for severe infection and those in racial and ethnic groups disproportionately affected by COVID–19.²²⁰ In the presence of high community prevalence of COVID–19, residents of nursing homes with low staff vaccination coverage had cases of COVID–19-related deaths 195 percent higher than those among residents of nursing homes with high staff vaccination coverage.²²¹ Currently available data demonstrate that COVID–19 vaccines are effective and prevent severe disease, including hospitalization, and death.

As SARS-COV-2 persists and evolves, our COVID-19 vaccination strategy must remain responsive. When we adopted the COVID-19 Vaccination Coverage Among HCP measure in the FY 2022 IPF PPS final rule, we stated that the need for booster doses of the COVID-19 vaccine had not been established and no additional doses had been recommended (86 FR 42639). We also stated that we believed the numerator was sufficiently broad to include potential future boosters as part of a "complete vaccination course" and that the measure was sufficiently specified to address boosters (86 FR 42639). Since we adopted the COVID-19 Vaccination Coverage Among HCP measure in the FY 2022 IPF PPS final rule, new variants of SARS- COV-2 have emerged around the world and within the United States. Specifically, the Omicron variant (and its related subvariants) is listed as a variant of concern by the Centers for

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²¹⁹ Centers for Disease Control and Prevention. (August 27, 2021). Morbidity and Mortality Weekly Report (MMWR). Effectiveness of COVID-19 Vaccines in Preventing SARS-COV-2 Infection Among Frontline Workers Before and During B.1.617.2 (Delta) Variant Predominance – Eight U.S. Locations, December 2020-August 2021. Available at: https://cdc.gov/mmwr/volume/70/wr/mm7034e4.htm

²²⁰ Pilishivi, T. et al. (December 2022). Effectiveness of mRNA Covid-19 Vaccine among U.S. Health Care Personnel. New England Journal of Medicine. 2021 Dec 16;385(25):e90. Available online at: https://pubmed.ncbi.nlm.nih.gov/34551224/.

McGarry BE et al. (January 2022). Nursing Home Staff Vaccination and Covid-19 Outcomes. New England Journal of Medicine. 2022 Jan 27;386(4):397-398. Available online at: https://pubmed.ncbi.nlm.nih.gov/34879189/.

Disease Control and Prevention (CDC) because it spreads more easily than earlier variants.²²² Vaccine manufacturers have responded to the Omicron variant by developing bivalent COVID- 19 vaccines, which include a component of the original virus strain to provide broad protection against COVID-19 and a component of the Omicron variant to provide better protection against COVID-19 caused by the Omicron variant.²²³ These booster doses of the bivalent COVID-19 vaccine have been shown to increase immune response to SARS-COV-2 variants, including Omicron, particularly in individuals who are more than 6 months removed from receipt of their primary series.²²⁴ The FDA issued EUAs for two bivalent COVID-19 vaccine booster doses, one from Pfizer-BioNTech²²⁵ and one from Moderna, ²²⁶ and strongly encourages anyone who is eligible to consider receiving a booster dose with a bivalent COVID- 19 vaccine to provide better protection against currently circulating variants.²²⁷ COVID-19 booster doses are associated with a greater reduction in infections among HCP and their patients relative to those who only received primary series vaccination. One study showed a rate of breakthrough infections among HCP who received only the two-dose regimen of the COVID-19 vaccine of 21.4 percent compared to a rate of 0.7 percent among HCP who received a third dose of the COVID-19 vaccine.²²⁸

Despite the efficacy of COVID-19 vaccination generally, data submitted to the CDC via the National Healthcare Safety Network (NHSN) demonstrate clinically significant variation in

²²² Centers for Disease Control and Prevention. (August 2021). Variants of the Virus. Available at: https://www.cdc.gov/coronavirus/2019-ncov/variants/index.html.

²²³ Food and Drug Administration. (November 2022). COVID-19 Bivalent Vaccine Boosters.

²²⁴ Chalkias, S et al. (October 2022). A Bivalent Omicron-Containing Booster Vaccine against Covid-19. N Engl J Med 2022; 387:1279-1291. Available online at: https://www.nejm.org/doi/full/10.1056/NEJMoa2208343.

²²⁵ Food and Drug Administration. (November 2022). Pfizer-BioNTech COVID-19 Vaccines. Available

at: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontechcovid-19-vaccines.

²²⁶ Food and Drug Administration. (November 2022). Moderna COVID-19 Vaccines. Available

at: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-

²²⁷ Food and Drug Administration. (August 2022). Coronavirus (COVID-19) Update: FDA Authorizes Moderna, Pfizer-BioNTech Bivalent COVID-19 Vaccines for Use as a Booster Dose. Available at: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-modernapfizer-biontech-bivalent-covid-19-vaccines-use

²²⁸ Oster Y et al. (May 2022). The effect of a third BNT162b2 vaccine on breakthrough infections in health care workers: a cohort analysis. Clin Microbiol Infect. 2022 May;28(5): 735.e1-735.e3. Available online at: https://pubmed.ncbi.nlm.nih.gov/35143997/.

booster dose vaccination rates across facilities, including IPFs. During the first quarter of 2022, IPFs reported a median coverage rate of booster or additional dose(s) of 19.1 percent, with an interquartile range of 8.7 percent to 37.9 percent. These data, which show a performance gap in booster coverage, indicate that there is opportunity to improve booster vaccination coverage among HCP in IPFs.²²⁹

We believe that vaccination remains the most effective means to prevent the worst consequences of COVID–19, including severe illness, hospitalization, and death. Given the availability of vaccine efficacy data, EUAs issued by the FDA for bivalent boosters, the continued presence of SARS–COV–2 in the United States, and variance among rates of booster dose vaccination, it is important to modify the COVID-19 Vaccination Coverage Among HCP measure to refer explicitly to HCP who receive primary series and booster vaccine doses in a timely manner. Given the persistent spread of COVID-19, we continue to believe that monitoring and surveillance of vaccination rates among HCP is important and provides patients, beneficiaries, and their caregivers with information to support informed decision-making.

Beginning with the fourth quarter of the CY 2023 reporting period/FY 2025 payment determination, we proposed to modify the COVID-19 Vaccination Coverage Among HCP measure in the IPFQR Program to replace the term "complete vaccination course" with the term "up-to-date" in the HCP vaccination definition. We also proposed to update the numerator to specify the time frames within which an HCP is considered "up-to-date" with recommended COVID–19 vaccines, including booster doses.

In the FY 2022 IPF PPS final rule (86 FR 42638), we stated, and reiterate now, that the COVID-19 Vaccination Coverage Among HCP measure is a process measure that assesses HCP vaccination coverage rates. Unlike outcome measures, process measures do not assess a particular clinical outcome.

²²⁹ Measure Applications Partnership (MAP) Hospital Workgroup Preliminary Analyses. Available at: https://mmshub.cms.gov/sites/default/files/map-hospital-measure-specifications-manual-2022.pdf.

2. Overview of Measure

The proposed COVID-19 Vaccination Coverage Among HCP measure is a process measure developed by the CDC to track COVID-19 vaccination coverage among HCP in settings such as acute care facilities, including IPFs, and post-acute care facilities.

We refer readers to the FY 2022 IPF PPS final rule (86 FR 42635 through 42636) for more information on the initial review of the current COVID-19 Vaccination Coverage Among HCP measure by the Measure Applications Partnership (MAP). We included an updated version of the proposed modification of the COVID-19 Vaccination Coverage Among HCP measure on the list of measures under consideration (MUC List), which is published annually on behalf of CMS by the CBE with which the Secretary must contract as required by section 1890(a) of the Act, for the 2022 to 2023 pre-rulemaking cycle for consideration by the MAP.

In December 2022, the MAP Hospital Workgroup discussed the proposed modification of the COVID-19 Vaccination Coverage Among HCP measure. The MAP Hospital Workgroup stated that the proposed modification of the current measure captures "up-to-date" vaccination information in accordance with the CDC's recommendations, which have been updated since their initial development. Additionally, the MAP Hospital Workgroup appreciated that the modified measure's denominator is broader and simplified from seven categories of healthcare personnel to four.²³⁰

During review on December 6 and 7, 2022, the MAP Health Equity Advisory Group highlighted the importance of COVID–19 measures and asked whether the proposed modified measure excludes individuals with contraindications to Food and Drug Administration (FDA) authorized or approved COVID-19 vaccines, and whether the measure will be stratified by demographic factors.²³¹ The CDC, the measure developer for this measure, responded to the

²³⁰ Centers for Medicare & Medicaid Services. 2022-2023 MAP Final Recommendations. Available at: https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.

²³¹ Centers for Medicare & Medicaid Services. 2022-2023 MAP Final Recommendations. Available at: https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.

question regarding individuals with contraindications by confirming that HCP with contraindications to the vaccines are excluded from the measure denominator. The CDC further explained that the modified measure will not be stratified since the data are submitted at an aggregate rather than an individual level.

During review on December 8 through 9, 2022, the MAP Rural Health Advisory Group expressed concerns about data collection burden, citing that collection is performed manually and that small rural hospitals may not have employee health software.²³² The measure developer (that is, the CDC) acknowledged the challenge of getting adequate documentation and emphasized the goal to ensure the measure does not present a burden on providers. The measure developer also noted that the model used for this measure is based on the Influenza Vaccination Coverage Among HCP measure (CBE #0431), and it intends to utilize a similar approach to the modified COVID-19 Vaccination Coverage Among HCP measure if vaccination strategy becomes seasonal. The modified COVID-19 Vaccination Coverage Among HCP measure received conditional support for rulemaking pending testing indicating the measure is reliable and valid, and endorsement by the CBE. The MAP noted that the previous version of the measure received endorsement from the CBE (CBE #3636)²³³ and that the CDC intends to submit the proposed updated measure for endorsement.

a. Measure Specifications

The modification of the COVID-19 Vaccination Coverage Among HCP measure will require that IPFs continue to collect data at least one week each month for each of the three months in a quarter.

The denominator is the number of HCP eligible to work in the facility for at least one day during the reporting period, excluding persons with contraindications to COVID- 19 vaccination

²³² Centers for Medicare & Medicaid Services. 2022-2023 MAP Final Recommendations. Available at: https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.

²³³ Centers for Medicare & Medicaid Services. 2022-2023 MAP Final Recommendations. Available at: https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports. and CMS Measures Inventory Tool. Available at:

that are described by the CDC.²³⁴ There are not any changes to the denominator exclusions for the current COVID-19 Vaccination Coverage Among HCP measure, and the modified COVID-19 Vaccination Coverage Among HCP measure will continue to exclude otherwise denominator-eligible HCPs with contraindications as defined by the CDC.²³⁵ IPFs report the following four categories of HCP to NHSN²³⁶; the first three categories are included in the measure denominator:

- 1. <u>Employees</u>: This category includes all persons who receive a direct paycheck from the IPF (that is, on the IPF's payroll), regardless of clinical responsibility or patient contact.
- 2. <u>Licensed independent practitioners (LIPs)</u>: This category includes physicians (MD, DO), advanced practice nurses, and physician assistants who are affiliated with the IPF but are not directly employed by it (that is, they do not receive a paycheck from the IPF), regardless of clinical responsibility or patient contact. Post-residency fellows are also included in this category if they are not on the IPF's payroll.
- 3. <u>Adult students/trainees and volunteers</u>: This category includes medical, nursing, or other health professional students, interns, medical residents, or volunteers aged 18 or older who are affiliated with the healthcare facility, but are not directly employed by it (that is, they do not receive a paycheck from the facility), regardless of clinical responsibility or patient contact.
- 4. Other contract personnel: Contract personnel are defined as persons providing care, treatment, or services at the IPF through a contract who do not fall into any of the previously discussed denominator categories. Please note that this also includes vendors providing care, treatment, or services at the facility who may or may not be paid through a contract. Facilities are required to enter data on other contract personnel for submission

²³⁴ Centers for Disease Control and Prevention. (2022). Contraindications and precautions. Available at: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#contraindications.

²³⁵ Centers for Disease Control and Prevention. (2022). Contraindications and precautions. Available at: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#contraindications.

https://www.cdc.gov/nhsn/pdfs/nqf/covid-vax-hcpcoverage-rev-2023-508.pdf

in the NHSN application, but reporting for this category is not included in the COVID- 19 Vaccination Coverage Among HCP measure.

The numerator is the cumulative number of HCP in the denominator population who are "up-to-date" with CDC recommended COVID-19 vaccines. IPFs would refer to the CDC's guidance, to determine the then-applicable definition of "up-to-date," as of the first day of the applicable reporting quarter. The CDC's guidance can be found at:

https://www.cdc.gov/nhsn/pdfs/hps/covidvax/UpToDateGuidance-508.pdf. For purposes of NHSN surveillance, the CDC used the following definition of "up-to-date" during the fourth quarter of CY 2022 surveillance period (September 26, 2022 through December 25, 2022):

- 1. Individuals who received an updated bivalent²³⁷ booster dose, or
- 2a. Individuals who received their last booster dose less than 2 months ago, or
- 2b. Individuals who completed their primary series²³⁸ less than 2 months ago.

Subsequent to the publication of the FY 2024 IPF PPS proposed rule, the CDC has updated the definition of "up-to-date" for the second quarter of CY 2023 surveillance period:

- 1. Individuals who received an updated bivalent²³⁹ booster dose, or
- 2. Individuals who completed their primary series²⁴⁰ less than 2 months ago.

We refer readers to https://www.cdc.gov/nhsn/nqf/index.html for more details on the modified measure specifications.

We proposed that public reporting of the modified version of the COVID-19 Vaccination Coverage Among HCP measure would begin with the October 2024 Care Compare refresh, or as soon as technically feasible after that refresh.

²³⁷ The updated (bivalent) Moderna and Pfizer-BioNTech boosters target the most recent Omicron subvariants. The updated (bivalent) boosters were recommended by the CDC on 9/2/2022. As of this date, the original, monovalent mRNA vaccines are no longer authorized as a booster dose for people ages 12 years and older.

²³⁸ Completing a primary series means receiving a two-dose series of a COVID–19 vaccine or a single dose of Janssen/J&J COVID–19 vaccine.

²³⁹ The updated (bivalent) Moderna and Pfizer-BioNTech boosters target the most recent Omicron subvariants. The updated (bivalent) boosters were recommended by the CDC on 9/2/2022. As of this date, the original, monovalent mRNA vaccines are no longer authorized as a booster dose for people ages 12 years and older.

²⁴⁰ Completing a primary series means receiving a two-dose series of a COVID–19 vaccine or a single dose of Janssen/J&J COVID–19 vaccine.

b. CBE Endorsement

The current version of the COVID-19 Vaccination Coverage Among HCP measure received CBE endorsement (CBE #3636, "Quarterly Reporting of COVID-19 Vaccination Coverage Among Healthcare Personnel") on July 26, 2022.²⁴¹

Although section 1886(s)(4)(D)(i) of the Act generally requires that measures specified by the Secretary must be endorsed by the entity with a contract under section 1890(a) of the Act, section 1886(s)(4)(D)(ii) of the Act states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to a measure that has been endorsed or adopted by a consensus organization identified by the Secretary.

We reviewed measures endorsed by consensus organizations and were unable to identify any other measures on this topic endorsed by a consensus organization; therefore, we believe the exception in section 1886(s)(4)(D)(ii) of the Act applies. The CDC, as the measure developer, is currently pursuing endorsement for the modified version of the measure as the current version of the measure has already received endorsement.

3. Data Collection, Submission, and Reporting

We refer readers to the FY 2022 IPF PPS final rule (86 FR 42636 through 42640) for information on data submission and reporting of the current COVID-19 Vaccination Coverage Among HCP measure. While we did not propose any changes to the data submission or reporting process, we proposed that reporting of the updated modified measure would begin with the fourth quarter of CY 2023 reporting period for FY 2025 payment determination. Beginning with the FY 2026 payment determination, we proposed that IPFs would be required to submit data for the modified measure for the entire calendar year.

²⁴¹ CMS Measures Inventor Tool. COVDI-19 Vaccination Coverage among Healthcare Personnel. Available at: https://cmit.cms.gov/cmit/#/MeasureView?variantId=5273§ionNumber=1.

Under the data submission and reporting process, IPFs collect the numerator and denominator for the COVID-19 Vaccination Coverage Among HCP measure for at least one self-selected week during each month of the reporting quarter and submit the data to the CDC's National Health Safety Network (NHSN) Healthcare Personnel Safety (HPS) Component before the quarterly deadline. If an IPF submits more than one week of data in a month, the CDC would use most recent week's data to calculate the measure results which would be publicly reported. Each quarter, the CDC calculates a single quarterly COVID-19 HCP vaccination coverage rate for each IPF, which is calculated by taking the average of the data from the three weekly rates submitted by the IPF for that quarter. CMS publicly reports each quarterly COVID-19 HCP vaccination coverage rate as calculated by the CDC based on the data IPFs submit to the NHSN (86 FR 42636 through 42640).

We invited public comment on our proposal.

Comment: Some commenters supported the proposed modification to the COVID-19 Vaccination Coverage Among HCP measure. One of these commenters stated that the modified specifications would lead to increased vaccination and booster adoption among HCP. One commenter stated that patients with mental illness are more vulnerable to COVID- 19 driving the increased need for their providers to be vaccinated.

Response: We thank the commenters for their support. We agree that vaccination plays a critical part of the nation's strategy to effectively counter the spread of COVID–19. We continue to believe it is important to incentivize and track rates of vaccination among HCP through quality measurement across care settings, including the IPF setting, in order to protect healthcare workers, patients, and caregivers, and to help sustain the ability of HCP in each of these care settings to continue serving their communities.

<u>Comment</u>: Several commenters did not support updating the specifications for the COVID-19 Vaccination Coverage Among HCP measure because the PHE has expired and the Conditions of Participation (COPs) for hospitals have been revised to no longer require reporting

of these data. Some of these commenters requested clarification regarding whether the change in COPs means that we will remove the measure from our quality reporting programs. One commenter expressed concern that retaining measurement of COVID-19 Vaccination Coverage Among HCP after the vaccination requirement has been removed from COPs sends an inconsistent message regarding CMS's priorities.

Response: As commenters noted, the PHE for COVID-19 expired on May 11, 2023.²⁴² Since May 11, 2023, some state and federal reporting requirements have changed. While CMS requirements for Medicare and Medicaid-certified providers and suppliers to ensure that their staff were fully vaccinated for COVID-19 have ended with the expiration of the COVID-19 PHE (88 FR 36488), CMS revised the hospital and critical access hospitals (CAHs) infection prevention and control Condition of Participation so that hospitals and CAHs will continue to report on a reduced number of COVID-19 data elements after the conclusion of the COVID-19 PHE until April 30, 2024, unless the Secretary establishes an earlier end date.²⁴³ While these changes may impact certain aspects of facility reporting on COVID-19 data, we note that the reporting requirements of the IPFQR Program are distinct from those related to the expiration of the COVID-19 PHE and facilities participating in the IPFQR Program are required to report the COVID-19 Vaccination Coverage Among HCP measure. We further note that in our final rule removing staff vaccination requirements, we clarified that we were aligning our approach with that for other infectious diseases, specifically influenza, and that we would encourage ongoing COVID-19 vaccination through our quality reporting and value-based incentive programs (88 FR 38486).

We believe this measure continues to align with our goals to promote wellness and disease prevention. Under CMS' Meaningful Measures Framework 2.0, the COVID-19

²⁴² U.S. Dept. of Health and Human Services. Fact Sheet: COVID-19 Public Health Emergency Transition Roadmap. February 9, 2023. Available at: https://www.hhs.gov/about/news/2023/02/09/fact-sheet-covid-19-public-health-emergency-transition-roadmap.html.

²⁴³ https://www.hhs.gov/about/news/2023/05/09/fact-sheet-end-of-the-covid-19-public-health-emergency.html

Vaccination Coverage Among HCP measure addresses the quality priorities of "Immunizations" and "Public Health" through the Meaningful Measures Area of "Wellness and Prevention."

Under the National Quality Strategy, the measure addresses the goal of "Safety" under the priority area "Safety and Resiliency." Our response to COVID-19 is not fully dependent on the emergency declaration for the COVID-19 PHE and, beyond the end of the COVID-19 PHE, we continue to work to protect individuals and communities from the virus and its worst impacts by supporting access to COVID-19 vaccines, treatments, and tests.

Comment: Many commenters did not support updating the COVID-19 Vaccination

Coverage Among HCP measure because of concerns that the frequency of changes to the CDC's definition of "up-to-date" combined with the uncertainty around future vaccination schedules creates unnecessary burden for facilities. Some of these commenters recommended allowing voluntary reporting until the appropriate definitions and guidance are stable. One commenter stated that understanding how changing guidelines apply to all members of staff (such as those with risk factors) is burdensome. Others stated that publicly reporting these data may not be meaningful to consumers due to the changing definitions and the time lag between collection and public reporting.

Response: Since the adoption of the current version of the measure, the public health response to COVID-19 has necessarily adapted to respond to the changing nature of the virus's transmission and community spread. When we finalized the adoption of the COVID-19 Vaccination Coverage Among HCP measure in the FY 2022 IPF PPS final rule (86 FR 42640), we received several comments encouraging us to continue to update the measure as new evidence on COVID-19 continues to arise and we stated our intention to continue to work with partners including FDA and CDC to consider any updates to the measure in future rulemaking as appropriate. We believe that the measure modification aligns with the CDC's responsive approach to COVID-19 and will continue to support vaccination as the most effective means to prevent the worst consequences of COVID-19, including severe illness, hospitalization, and

death. We agree with commenters who 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 immediate vaccination rates.

<u>Comment</u>: Many commenters recommended that CMS reduce the mandatory reporting frequency to quarterly or to annually to reduce reporting burden for facilities. Some of these commenters stated that this mirrors the reporting schedule for the Influenza Vaccination Coverage Among HCP measure which is in some quality reporting programs.

Response: As we stated in the FY 2024 IPF PPS proposed rule (88 FR 21292), the measure developer noted that the model used for this measure is based on the Influenza Vaccination Coverage Among HCP measure (CBE #0431), and it intends to utilize a similar approach to the modified COVID-19 Vaccination Coverage Among HCP measure if vaccination strategy becomes seasonal. We continue to monitor COVID-19 as part of our public health response and will consider information we collect to inform any potential action that may address seasonality in future rulemaking.

<u>Comment</u>: Some commenters expressed concern that the COVID-19 Vaccination Coverage Among HCP measure has not been endorsed by the CBE.

Response: The current version of the measure received CBE endorsement (CBE #3636, "Quarterly Reporting of COVID–19 Vaccination Coverage Among Healthcare Personnel") on July 26, 2022. As we stated in the FY 2024 IPF PPS proposed rule (88 FR 21292 through 21293), 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. As discussed in section V.E.2.b. of the proposed rule (88 FR 21292 through 21293) and this final rule, we reviewed measures endorsed by consensus organizations and were unable to identify any other measures on this topic endorsed by a consensus organization; therefore, we believe the exception for non- CBE- endorsed measures applies. The measure steward, CDC, is currently pursuing endorsement for the modified version of the measure as the current version of the measure has already received endorsement.

Comment: Some commenters recommended that CMS include an exclusion for sincerely held religious beliefs to adhere to HHS Office of Civil Rights Guidance. Some of these commenters also requested the measure be updated to track the number of HCP who decline vaccination. Several commenters stated that there are many factors beyond an IPF's control (such as weather, holidays, vaccine supply, etc.) that may affect performance on this measure.

Response: We recognize that there are many reasons, including religious objections or concerns regarding an individual HCP'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 religious or philosophical objections. He could affect vaccination coverage; however, we believe that all IPFs face such concerns and that public reporting of these data can help patients and their caregivers identify which IPFs have better vaccination coverage among their HCP. Furthermore, we believe that reporting of the measure based on one week per month over three months will allow some seasonal or other effects to be mitigated. We wish to emphasize that neither the modified measure nor the current version of the measure mandate vaccines. The COVID–19 Vaccination Coverage Among HCP measure only requires reporting of vaccination rates for successful program participation.

²⁴⁴ https://www.cdc.gov/nhsn/forms/COVIDVax.HCP .FORM May2022-508.pdf

<u>Final Decision</u>: After consideration of the public comments we received, we are finalizing modification of the COVID–19 Vaccination Coverage Among HCP measure as proposed.

F. Removal or Retention of IPFQR Program Measures

1. Background

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38463 through 38465) and FY 2019 IPF PPS final rule (83 FR 38591 through 38593), we adopted several considerations for removing or retaining measures within the IPFQR Program.

Specifically, we have adopted eight factors that we consider when evaluating whether to propose a measure for removal from the IPFQR Program. These factors are: (1) measure performance among IPFs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made ("topped out" measures); (2) measure does not align with current clinical guidelines or practice; (3) measure can be replaced by a more broadly applicable measure (across setting or populations) or a measure that is more proximal in time to desired patient outcomes for the particular topic; (4) measure performance or improvement does not result in better patient outcomes; (5) measure can be replaced by a measure more strongly associated with desired patient outcomes for the particular topic; (6) measure collection or public reporting leads to negative intended consequences other than patient harm; (7) measure is not feasible to implement as specified; and (8) the costs associated with a measure outweigh the benefit of its continued use in the program. For measure removal factor one, we specified that a measure is "topped out" if it meets the following criteria: (1) statistically indistinguishable performance at the 75th and 90th percentiles; and (2) the truncated coefficient of variation is less than or equal to 0.10.

We also adopted three factors for consideration in determining whether to retain a measure in the IPFQR Program, even if the measure meets one or more factors for removal.

These retention factors are: (1) measure aligns with other CMS and HHS policy goals, such as

those delineated in the National Quality Strategy and CMS Quality Strategy; (2) measure aligns with other CMS programs, including other quality reporting programs; and (3) measure supports efforts to move IPFs towards reporting electronic measures. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38464), we stated that these removal and retention factors are considerations that we consider in balancing the benefits and drawbacks of removing or retaining measures on a case-by-case basis.

Since adoption, we have not proposed any changes to these policies for removal or retention 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 did not propose any updates to these measure retention and removal policies. We proposed to codify these previously adopted policies at § 412.433(e).

We welcomed comments on this proposal.

<u>Comment</u>: One commenter recommended an additional factor, relevance and importance of the measure to patients, for CMS to consider when deciding whether to remove or modify a measure in the IPFQR. The commenter stated this was consistent with TEPs which inform the measure development process and would improve the patient centeredness of the program.

Response: We appreciate this recommendation and will consider it in the future as we continue to evaluate all elements of the IPFQR Program.

<u>Final Decision</u>: After consideration of the public comments we received, we are finalizing codification of our measure retention and removal policies as proposed.

2. Measures for Removal

We continue to evaluate our measure set against these removal and retention factors on an ongoing basis. In this continual evaluation of the IPFQR Program measure set under our Meaningful Measures Framework and according to our measure removal and retention factors, we identified two measures that we believe are appropriate to remove from the IPFQR Program

beginning with the FY 2025 payment determination. Our discussion of these measures follows.

a. Removal of the Patients Discharged on Multiple Antipsychotic Medications with Appropriate

Justification (HBIPS-5) (previously endorsed under CBE #0560) Measure Beginning with

FY 2025 Payment Determination

As we assessed our existing measure set to ensure that it remains appropriate for the IPFQR Program, we determined that measure removal factor two (that is, measure does not align with current clinical guidelines or practice) applies to the Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification (HBIPS-5) (CBE #560) measure due to the American Psychiatric Association's (APA's) updated guidelines for patients with schizophrenia.

We adopted the HBIPS-5 measure in the FY 2013 IPPS/LTCH PPS final rule as part of a set with the Patients Discharged on Multiple Antipsychotic Medications (HBIPS-4) (previously endorsed under CBE #0552) measure because of the belief that these two measures would help reduce unnecessary use of multiple antipsychotics, which would lead to better clinical outcomes and reduced side effects for patients (77 FR 53649 through 53650). We subsequently removed the HBIPS-4 measure in the FY 2016 IPF PPS final rule (80 FR 46695 through 46696). As we described in that final rule, following our adoption of these measures, some experts, including the CBE, provided input that the HBIPS-4 measure did not provide meaningful information about the quality of care received by IPF patients. This led to the removal of the HBIPS-4 measure's CBE endorsement in January 2014. During the CBE's review of the HBIPS-4 measure in 2014, the CBE observed that the HBIPS-4 and HBIPS-5 measures could be collected and reported separately and expressed that the HBIPS-5 measure should be retained in the IPFQR Program as it continued to provide meaningful quality of care information (80 FR 046695 through 46696).

Evidence supporting development and adoption of the HBIPS-5 measure included the APA Workgroup on Schizophrenia's 2004 Practice Guideline for the Treatment of Patients with

Schizophrenia. These guidelines stated that the "combinations of antipsychotics . . . should be justified by strong documentation that the patient is not equally benefited by monotherapy."²⁴⁵ In December 2019, the APA Board of Trustees approved updated guidelines for treatment of patients with schizophrenia. The updated guidelines are based on evolving clinical knowledge and have increased focus and specificity of recommendations for the use of pharmacotherapy; they also underscore the importance of patient preference and shared-decision making. These guidelines no longer contain the recommendation that combinations of antipsychotics should be justified by strong documentation that patients are not equally benefited by monotherapy. Therefore, the guidelines that originally supported the HBIPS-5 measure have changed substantially, and the HBIPS-5 measure is no longer aligned with current clinical guidelines and practice.

Furthermore, the HBIPS-5 measure is no longer supported by the measure steward (that is, The Joint Commission), who withdrew it from the CBE endorsement process in 2019. As a result, the HBIPS-5 measure lost its CBE endorsement in October 2019.²⁴⁸ Subsequent to this, the CBE-convened MAP's discussion of measure set removal for 2021-2022 included a discussion of this measure. Because the HBIPS-5 measure no longer aligns with clinical guidelines and is no longer CBE endorsed due to lack of support from the measure developer, the MAP recommended that the measure should be removed from the IPFQR Program.²⁴⁹

We agree with the MAP's assessment that the measure no longer aligns with clinical guidelines and therefore proposed to remove the measure from the IPFQR Program beginning

²⁴

https://www.researchgate.net/publication/298561608_Practice_guideline_for_the_treatment_of_patients_with_schiz ophrenia second edition.

https://ajp.psychiatryonline.org/doi/10.1176/appi.ajp.2020.177901.

²⁴⁷ The American Psychiatric Association. Practice Guideline for the Treatment of Patients with Schizophrenia, Third Edition. Available at: https://psychiatryonline.org/doi/book/10.1176/appi.books.9780890424841. Accessed on February 15, 2023.

²⁴⁸ CMS Measures Inventory Tool. Patients Discharged on multiple antipsychotic medications with appropriate justification. Available at: https://cmit.cms.gov/cmit/#/MeasureView?variantId=1141§ionNumber=1.

²⁴⁹ MAP 2021-2022 Considerations for Implementing Measures in Federal Programs. Available at:

https://mmshub.cms.gov/sites/default/files/map 2021-

 $^{2022\}_considerations_for_implementing_measures_in_federal_programs_final_report.pdf.$

with the FY 2025 payment determination. We note that data for the FY 2024 payment determination represents care provided in CY 2022 and will be reported to CMS prior to the publication of this FY 2024 IPF PPS final rule; therefore, the FY 2025 payment determination is the first period for which we can remove this measure.

We invited comments on our proposal.

<u>Comment</u>: Many commenters supported removing HBIPS-5 from the IPFQR Program. These commenters agreed that the measure no longer aligns with the updated clinical guidance from the APA.

Response: We thank these commenters for their support.

<u>Comment</u>: Several commenters expressed concern about the long-term effects of psychotropic medications, especially antipsychotics, and recommended that CMS defer removal until additional research can be performed to ensure there are minimal long-term effects of antipsychotic medications.

Response: We appreciate commenters' concern about the long-term effects of psychotropic medications. We note that our proposed removal of the measure was based on the updated APA guidelines for treatment of patients with schizophrenia. These guidelines underwent a rigorous review process prior to being updated, which included a review of the benefits and harms of each treatment.²⁵⁰

<u>Final Decision</u>: After consideration of the public comments we received, we are finalizing removal of the Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification (HBIPS-5) measure as proposed.

b. Removal of the Tobacco Use Brief Intervention Provided or Offered and Tobacco Use Brief Intervention (TOB-2/2a) Measure Beginning with the FY 2025 Payment Determination

We adopted the Tobacco Use Brief Intervention Provided or Offered and Tobacco Use

²⁵⁰

Brief Intervention (TOB-2/2a) measure in the FY 2015 IPF PPS final rule (79 FR 45971 through 45972) because of our belief that it is important to address the common comorbidity of tobacco use among IPF patients. The TOB-2/2a measure requires IPFs to chart-abstract measure data on a sample of IPF patient records, in accordance with established sampling policies (80 FR 46717 through 46719). When we introduced the TOB-2/2a measure to the IPFQR Program, the benefits of this measure were high because IPF performance was not consistent with respect to, and there were no other measures addressing, provision of tobacco use cessation counseling or treatment. At the time, the TOB-2/2a measure provided a means of distinguishing IPF performance regarding, and incentivized facilities to improve rates of, treatment for this common comorbidity. To further address tobacco use, we subsequently adopted the Tobacco Use Treatment Provided or Offered at Discharge and Tobacco Use Treatment at Discharge (TOB-3/3a) measure in the FY 2016 IPF PPS final rule (80 FR 46696 through 46699).

In the FY 2022 IPF PPS proposed rule, we proposed to remove the Tobacco Use Brief Intervention Provided or Offered and Tobacco Use Brief Intervention (TOB-2/2a) measure from the IPFQR Program beginning with the FY 2024 payment determination under our measure removal factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program (86 FR 19508 through 19509). We expressed our belief that the quality improvement benefits from the TOB-2/2a measure had greatly diminished because performance had leveled off, that is overall performance on the measure was no longer improving. We took this to mean that most IPFs routinely offer tobacco use brief interventions.

In the FY 2022 IPF PPS proposed rule, we also expressed our belief that the costs of maintaining this measure are high because costs are multi-faceted and include not only the IPFs' burden associated with reporting, but also our costs associated with implementing and maintaining the measure (86 FR 19508 through 19509). Additionally, we must expend resources in maintaining information collection systems, analyzing reported data, and providing public

reporting of the collected information. We expressed that, for this measure, IPF information collection burden and related costs associated with reporting this measure to CMS were high because the measure is a chart-abstracted measure. Furthermore, we observed CMS incurs costs associated with the program oversight of the measure for public display.

However, in the FY 2022 IPF PPS final rule, we did not finalize our proposal to remove the Tobacco Use Brief Intervention Provided or Offered and Tobacco Use Brief Intervention (TOB-2/2a) measure (86 FR 42648 through 42651). We stated that, following review of the public comments we received, we believed the benefits of continuing to encourage facilities to offer tobacco use brief interventions were greater than we had estimated. We noted that these benefits included the potential for IPFs to continue improving performance on the TOB-2/2a 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.

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 observed that having two measures addressing tobacco use, which are both associated with relatively high information collection burden, may not appropriately balance costs and benefits within the program. While we believe that both the TOB-2/2a measure and the TOB-3/3a measure address clinically important interventions to address smoking in this population, we believe that the overall cost associated with retaining both of these measures outweighs the benefit of having two measures to address treatment for the same comorbidity among the same patient population.

Both measures capture information about tobacco cessation counseling and FDA- approved tobacco cessation medications. The difference between the measures is that the TOB-2/2a measure captures whether the tobacco cessation counseling and FDA-approved tobacco cessation medications were offered or refused during the inpatient stay, while the TOB- 3/3a measure captures whether a referral to outpatient tobacco cessation counseling and

FDA-approved tobacco cessation medications were offered or refused at the time of the patient's discharge.

As we considered each of these measures, we determined that it would be more appropriate to retain the TOB-3/3a measure in the IPFQR Program, that is, to remove the TOB- 2/2a measure instead of the TOB-3/3a measure, because there is more opportunity for improvement on the TOB-3/3a measure. Specifically, the performance on the TOB-3/3a measure is lower than performance on the TOB-2/2a measure. National performance on TOB- 2 and 2a measure and TOB-3 and 3a measure for the last five payment determination years in the IPFQR Program is presented in Table 19. Given the relatively high performance on the TOB-2/2a measure compared to the TOB-3/3a measure, we believe that retaining the TOB-3/3a measure, and removing the TOB-2/2a measure, would provide more opportunity to drive improvement among IPFs; therefore, would potentially impact more patients.

TABLE 19: NATIONAL PERFORMANCE ON TOB-2 AND TOB-2A AND TOB-3 AND TOB-3A FROM CY 2017 THROUGH CY 2021

Performance Period/Payment	TOB-2 Performance	TOB-2a Performance	TOB-3 Performance	TOB-3a Performance
Determination Year				
CY 2017/FY 2019	79.7%	44.9%	54.1%	15.0%
CY 2018/FY 2020	81.0%	46.2%	57.5%	17.8%
CY 2019/FY 2021	82.0%	46.8%	59.9%	21.6%
CY 2020/FY 2022	80.4%	44.9%	60.7%	21.7%
CY 2021/FY 2023	72.2%	39.0%	57.4%	18.3%

As described earlier in this section VI.F.2.b of this final rule, because the TOB-2/2a measure has a high cost (especially due to its high information collection burden), we believe that these high costs are no longer greater than the benefits of retaining this measure. Therefore, we believe measure removal factor 8 (that is, the costs associated with a measure outweigh the benefit of its continued use in the IPFQR Program), applies to the TOB-2/2a measure.

Furthermore, the TOB-2/2a measure is no longer supported by the measure steward (that is, The Joint Commission), who withdrew it from the CBE endorsement process in 2018.

Therefore, the TOB-2/2a measure has not been CBE endorsed since October 2018.²⁵¹ Subsequent to this, the CBE-convened MAP's discussion of measure set removal for 2021and 2022 included a discussion of this measure. Because the TOB-2/2a measure is a high-cost measure and is no longer CBE endorsed, the MAP recommended that we remove the measure from the IPFQR Program.²⁵²

We agree with the MAP that this is a high-cost measure. Furthermore, we recognize that it is similar to the other tobacco use measure in the IPFQR Program measure set (that is, the TOB-3/3a measure) which we did not propose to remove. Therefore, we proposed to remove Tobacco Use Brief Intervention Provided or Offered and Tobacco Use Brief Intervention (TOB- 2/2a) measure under our measure removal factor 8, "the costs associated with a measure outweigh the benefit of its continued use in the program," beginning with FY 2025 payment determination. We note that data for the FY 2024 payment determination represents care provided in CY 2022 and will be reported to CMS prior to the publication of this FY 2024 IPF PPS final rule; therefore, the FY 2025 payment determination is the first period for which we can remove this measure.

We invited public comment on this proposal.

<u>Comment</u>: Many commenters supported removal of the TOB-2/2a measure because it will reduce burden with minimal impact on patient outcomes due to the retention of the TOB- 3/3a measure. Some of these commenters stated that the TOB-3/3a measure has more room for improvement and is more likely to lead to improved patient outcomes.

Response: We thank these commenters for their support.

<u>Comment</u>: Many commenters opposed removal of the TOB-2/2a measure. These commenters stated that tobacco use is a common comorbidity among this patient population that

²⁵¹ CMS Measures Inventory Tool. Tobacco Use Treatment Provided or Offered. Available at: https://cmit.cms.gov/cmit/#/MeasureView?variantId=1818§ionNumber=1.

²⁵² MAP 2021-2022 Considerations for Implementing Measures in Federal Programs. Available at: https://mmshub.cms.gov/sites/default/files/map_2021-

²⁰²²_considerations_for_implementing_measures_in_federal_programs_final_report.pdf.

leads to negative long-term health outcomes. These commenters expressed that the TOB- 2/2a and TOB-3/3a measures both address important interventions to reduce tobacco use and therefore recommended retaining both measures. Some of these commenters expressed concern that, without the TOB-2/2a measure, IPFs will not offer tobacco use interventions in the inpatient setting which represents a missed opportunity to increase the likelihood that these patients will quit using tobacco. Some of these commenters stated that there is still room for improvement on the TOB-2/2a measure.

Response: We agree with commenters that tobacco use is a common comorbidity among this patient population that leads to negative long-term health outcomes. We remain committed to the screening, counseling and provision of smoking intervention services in this population of patients. We note that studies have demonstrated that during the acute hospital stay, there is no statistically significant increase in smoking cessation for non-intensive counseling interventions, such as brief intervention,²⁵³ which is what TOB-2/2a measures. We will retain TOB-3/3a which focuses on the provision of smoking cessation referral and treatment for smoking cessation at discharge, to be continued in the ambulatory setting, which studies have shown a greater benefit to the patient. Even though we are finalizing the removal of the TOB-2/2a measure, and therefore IPFs and IPFs will no longer be required to collect and submit TOB-2/2a data to CMS, IPFs are still encouraged to continue to provide smoking cessation counseling and brief interventions during the psychiatric stay as determined appropriate by the patient's provider and patient. We appreciate commenters concerns and will continue to monitor whether additional measures related to smoking cessation and/or intensive behavioral counseling are necessary. We also support the extensive other work that is being done by HHS and the broader Administration

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https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4498489/

²⁵³: Rigotti NA, Clair C, Munafò MR, Stead LF. Interventions for smoking cessation in hospitalised patients. Cochrane Database Syst Rev. 2012 May 16;5(5):CD001837. doi: 10.1002/14651858.CD001837.pub3. PMID: 22592676; PMCID: PMC4498489. Available at: :

to reduce smoking, including the framework proposed by the Office of the Assistant Secretary for Health (OASH) (88 FR 42377).

We agree with commenters that TOB-2/2a and TOB-3/3a both address important interventions (that is, tobacco use treatment brief intervention provided or offered during the inpatient stay and tobacco use treatment provided or offered at discharge) and that there is still room for improvement for both measures. While it is possible that, without the TOB-2/2a measure, some IPFs may stop providing inpatient tobacco use interventions prior to during the patient's discharge planning, we continue to believe that the benefit of having two measures to address this comorbidity does not outweigh the significant reporting burden for IPF's associated with these specific measures. We note that we believe that the benefits of tobacco use interventions during the inpatient stay are high; however, we do not believe the benefits of measuring these interventions along with similar interventions at discharge are sufficiently high to outweigh the burden.

<u>Final Decision</u>: After consideration of the public comments we received, we are finalizing removal of the Tobacco Use Brief Intervention Provided or Offered and Tobacco Use Brief Intervention measure as proposed.

G. Summary of IPFQR Program Measures

1. IPFQR Program Measures for the FY 2024 Payment Determination

We did not propose any changes to our measure set for the FY 2024 payment determination. The 14 measures which will be in the program for FY 2024 payment determination are shown in Table 20.

TABLE 20: IPFQR PROGRAM MEASURE SET FOR THE FY 2024 PAYMENT DETERMINATION

CBE#	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
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	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
3636	N/A	COVID-19 Healthcare Personnel (HCP) Vaccination Measure

^{*} Measure is no longer endorsed by the CBE but was endorsed at the time of adoption. We note that although section 1886(s)(4)(D)(i) of the Act generally requires measures specified by the Secretary be endorsed by the entity with a contract under section 1890(a) of the Act, section 1886(s)(4)(D)(ii) states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We 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 2025 Payment Determination

In this final rule, we are removing two measures for the FY 2025 payment determination and subsequent years. We also are modifying one measure for the FY 2025 payment determination and subsequent years. The 12 measures, which will be in the program for FY 2025 payment determination are shown Table 21.

TABLE 21: IPFQR PROGRAM MEASURE SET FOR THE FY 2025 PAYMENT DETERMINATION

CBE #	Measure ID	Measure
0640	HBIPS-2	Hours of Physical Restraint Use
0641	HBIPS-3	Hours of Seclusion Use
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-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
N/A	N/A	Modified COVID-19 Vaccination Coverage Among Healthcare Personnel

CBE #	Measure ID	Measure
		$(HCP)^1$

^{*} Measure is no longer endorsed by the CBE but was endorsed at the time of adoption. We note that although section 1886(s)(4)(D)(i) of the Act generally requires measures specified by the Secretary be endorsed by the entity with a contract under section 1890(a) of the Act, section 1886(s)(4)(D)(ii) states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We 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.

We are modifying the COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP) measure in section VI.E of this final rule.

3. IPFQR Program Measures for the FY 2026 Payment Determination

The measure set for FY 2026 payment determination and subsequent years will include 13 mandatory and two voluntary measures. This includes the 12 mandatory measures listed in Table 21 of this final rule for the FY 2025 payment determination and subsequent years, as well as the one mandatory measure and two voluntary measures we adopted for the FY 2026 payment determination and subsequent years. The measures which will be in the program for FY 2026 payment determination are shown Table 22.

TABLE 22: IPFQR PROGRAM MEASURE SET FOR THE FY 2026 PAYMENT DETERMINATION

CBE #	Measure ID	Measure
Mandatory Measures		
0640	HBIPS-2	Hours of Physical Restraint Use
0641	HBIPS-3	Hours of Seclusion Use
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-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
N/A	N/A	Modified COVID-19 Vaccination Coverage Among Healthcare Personnel
		$(HCP)^1$
N/A	Facility Commitment	Facility Commitment to Health Equity ²
Voluntary	Voluntary Measures	
N/A	Screening for SDOH	Screening for Social Drivers of Health ³
N/A	Screen Positive	Screen Positive Rate for Social Drivers of Health ⁴
		by the CDE but was and read at time of adoption. We note that although

^{*} Measure is no longer endorsed by the CBE but was endorsed at time of adoption. We note that although

section 1886(s)(4)(D)(i) of the Act generally requires measures specified by the Secretary be endorsed by the entity with a contract under section 1890(a) of the Act, section 1886(s)(4)(D)(ii) states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We 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.

- ¹ We are modifying the COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP) measure in section VI.E. of this final rule.
- ² We have adopted the Facility Commitment measure in section VI.D.2. of this final rule.
- ³ We have adopted voluntary reporting of the Screening for SDOH measure in section VI.D.3. of this final rule.
- ⁴ We have adopted voluntary reporting of the Screen Positive Rate for SDOH measure in section VI.D.4 of this final rule.

4. IPFQR Program Measures for the FY 2027 IPFQR Program's Payment Determination

The measure set for the FY 2027 payment determination and subsequent years, will include 15 mandatory measures and one voluntary measure. This includes the 13 mandatory measures listed in Table 22 of this final rule for the FY 2026 payment determination and subsequent years, as well as the two measures which we are requiring for the FY 2027 payment determination and subsequent years. It also includes the one new voluntary measure adopted in section VI.D.5 of this final rule. The measures which we are finalizing for the FY 2027 payment determination and subsequent years are shown Table 23.

TABLE 23: IPFQR PROGRAM MEASURE SET FOR THE FY 2027 PAYMENT DETERMINATION

CBE #	Measure ID	Measure	
Required N	Required Measures		
0640	HBIPS-2	Hours of Physical Restraint Use	
0641	HBIPS-3	Hours of Seclusion Use	
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-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	
N/A	N/A	Modified COVID-19 Vaccination Coverage Among Healthcare Personnel	
		(HCP) ¹	

CBE #	Measure ID	Measure	
Required M	Required Measures		
N/A	Facility Commitment	Facility Commitment to Health Equity ²	
N/A	Screening for SDOH	Screening for Social Drivers of Health ³	
N/A	Screen Positive	Screen Positive Rate for Social Drivers of Health ⁴	
Voluntary Measure			
N/A	PIX	Psychiatric Inpatient Experience Survey ⁵	

^{*} Measure is no longer endorsed by the CBE but was endorsed at time of adoption. Although section 1886(s)(4)(D)(i) of the Act generally requires that any measures specified by the Secretary must be endorsed by the entity with a contract under section 1890(a) of the Act, section 1886(s)(4)(D)(ii) states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We 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.

5. IPFQR Program Measures for the FY 2028 Payment Determination

The measure set for the FY 2028 payment determination and subsequent years will include 16 mandatory measures. This includes the 15 mandatory measures listed in Table 23 of this final rule for the FY 2027 payment determination as well as the measure which we finalized beginning with the FY 2028 payment determination. The measures which will be in the program beginning with the FY 2028 payment determination are shown Table 24.

TABLE 24: IPFQR PROGRAM MEASURE SET FOR THE FY 2029 PAYMENT DETERMINATION

CBE #	Measure ID	Measure
0640	HBIPS-2	Hours of Physical Restraint Use
0641	HBIPS-3	Hours of Seclusion Use
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-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

¹ We are modifying the COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP) measure in section VI.E. of this final rule.

² We have adopted the Facility Commitment measure in section VI.D.2. of this final rule.

³ We have adopted the Screening for SDOH measure in section VI.D.3. of this final rule.

⁴ We have adopted the Screen Positive measure in section VI.D.4. of this final rule.

⁵ We have adopted voluntary reporting of the Psychiatric Inpatient Experience (PIX) survey measure for the FY 2027 payment determination in section VI.D.5. of this final rule

CBE #	Measure ID	Measure
3205	Med Cont	Medication Continuation Following Inpatient Psychiatric
		Discharge
N/A	N/A	Modified COVID-19 Vaccination Coverage Among Healthcare
		Personnel (HCP) ¹
N/A	Facility Commitment	Facility Commitment to Health Equity ²
N/A	Screening for SDOH	Screening for Social Drivers of Health ³
N/A	Screen Positive	Screen Positive Rate for Social Drivers of Health ⁴
N/A	PIX	Psychiatric Inpatient Experience Survey ⁵

^{*} Measure is no longer endorsed by the CBE but was endorsed at time of adoption. Although section 1886(s)(4)(D)(i) of the Act generally requires that any measures specified by the Secretary must be endorsed by the entity with a contract under section 1890(a) of the Act, section 1886(s)(4)(D)(ii) states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We 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. Public Display and Review Requirements

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53653 through 53654), we adopted procedures for making data submitted under the IPFQR Program available to the public, after an IPF has the opportunity to review such data prior to public display, as required by section 1886(s)(4)(E) of the Act. We adopted modifications to these procedural requirements in 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).

Specifically, the IPFQR Program adopted a policy to provide IPFs a 30-day period to review their data, and submit corrections to errors resulting from CMS calculations, prior to public display on a CMS website. The IPFQR Program notifies IPFs of the exact timeframes for this preview period and public display through subregulatory guidance. We did not propose any changes to these requirements.

We proposed to codify the procedural requirements for public reporting of IPFQR Program data at § 412.433(g). If finalized, paragraph (g) would provide that IPFs will have a

¹ We are modifying the COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP) measure in section VI.E. of this final rule.

² We have adopted the Facility Commitment measure in section VI.D.2. of this final rule.

³ We have adopted the Screening for SDOH measure in section VI.D.3. of this final rule.

⁴ We have adopted the Screen Positive measure in section VI.D.4. of this final rule.

⁵ We have adopted mandatory reporting of the Psychiatric Inpatient Experience (PIX) survey measure for FY 2028 payment determination in section VI.D.5. of this final rule

period of 30 days to review data on quality measures that CMS received under the IPFQR Program, and submit corrections to errors resulting from CMS calculations, prior to CMS publishing this data on a CMS website.

We welcomed comments on our proposal to codify these policies.

We did not receive any comments on this proposal.

Final Decision: We are finalizing codification of these policies.

- I. Form, Manner, and Timing of Quality Data Submission for the FY 2024 Payment
 Determination and Subsequent Years
- 1. Procedural Requirements for the FY 2024 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), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38471 through 38472), and the FY 2022 IPF PPS final rule (86 FR 42656 through 42657) for our previously finalized procedural requirements for participation in, and withdrawal from, the IPFQR Program, as well as data submission requirements. We did not propose any changes to our previously finalized procedural requirements.

We proposed to codify these procedural requirements for participation in the IPFQR Program at § 412.433(b) through (d). Paragraphs (b) through (d) will set forth the procedural requirements for an IPF to register for, or withdraw from, participation in the IPFQR Program and to submit the required data on measures in a form and manner and time specified by CMS.

We welcomed comments on our proposal to codify these policies.

We did not receive any comments on this proposal.

<u>Final Decision</u>: We are finalizing codification of the procedural requirements for participation in the IPFQR Program at § 412.433(b) through (d). We are finalizing the regulation text as proposed except to replace references to "QualityNet" with "CMS-designated information system" and update the description of the registration process because we inadvertently referred

to QualityNet in the proposed rule. We have migrated to a new internet system for many quality reporting programs, and we use the term "CMS-designated information system" to refer both to that system and any future updates to it.

 Data Submission Requirements for the FY 2025 Payment Determination and Subsequent Years

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), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38472 through 38473), and the FY 2022 IPF PPS final rule (86 FR 42657 through 42661) for our previously finalized data submission requirements.

The measure we are modifying beginning with the FY 2025 payment determination—the COVID-19 Vaccination Coverage Among HCP measure — requires facilities to report data on the number of HCP who have received a complete vaccination course of a COVID-19 vaccine through the Centers for Disease Control and Prevention's (CDC's) National Healthcare Safety Network (NHSN). We are updating this measure to no longer refer to "complete vaccination course" but instead to refer to "up-to-date" vaccination, as described in section VI.E. of this final rule.

We did not propose any updates to the form, manner, and timing of data submission for the COVID-19 Vaccination Coverage Among HCP measure and refer readers to the FY 2022 IPF PPS final rule (86 FR 42657) for these policies.

3. Data Submission Requirements for the FY 2026 Payment Determination and Subsequent Years

In sections VI.D 3 and VI.D.4 of this final rule, we are adopting measures for voluntary reporting for the FY 2026 IPFQR Program and mandatory reporting for the FY 2027 IPFQR Program's payment determination and subsequent years. These measures are the Screening for Social Drivers of Health measure and Screen Positive Rate for Social Drivers of Health measure. We proposed that our previously finalized data submission requirements, specifically, our

previously finalized data submission requirements for aggregate data reporting described in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38472 through 38473) would apply to these measures.

We invited public comment on our proposal.

We did not receive any public comments on this proposal.

<u>Final Decision</u>: We are finalizing our proposal for data submission requirements for the FY 2026 payment determination and subsequent years.

4. Data Submission Requirements for the FY 2027 Payment Determination and Subsequent Years

In section VI.D.5. of this final rule, we are adopting one patient-reported measure, Psychiatric Inpatient Experience (PIX) measure for voluntary reporting beginning with the CY 2025 performance period (the data for which will be submitted to CMS during CY 2026) and mandatory reporting beginning with the FY 2028 payment determination (that is, data from the CY 2026 performance period submitted to CMS during CY 2027). Because, unlike other patient experience of care measures, this measure is collected by facilities prior to discharge, we proposed that facilities would report these data using the patient-level data reporting described in the FY 2022 IPF PPS final rule (86 FR 42658 through 42661).

We invited public comment on our proposal.

We did not receive any public comments on this proposal.

<u>Final Decision</u>: We are finalizing our proposal for data submission requirements for the FY 2027 payment determination and subsequent years. We note that reporting these data will be voluntary for the FY 2027 payment determination and will be mandatory beginning with the FY 2028 payment determination.

5. Data Validation Pilot Beginning with Data Submitted in CY 2025

As discussed in the FY 2019 IPF PPS final rule (83 FR 28607) and in the FY 2022 IPF PPS final rule (86 FR 42661), we are concerned 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, for example, whether the patient was included in the numerator and denominator of the measure). In the FY 2022 IPF PPS final rule, we noted that adoption of patient-level data requirements would enable us to adopt a data validation policy for the IPFQR Program in the future (86 FR 42661). 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 a potential data validation pilot, and many commenters supported the concept of data validation following implementation of patient-level reporting (86 FR 42661). In the FY 2022 IPF PPS final rule, we adopted mandatory patient-level reporting beginning with data submitted in CY 2023 affecting the FY 2024 payment determination and reflecting care provided during CY 2022 (86 FR 42658 through 42661).

We are now finalizing a data validation pilot beginning with data submitted in CY 2025 (reflecting care provided during CY 2024). When we sought public comment on a data validation pilot in the FY 2022 IPF PPS proposed rule (86 FR 19515), we requested input on potential elements of such a pilot, including the number of measures and the number of participating IPFs. As summarized in the FY 2022 IPF PPS final rule (86 FR 42661), one commenter recommended selecting two measures and 200 IPFs for this pilot. We considered that recommendation; however, to align with validation policies in our other quality reporting programs, we decided to request a specific number of charts. Specifically, we proposed to request eight charts per quarter from each IPF as opposed to requesting all of the charts that each facility used to calculate one or more specific measures. We also decided to initiate our pilot with fewer IPFs than the commenter recommended to limit the burden associated with this pilot.

We also reviewed the validation policies of other quality reporting programs. We specifically reviewed the Hospital IQR Program's chart-abstracted measure validation policies described in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57179 through 57180), the Hospital

IQR Program's pilot for eCQM validation described in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50262 through 50273), the Hospital Outpatient Quality Reporting (OQR) Program's planned pilot of data validation as described in the CY 2009 OPPS/ASC final rule (73 FR 68502), and the Hospital OQR Program's finalized validation policies as described in the CY 2012 OPPS/ASC final rule (76 FR 74485) and the CY 2018 OPPS/ASC final rule (82 FR 59441 through 5944) because these programs are also pay-for-reporting programs, like the IPFQR Program.

Following our review of the validation policies within these programs, we proposed a validation pilot in which we would randomly select on an annual basis up to 100 IPFs and request each selected IPF to provide to CMS eight charts per quarter, a total of 32 charts per year, used to calculate all chart-based measures beginning with data submitted in CY 2025. We believe that randomly selecting up to 100 IPFs would provide a sufficiently large set of IPFs to meaningfully test our validation procedures while minimizing burden for IPFs. We will specify the timeline and mechanism for submitting data in our data requests to individual IPFs that have been selected to participate in the validation pilot. We note that consistent with the Hospital IQR Program, we will reimburse IPFs for the cost of submitting charts for validation at a rate of \$3.00 per chart (85 FR 58949).

Because this is a voluntary pilot, we recognize that some selected IPFs will not participate; however, we believe that this pilot would be beneficial for IPFs that do participate as an opportunity to receive education and feedback on the data they submit prior to future proposal and adoption of a validation requirement in the IPFQR Program.

We invited comments on our proposal.

Comment: Several commenters expressed support for the data validation pilot.

Response: We thank these commenters for their support.

<u>Comment</u>: Several commenters provided recommendations for the data validation pilot.

One commenter suggested allowing participants to opt into the pilot as opposed to selecting

potential participants. One commenter requested that CMS ensure that the individuals doing the data validation have clinical expertise in the psychiatric setting to ensure appropriate interpretation of data. Another commenter recommended that CMS complete the pilot and analyze the data generated by the pilot prior to proposing and adopting a full data validation program.

Response: We thank these commenters for their input. We note that the data validation pilot described in this section is based on validation programs in other quality reporting programs. We believe that selecting IPFs to participate will allow us to test our processes for selection and notification and therefore we believe that this will be a more effective test than allowing IPFs to opt into the pilot. We note that participation in the data validation pilot will be voluntary for the IPFs which we select. We will consider recommendations for qualifications for personnel to perform the data validation and for analysis of the results as we implement this program. We believe it is appropriate to develop a data validation policy incrementally through adoption of a data validation pilot prior to national implementation of data validation within the IPFOR Program. We intend to analyze data collected through this data validation pilot to inform development of a future nationally implemented data validation program. We note that while we will analyze data collected through the data validation pilot in developing the program for national implementation, the pilot will be ongoing until national implementation so that we can continue to collect data and IPFs can continue to receive education and feedback on the data they submit.

Comment: One commenter expressed that a data validation pilot with payment ramifications is premature because patient-level data submission is still new to the IPFQR Program, because CMS has not sufficiently defined the pilot elements, and because it is unclear that there would be auditors with sufficient clinical expertise. Another commenter recommended that CMS use the data in the future IPF patient assessment instrument (PAI) to validate quality

measure data. Another commenter recommended postponing this pilot until the financial and staffing shortages caused by the COVID-19 pandemic have been resolved.

Response: We note that the participation in the data validation pilot is voluntary, and that IPFs will not receive any payment penalties during the data validation program's pilot period. With respect to the future IPF PAI, we will consider the potential interplay between data elements included in the PAI and IPFQR Program quality measure data for validation purposes, but believe those considerations are premature as a PAI has not yet been implemented for the IPF setting. Finally, we recognize that healthcare providers, including IPFs, are still recovering from the effects of the COVID-19 pandemic, but note that participation in the data validation pilot is voluntary.

<u>Comment</u>: One commenter stated that the reimbursement rate of \$3.00/chart is insufficient to cover the time and materials associated with participating in the pilot.

Response: We understand the commenters concern that \$3.00/chart may not cover the time and materials associated with participating in the pilot. We note that this reimbursement is consistent with the reimbursement rates for submitting charts for validation in other quality reporting programs. However, we intend to use the pilot program to identify potential modifications prior to adopting a full validation program. We will consider the appropriateness of our reimbursement at that time.

<u>Final Decision</u>: After consideration of the public comments we received, we are finalizing our data validation pilot as proposed.

6. 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.

Because the Facility Commitment to Health Equity measure proposed in section VI.D.2

of this final rule is a structural attestation measure, these policies do not apply to that measure. Additionally, because the Screening for Social Drivers of Health measure (described in section VI.D.3 of this final rule) applies to all patients and the Screen Positive Rate for Social Drivers of Health measure (described in section VI.D.4 of this final rule) applies to all patients who have been screened for health-related social needs (HRSNs), our previously finalized sampling policies would not apply to these two measures. As described in the FY 2022 IPF PPS final rule, our sampling policies do not apply to the COVID-19 Vaccination Coverage Among Healthcare Personnel measure because the denominator is all healthcare personnel (86 FR 42661).

Generally, we have applied our sampling procedures to chart-abstracted measures, where appropriate (that is, where the measure does not require application to the entire patient population). However, because the PIX survey measure is a patient reported measure, we have considered whether our sampling procedures for chart-abstracted measures are appropriate for this measure. After consideration of our current sampling procedures and sampling for patient reported measures in other quality reporting programs (specifically, the requirements for reporting the HCAHPS measure), we proposed that the PIX survey measure (described in section VI.D.5 of this final rule) would be eligible for sampling but would not be included in the global sample. Instead, we proposed that sampling for this measure would align with sampling for the HCAHPS survey measure in acute care hospitals and the Hospital IOR Program as described in the HCAHPS Quality Assurance Guidelines.²⁵⁴ Specifically, we proposed to require IPFs to develop sampling plans that ensure that IPFs are able to submit data for 300 completed PIX surveys per year. IPFs will be required to sample from every month throughout the entire reporting period and not stop sampling or curtail ongoing interview activities once a certain number of completed surveys has been attained. IPFs that are unable to reach 300 completed surveys through sampling will be required to submit data on survey results for all eligible patient

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²⁵⁴ HCHAPS Quality Assurance Guidelines, Version 17.0. March 2022. Available at: https://hcahpsonline.org/globalassets/hcahps/quality-assurance/2022_qag_v17.0.pdf.

discharges.

We invited public comment on our proposal.

<u>Comment</u>: One commenter recommended allowing facilities to apply their sampling methodologies to the Screening for Social Drivers of Health measure and the Screen Positive Rate for Social Drivers of Health measure to reduce burden.

Response: We acknowledge that applying sampling methodologies for these two measures would impact abstraction and reporting burden. We have proposed these measures to align with other quality reporting and value-based purchasing programs (specifically, the Hospital IQR Program) as well as the same measure proposals for the PPS-Exempt Cancer Hospital Quality Reporting Program in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27122 through 27130) and the End-Stage Renal Disease (ESRD) Quality Incentive Program in the CY 2024 ESRD Prospective Payment System proposed rule (88 FR 42509 through 42518). We note that the Hospital IQR Program adopted these two measures without sampling in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49191 through 49220). We believe that adopting these measures consistently across programs will increase the cross-setting comparability of measure results for the Screening for Social Drivers of Health measure; provide more information regarding community needs for specific communities that are served by multiple healthcare organizations for the Screen Positive Rate for Social Drivers of Health measure; and ensure that we are consistently conveying the importance of identifying and addressing HRSNs across all settings.

<u>Comment</u>: Several commenters recommended that CMS establish a statistically valid random sampling process for all IPFs to apply for the PIX survey measure to ensure that selection bias does not occur.

Response: We will provide updated guidance for developing sampling plans and other implementation guidance for the PIX survey measure. This guidance will align with sampling guidance for the HCAHPS measure in the Hospital IQR Program.

<u>Comment</u>: One commenter requested clarification regarding whether all patients would be eligible for inclusion in the sample for the PIX survey measure or only Medicare patients.

Response: To the extent feasible we believe that it is important to include all patients in our quality reporting measures. While some measures do not allow inclusion of all patients (specifically, measures abstracted from Medicare claims data); there are no feasibility issues which require the PIX survey measure to be limited to patients covered by any specific payer. Therefore, all patients, regardless of payer, are included in the population from which the sample for this measure is selected.

<u>Comment</u>: One commenter requested clarification regarding whether IPFs that were unable to reach 300 completed surveys would be penalized.

Response: IPFs that are unable to reach 300 completed PIX surveys because of the size or characteristics of their patient population should submit data on all eligible patients. IPFs that meet this requirement would not be penalized for not submitting data on 300 completed PIX surveys.

<u>Final Decision</u>: We are finalizing our proposals related to sampling for the newly adopted measures.

7. 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.

8. 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.

J. 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.

K. 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 Extraordinary Circumstances Exceptions policies. We did not propose any changes to these policies.

We proposed to codify the ECE policies at § 412.433(f). As finalized, paragraph (f) provides that we may grant an exception to one or more data submission deadlines and requirements in the event of extraordinary circumstances beyond the control of the IPF either in response to a request by the IPF or at our discretion if we determine an extraordinary circumstance occurred.

We solicited comments on our proposal to codify these policies.

We did not receive any comments on this proposal.

Final Decision: We are finalizing our proposal to codify these policies.

VII. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 et seq.), we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a "collection of information" requirement is submitted to the Office of Management and Budget (OMB) for review and approval. For the purposes of the PRA and this section of the preamble, collection of information is defined under 5 CFR 1320.3(c) of the PRA's implementing regulations.

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.

Our April 10, 2023 (88 FR 21238) proposed rule solicited public comment on each of the aforementioned issues for the following sections of the rule that contained information collection requirements beginning in CY 2024 through CY 2027. A summary of these comments and our responses is in section VII.C of this final rule. The remaining provisions are not associated with any information collection requirements. In that regard they are not subject to the requirements of the PRA and are not addressed under this section of the preamble. For this rule's full burden implications, please see the Regulatory Impact Analysis under section VIII of this final rule.

A. Wage Estimates

To derive average costs for this FY 2024 IPF PPS final rule, we used data from the U.S. Bureau of Labor Statistics' (BLS') May 2021 National Occupational Employment and Wage Estimates for all salary estimates (https://www.bls.gov/oes/2021/may/oes292072.htm). In this regard, Table 25 presents BLS' median hourly wage for Medical Records Specialists²⁵⁵ (the occupation title that we have estimated is appropriate for completing data collection and reporting under the IPFQR Program), our estimated cost of fringe benefits and other indirect costs (calculated at 100 percent of salary), and our adjusted hourly wage.

TABLE 25: WAGE ASSUMPTIONS FOR THE IPFQR PROGRAM

Occupation Title	Occupation Code	Median Hourly Wage (\$/hour)	Fringe Benefits and Other Indirect Costs (\$/hour)	Adjusted Hourly Wage (\$/hour)
Medical Records Specialists	29-2072	22.43	22.43	44.86

As indicated, we are adjusting our hourly wage estimates by a factor of 100 percent. This is

We have previously estimated that labor performed could be accomplished by Medical Records and Health Information Technician staff and note that this BLS occupation category has been replaced with Medical Records Specialists.

necessarily a rough adjustment, both because fringe benefits and other indirect costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, we believe that doubling the hourly wage to estimate the total cost is a reasonably accurate estimation method.

In the FY 2022 IPF PPS final rule (86 FR 42662), 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: 29–2072) with a median hourly wage of \$20.50/hour (BLS, May 2019). We note that since the publication of the FY 2022 IPF PPS final rule, the BLS occupation category of 'Medical Records and Health Information Technician (BLS Occupation Code: 29-2071)' has been replaced with 'Medical Records Specialist (BLS Occupation Code: 29-2072). Therefore, in the FY 2024 IPF PPS proposed rule, we proposed to adjust our cost estimates using BLS' May 2021 median wage rate figure of \$22.43/hour, an increase of \$1.93/hour (\$22.43/hour - \$20.50/hour). When factoring in our overhead and other indirect cost adjustments, the wage is increased by \$3.86/hour (\$44.86/hour - \$41.00/hour).

We have also estimated the average hourly cost for patients undertaking administrative and other tasks on their own time. Based on recommendations from the Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses²⁵⁶ guidance we have estimated a post-tax wage of \$20.71/hr. The Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices identifies the approach for valuing time when individuals undertake activities on their own time. To derive the costs for patients, a measurement of the usual weekly earnings of wage and salary workers of \$998, divided by 40 hours to calculate an hourly pre-tax wage rate of \$24.95/hour. This rate is adjusted downwards by an estimate of the effective tax rate for median income households of about 17 percent, resulting in the post-tax hourly wage rate of \$20.71/hour.

²⁵⁶ https://aspe.hhs.gov/sites/default/files/private/pdf/257746/VOT.pdf

Unlike our State and private sector wage adjustments, we are not adjusting beneficiary wages for fringe benefits and other indirect costs since the individuals' activities, if any, will occur outside the scope of their employment.

B. Information Collection Requirements (ICRs) Regarding the IPFQR Program

The following changes will be submitted to OMB for approval under control number 0938-1171 (CMS-10432). We are not making changes to any of the data collection instruments that are currently approved under that control number. We are, however, adopting one new instrument, the Psychiatric Inpatient Experience survey, to calculate the patient experience of care measure described in section VI.D.5 of this final rule.

In section VII.B.1 of this final rule, we restate our currently approved burden estimates. In section VII.B.2 of this final rule, we estimate the changes in burden associated with the policies finalized in this rule and updated estimates for wage rates, facility counts, and case counts. Then in section VII.B.3 of this final rule, we provide an overview of the total estimated burden.

1. 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 FY 2022 IPF PPS final rule (86 FR 42661 through 42672).

Table 26 provides an overview of our currently approved burden estimates.

TABLE 26: CURRENTLY APPROVED BURDEN OMB CONTROL NUMBER 0938-1171 (CMS-10432)

Measure/ Response	# Respondents (Facilities)	Estimated Responses	Total Annual	Time per Response	Annual Time per Facility	Total Annual Time (hours)	Total Annual Cost (\$)
Description	(Tacinties)	per Facility	Responses	(hours)	(hours)	Time (nours)	σος (φ)
Hours of Physical Restraint Use	1,634	1,346	2,199,364	0.25	336.50	549,841	22,543,481
Hours of Seclusion Use	1,634	1,346	2,199,364	0.25	336.50	549,841	22,543,481
Patients Discharged on Multiple Antipsychotic	1,634	609*	995,106	0.25	152.25	248,776.5	10,199,836.50
Medications with Appropriate Justification							

Measure/	# Respondents	Estimated	Total	Time per	Annual Time	Total Annual	Total Annual
Response	(Facilities)	Responses	Annual	Response	per Facility	Time (hours)	Cost (\$)
Description		per	Responses	(hours)	(hours)		
Alcohol Use Brief	1,634	Facility 609*	995,106	0.25	152.25	248,776.5	10,199,836.50
Intervention	1,034	009	993,100	0.23	132.23	246,770.3	10,199,630.30
Provided or Offered							
(SUB-2 and SUB-2a)							
Alcohol and Other	1,634	609*	995,106	0.25	152.25	248,776.5	10,199,836.50
Drug Use Disorder							
Treatment Provided							
or Offered at Discharge and							
Alcohol and Other							
Drug Use Disorder							
Treatment at							
Discharge (SUB-3							
and SUB-3a)	1.624	(00*	005 106	0.25	152.25	249.776.5	10 100 027 50
Tobacco Use Treatment Provided	1,634	609*	995,106	0.25	152.25	248,776.5	10,199,836.50
or Offered and							
Tobacco Use							
Treatment (TOB-2							
and TOB-2a)							
Tobacco Use	1,634	609*	995,106	0.25	152.25	248,776.5	10,199,836.50
Treatment Provided or Offered at							
Discharge and							
Tobacco Use							
Treatment at							
Discharge (TOB-3							
and TOB-3a)	1.624	C00#	005.106	0.25	150.05	240.55	10 100 02 (50
Influenza Immunization	1,634	609*	995,106	0.25	152.25	248,776.5	10,199,836.50
Transition Record	1,634	609*	995,106	0.25	152.25	248,776.5	10,199,836.50
with Specified	-,00		,				
Elements Received							
by Discharged							
Patients (Discharges from an Inpatient							
Facility to							
Home/Self Care or							
Any Other Site of							
Care)							
Screening for	1,634	609*	995,106	0.25	152.25	248,776.5	10,199,836.50
Metabolic Disorders Thirty-day all-cause	0	0**	0	0	0	0	0
unplanned	O O		0				
readmission							
following psychiatric							
hospitalization in an							
IPF Medication	0	0**	0	0	0	0	0
Continuation	l o	0	0	"	0	0	0
Following Inpatient							
Psychiatric							
Discharge		O.t.t.:					
COVID-19	0	0***	0	0	0	0	0
Vaccination Rate Among Healthcare							
Personnel							
Follow-Up After	0	0**	0	0	0	0	0
Psychiatric							
Hospitalization	1.624	7.5C4	10.050.555	27/4	1.001	2.000.001	126 607 671
SUBTOTAL	1,634	7,564	12,359,576	N/A	1,891	3,089,894	126,685,654
Non-Measure Data	1,634	4	6,536	0.5	2.0	3,268	133,988
Collection and Reporting							
Reporting	<u> </u>		<u> </u>			1	

Measure/	# Respondents	Estimated	Total	Time per	Annual Time	Total Annual	Total Annual
Response	(Facilities)	Responses	Annual	Response	per Facility	Time (hours)	Cost (\$)
Description		per	Responses	(hours)	(hours)		
		Facility					
TOTAL	1,634	7,568	12,366,112	Varies	1,893	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 mandatory to report data for 609 cases. Because facilities are only mandatory 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 the global sample requires abstraction of 609 records.

2. Adjustments Due to Changes in this Final Rule

We are finalizing provisions that impact policies beginning with the FY 2025 through FY 2028 payment determinations. For the purposes of calculating burden, we attribute the costs to the year in which the costs begin. For example, data submission for the measures that affect the FY 2025 payment determination occurs during CY 2024 and generally reflects care provided during CY 2023. The following discussion describes the burden changes for policies attributed to the year in which the costs begin. For the policies in this final rule, those years are CY 2024 through CY 2027.

Additionally, in the FY 2022 IPF PPS final rule (86 FR 42661 through 42672), which is the most recent rule that updated the IPFQR Program policies, we estimated that there were 1,634 participating IPFs and that (for measures that require reporting on the entire patient population) these IPFs will report on an average of 1,346 cases per IPF. In this FY 2024 IPF PPS final rule, we are adjusting our IPF count and case estimates by using the most recent data available. Specifically, we estimate that there are now approximately 1,596 facilities (a decrease of 38 facilities) and an average of 1,261 cases per facility (a decrease of 85 cases per facility). We will update our estimates, as applicable, using these revised estimates in the following subsections.

a. Policies Affecting Data Reporting Beginning in CY 2023

In section VI.E. of this final rule, we are modifying the COVID-19 Vaccination Coverage

^{**} 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).

Among Healthcare Personnel (HCP) measure beginning with data reflecting the fourth quarter of CY 2023 affecting the FY 2025 payment determination. We do not believe that this modification (that is, a change in terminology to refer to "up-to-date" instead of "complete vaccination course") will impact our currently approved IPF information collection requirements or burden estimates because the modified measure will be calculated using data already being submitted by IPFs to the CDC for healthcare safety surveillance under the CDC's OMB control number 0920-1317. In this regard, the CDC owns the requirements and burden that fall under that control number, including those of the COVID-19 Vaccination Coverage Among HCP measure.

- b. Policies Affecting Burden Beginning with CY 2024
- (1) Updates Affecting Facility Reporting Burden

In section VI.F.2 of this final rule, we are removing two measures beginning with the FY 2025 payment determination. Data for these measures would have been submitted in CY 2024, so we are estimating the reduced burden to occur in CY 2024. The two measures are:

- Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification (HBIPS-5); and
- Tobacco Use Treatment Provided or Offered and Tobacco Use Treatment (TOB-2 and TOB-2a).

Using our currently approved burden estimates as a baseline, the changes associated with removing these measures are: a decrease of 1,990,212 responses, a decrease of 497,553 hours, and a decrease of \$20,339,673 as set forth in Table 27.

TABLE 27: UPDATES TO BURDEN ASSOCIATED WITH MEASURE REMOVALS

Measure/ Response Description	# Respondents (Facilities) (a)	Estimated Responses per Facility (b)	Total Annual Responses (c)=(a)x(b)	Time per Response (hours) (d)	Annual Time per Facility (hours) (e)=(b)x(d)	Total Annual Time (hours) (f)=(a)x(e)	Total Annual Cost (\$) (g)=(f) x \$41.00/hour
Patients Discharged on Multiple Antipsychotic Medications	1,634	(609*)	(995,106)	0.25	(152.25)	(248,776.5)	(10,199,836.50)

Measure/ Response Description	# Respondents (Facilities) (a)	Estimated Responses per Facility (b)	Total Annual Responses (c)=(a)x(b)	Time per Response (hours) (d)	Annual Time per Facility (hours) (e)=(b)x(d)	Total Annual Time (hours) (f)=(a)x(e)	Total Annual Cost (\$) (g)=(f) x \$41.00/hour
with							
Appropriate Justification							
Tobacco Use	1,634	(609*)	(995,106)	0.25	(152.25)	(248,776.5)	(10,199,836.50)
Treatment							
Provided or							
Offered and							
Tobacco Use							
Treatment							
(TOB-2 and							
TOB-2a)							
TOTAL	1,634	(1,218)	(1,990,212)	0.25	(304.5)	(497,553)	(20,339,673)

^{*} 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 will 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 the global sample requires abstraction of 609 records.

Additionally, we are applying our updated wage rate (from \$41.00/hour to \$44.86/hour), case count (from 1,346 to 1,261), and facility counts (from 1,634 to 1,596) to the remaining measure set and program requirements for data submission in CY 2024. See Table 28 and 29 for information on the effects of these updates. Specifically, we estimate that there are now approximately 1,596 facilities (a decrease of 38 facilities) and an average of 1,261 cases per facility (a decrease of 85 cases per facility). We also estimate a wage increase of \$3.86/hour as described in section VI.A of this final rule. Our previous estimate shows that the two measures which do not allow sampling had 1,346 cases per measure and the six remaining measures which do allow sampling require 609 cases per measure per facility. We have estimated that these measures will take 0.25 hours per case. The effects of the updated hourly wage are set forth in Table 28.

TABLE 28: EFFECTS OF UPDATED HOURLY WAGE

Data collection type	Number of measures	Number of estimated cases per measure per facility	Total number of cases per facility	Effort per case (hours)	Total effort per facility (hours)	Change in cost per facility (\$) (effort * 3.86/hour)
Non-sampling measures	2	1,346	2,692	0.25	673	2,597.78
Sampling measures	6	609	3,654	0.25	913.5	3,526.11

Data collection type	Number of measures	Number of estimated cases per measure per facility	Total number of cases per facility	Effort per case (hours)	Total effort per facility (hours)	Change in cost per facility (\$) (effort * 3.86/hour)		
Non-Measure	1	4	4	0.5	2	7.72		
Data								
Total Change pe	Total Change per Facility							

The remaining calculations will use the updated hourly wage to calculate the effects of other updates.

Our active burden estimates account for 1,346 cases for measures that do not allow sampling. Based on more recent data, we are updating our estimate for measures that do not allow sampling to 1,261 cases per IPF (a decrease of 85 cases for each of the 2 measures which do not allow sampling). This is equivalent to 138,890 cases across the 1,634 IPFs (85 cases x 1,634 IPFs) in our previous estimate for each measure. We are not changing our estimated case counts for measures that allow sampling. We continue to assume an average of 0.25 hours of effort per case. Therefore, this change in cases reflects a total annual effort of 42.5 hours per facility (2 measures * 85 cases per measure * 0.25 hours per case) at a cost of \$1,907 (42.5 hours * \$44.86/hour).

As indicated above we estimate a reduction of 38 facilities based on updated numbers.

Table 29 shows the effects of this reduction in facilities on the reporting burden associated with each measure type.

TABLE 29: EFFECTS OF UPDATED FACILITY COUNTS

Measure Type	Number of Measures	Number of Estimated Cases (per measure per facility)	Cases per Facility	Effort per case	Effort per facility	Change in Annual Effort for removing 38 facilities (hours)	Change in Annual Effort for removing 38 facilities (dollars)
Non Sampling	2	1,261	2,522	0.25	630.5	(23,959)	(1,074,800.74)
Sampling	6	609	3,654	0.25	913.5	(34,713)	(1,557,225.18)
Non-Measure Data Collection	1	4	4	0.5	2	(76)	(3,409.36)
TOTAL	9	Varies	6,180	Varies	1,546	(58,748)	(2,635,435.28)

We note that at 6,180 cases per facility, removing 38 facilities from our estimate removes a total of 234,840 cases (6,180 cases per facility * 38 facilities).

The total effects of changes for the CY 2024 calendar year on our burden estimates are

summarized in Table 30.

Table 30: Total CY 2024 Facility Information Collection Burden Changes

	Total Responses	Total Annual Time (hours)	Total Annual Cost (\$)
Remove Two Measures (See Table 27)	(1,990,212)	(497,553)	(20,339,673)
Update Wage Estimate (See Table 28)	N/A	N/A	10,019,051
Update Case Estimate	(277,280)	(69,445)	(3,115,303)
Update Facility Estimate (See Table 29)	(234,840)	(58,748)	(2,635,435)
Total	(2,502,332)	(625,746)	(16,071,360)

(2) Updates Affecting Patient Survey Burden

In section VI.D.3 of this final rule, we are adopting the Screening for Social Drivers of Health measure beginning with a voluntary data submission in CY 2025 (reflecting care provided in CY 2024). IPFs will be able to collect data and report the measure via multiple methods, potentially including administrative claims data, electronic clinical data, standardized patient assessments, or patient-reported data and surveys. For additional information on these methods, we refer readers to section VI.D.3.c of this final rule. We believe that most IPFs will likely collect data during the patient intake process. Because this measure reflects care provided in CY 2024, the burden for administering the screening to patients will occur during CY 2024.

Under OMB Control Number 0938-1022 (CMS-10210) and the FY 2022 IPPS/LTCH PPS final rule (87 FR 49385 through 49386), the Hospital IQR Program, which adopted the Screening for Social Drivers of Health measure, estimates that it will take 2 minutes (0.033 hr) per patient to complete the selected screening instrument. The Hospital IQR Program also estimated that during the voluntary reporting period roughly 50 percent of hospitals will survey 50 percent of patients (87 FR 49385 through 49386).

We agree with these estimates and believe that a similar proportion of IPFs will participate in the voluntary reporting period. As described in section VII.A of this final rule, we estimate the cost of patients' time for completing surveys to be \$20.71/hour. Using these estimates, we believe that during the voluntary reporting period the annual burden of surveying

IPF patients will be 503,139 responses [(1,596 facilities x 50 percent of facilities) x (1,261 patients per facility x 50 percent of patients)], 16,604 hours (503,139 responses x 0.033 hours/response] at a cost of \$343,869 (16,604 hours x \$20.71/hour). These estimates are summarized in Table 31.

TABLE 31: TOTAL CY 2024 PATIENT SURVEY BURDEN CHANGES

	Total Responses	Total Annual Time	Total Annual Cost (\$)
		(hours)	
Screening for Social	503,139	16,603.59	343,860.29
Drivers of Health			

- c. Policies Affecting Burden Beginning with CY 2025
- (1) Updates Affecting Facility Reporting Burden

In section VI.I.5 of this final rule, we are adopting a data validation pilot for the IPFQR Program. Under this pilot we will reimburse hospitals directly for expenses associated with submission of charts for clinical process of care measure data validation. Because we will reimburse facilities directly for these expenses we do not believe that this pilot will increase information collection burden.

In section VI.D.2. of this final rule, we are adopting the Facility Commitment to Health Equity measure beginning with the FY 2026 payment determination. Data for this attestation measure will be submitted during CY 2025. Consistent with our burden estimate from the Hospital IQR Program, when we adopted the similar Hospital Commitment to Health Equity measure in the FY 2023 IPPS/LTCH PPS final rule, we estimated an average of 10 minutes per facility for a medical records specialist to collect and report this information (87 FR 49385). We recognize that some IPFs may take more than 10 minutes to collect this information, especially in the first year of reporting; however, we believe that many IPFs will require less than 10 minutes. In addition, we believe that many IPFs will be able to submit similar responses in future years. Using the estimate of 10 minutes (0.167 hour) per IPF per year at \$44.86/hour for a medical records specialist, we estimate that this policy will result in a total annual burden

increase of 267 hours (0.167 hours x 1,596 IPFs) at a cost of \$11,956.63 (267 hours x \$44.86/hour) across all participating IPFs.

In sections VI.D.3 and VI.D.4 of this final rule, we are adopting the Screening for Social Drivers of Health measure and the associated Screen Positive Rate for Social Drivers of Health measure beginning with a voluntary data submission in CY 2025 (reflecting care provided in CY 2024). We described our anticipated burden (16,604 hours at a cost of \$343,869) for administering the screening in the previous section because this burden will accrue during CY 2024. The burden associated with reporting each of these measures to CMS will occur during CY 2025. We anticipate that the burden for reporting the two measures will be consistent with the burden for other web-based submissions, such as the Facility Commitment to Health Equity measure described previously in this section and for similar measures adopted in the Ambulatory Surgical Center Quality Reporting (ASCQR) Program (OMB control number 0938-1270; CMS-10530), which we have estimated to have a reporting burden of 10 minutes (0.167 hours) per facility. We note that for the voluntary reporting year we have estimated only 50 percent or 798 IPFs (1,596 IPFs x 0.50) will report these data. Therefore, we estimate the burden associated with reporting of each of these measures to be 133 hours (0.167 hr. x 798 IPFs) at a cost of \$5,966 (133 hr. x \$44.86/hour) for a medical records specialist) for the voluntary reporting period. These estimates are summarized in Table 32.

TABLE 32: TOTAL CY 2025 FACILITY INFORMATION COLLECTION BURDEN CHANGES

Measure/ Response Description	# Respondents (Facilities)	Estimated Responses per Facility	Total Annual Responses	Time per Respon se (hours)	Annual Time per Facility (hours)	Total Annual Time (hours)	Total Annual Cost (\$)
Facility Commitment to Health Equity	1,596	1	1,596	0.167	0.167	267	11,978
Screening for Social Drivers of Health	798	1	798	0.167	0.167	133	5,966
Screen Positive Rate for Social Drivers of Health	798	1	798	0.167	0.167	133	5,966

Measure/ Response Description	# Respondents (Facilities)	Estimated Responses per Facility	Total Annual Responses	Time per Respon se (hours)	Annual Time per Facility (hours)	Total Annual Time (hours)	Total Annual Cost (\$)
Totals	1,596	3	3,192	0.167	0.167	534	23,911

(2) Updates Affecting Patient Survey Burden

Beginning with CY 2025, IPFs will need to screen 100 percent of their patients to prepare for mandatory reporting of the Screening for Social Drivers of Health measure in CY 2026 (for the FY 2027 payment determination). Therefore, we estimate that 100 percent of IPFs will screen 100 percent of their patients. We recognize that this may be an overestimate as some IPFs may choose not to participate and some patients may opt out of screening or be unable to provide responses; however, we believe that the numbers of IPFs and patients opting out will be relatively small and therefore 100 percent will be a reasonable approximation.

Using the facility counts (1,596 facilities), patient counts (1,261 patients per facility), average hourly earnings (\$20.71/hour), and time per response (10 min or 0.033 hours) described previously, we estimate the burden of surveying IPF patients for health-related social needs (HRSNs) under the Screening for Social Drivers of Health and Screen Positive Rate for Social Drivers of Health measures will be 66,414 hours (1,596 facilities x 1,261 patients per facility x 0.033 hr) at a cost of \$1,375,434 (66,414 hour x \$20.71/hour) across all patients. We note that 16,604 hours and \$343,960 of this burden was accounted for in our analysis of the burden of the voluntary reporting period described in section VII.B.2.c.(2). Therefore, the incremental burden of switching to mandatory reporting is 49,810 hours (66,414 hours - 16,604 hours) and \$1,031,474 (\$1,375,434 - \$343,960).

Additionally, in section VI.D.5 of this final rule, we are adopting the Psychiatric Inpatient Experience (PIX) survey measure beginning with voluntary data submission in CY 2026. To prepare for data submission in 2026, IPFs will begin administering this survey in CY 2025. We believe 50 percent or 798 (1,596 facilities x 0.50) of IPFs would begin collecting these data for the voluntary data submission period. We note that we proposed to allow IPFs with more than

300 eligible discharges to sample, which would require these facilities to survey 300 patients. Because the questions on the PIX survey are similar in content and response options to the questions on the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey, we believe that it will take patients a similar amount of time to respond to these questions. In the Information Collection Request associated with OMB control number 0938-0981 (CMS-10102), we have estimated this time to be 7.25 minutes (0.121 hours).

Therefore, we believe that the burden associated with conducting the PIX survey in CY 2025 will be 28,967 hours (798 facilities x 300 patients/facility x 0.121 hours/response) at a cost of \$599,907 (28,967 hours x \$20.71/hour).

Our estimates for the CY 2025 total patient survey burden changes are summarized in Table 33.

TABLE 33: TOTAL CY 2025 PATIENT SURVEY BURDEN CHANGES

	Total Responses	Total Annual Time	Total Annual Cost (\$)
		(hours)	
Screening for Social	1,509,417	49,811	1,031,580
Drivers of Health			
PIX Survey	239,400	28,967	599,915
Totals	1,748,817	78,778	1,631,496

d. Policies Affecting Burden Beginning with CY 2026

(1) Updates Affecting Facility Reporting Burden

Beginning with CY 2026 data submission (affecting the FY 2027 payment determination), we estimate that 100 percent of IPFs will submit data on the Screening for Social Drivers of Health measure and Screen Positive Rate for Social Drivers of Health measure.

Because we have already accounted for 50 percent of facilities submitting voluntary data on these measures, the incremental burden is the burden associated with the remaining 50 percent of facilities submitting data; that is, we estimate this burden to be 266 hours at a cost of \$11,933. We also believe that 50 percent of facilities will submit data on the PIX survey measure for the voluntary reporting period in CY 2025. Because the data for this measure will require

calculating an average of scores across a sample of patient surveys, we anticipate that the information collection and reporting burden for this measure will be approximately 15 minutes (0.25 hours) per patient for whom they are reporting data. The burden associated with reporting the Screening for Social Drivers of Health measure, the Screen Positive Rate for Social Drivers of Health measure, and the PIX survey measure to CMS is described in Table 34.

TABLE 34 TOTAL CY 2026 FACILITY INFORMATION COLLECTION BURDEN CHANGES

Measure/ Response Description	# Respondent s (Facilities)	Estimated Responses per	Total Annual Responses	Time per Response (hours)	Annual Time per Facility (hours)	Total Annual Time	Total Annual Cost (\$)
Screening	798	Facility 1	798	0.167	0.167	(hours) 133	5,978
for Social							
Drivers of							
Health							
Screen	798	1	798	0.167	0.167	133	5.978
Positive							
Rate for							
Social							
`Drivers of							
Health							
PIX Survey	798	300	239,400	0.25	75	59,850	2,684,871
Totals	798	302	240,996	Varies	75.33	60,116	2,696,827

(2) Updates Affecting Patient Survey Burden

Because reporting the PIX survey measure will be mandatory for the FY 2028 payment determination, the remaining 50 percent of facilities (those which did not participate in the voluntary reporting period) will begin surveying patients in CY 2026. To prepare for data submission of the PIX survey measure to CMS in CY 2027, IPFs that had not previously begun administering the PIX survey will begin administering this survey in CY 2026. The incremental burden of these 50 percent of facilities administering the survey will be equivalent to the burden associated with the 50 percent of facilities that participated in the voluntary reporting in CY 2025. These estimates are summarized in Table 35.

TABLE 35: TOTAL CY 2026 PATIENT SURVEY BURDEN CHANGES

	Total Responses	Total Annual Time	Total Annual Cost (\$)
		(hours)	
PIX Survey	239,400 (798 facilities x	28,967 (239,400	599,915 (28,967 hours x
	300 responses/facility)	responses x 0.121	\$20.71/hour)

hours/response)

e. Policies Affecting Facility Reporting Burden Beginning with CY 2027

For data submission occurring in CY 2027, submission on the PIX survey measure will be mandatory, therefore, we believe that an additional 50 percent of facilities will report the measure (that is, the 50 percent of facilities not previously accounted for under the voluntary reporting period). Therefore, we estimate that the incremental increase in burden for IPFs associated with this requirement will be reporting by the 50 percent of facilities that had not previously reported the PIX survey measure. This burden is set forth in Table 36.

TABLE 36: TOTAL CY 2027 FACILITY INFORMATION COLLECTION BURDEN CHANGES

Measure/ Response Description	#Respondents (Facilities)	Estimated Responses	Total Annual Responses	Time per Response (hours)	Annual Time per Facility	Total Annual Time	Total Annual Cost (\$)
Description		per Facility	Responses	(nours)	(hours)	(hours)	
PIX Survey	798	300	239,400 (798 facilities x 300 responses per facility)	0.25	75 (300 responses per facility x 0.25 hours/response)	59,850 (75 hours per facility * 798 facilities)	2,684,871 (59,850 hours x \$44.86/hour)

3. Overall Burden Summary

Table 37 summarizes the incremental changes in burden for IPFs associated with policies for data collection and submission in CYs 2024 through 2027 as well as updates to our estimated wage rate, facility counts, and case counts.

TABLE 37: INCREMENTAL CHANGES IN FACILITY BURDEN

	Total Responses	Total Annual Time	Total Annual Cost (\$)
		(hours)	
Changes Associated with	(2,502,832)	(625,746)	(16,131,359)
CY 2024 Updates			
Changes Associated with	3,192	534	23,911
CY 2025 Updates			
Changes Associated with	240,996	60,116	2,696,827
CY 2026 Updates			
Changes Associated with	239,400	59,850	2,684,871
CY 2027 Updates			
Total	(2,018,244)	(505,246)	(10,725,750)

Table 38 summarizes the incremental changes in burden for patients due to data collection associated with proposed policies for data collection and submission in CYs 2024 through CY 2026.

TABLE 38: INCREMENTAL CHANGES IN SURVEY BURDEN FOR PATIENTS

	Total Responses	Total Annual Time	Total Annual Cost (\$)
		(hours)	
Changes Associated with CY 2024 Updates	503,139	16,604	343,860
Changes Associated with CY 2025 Updates	1,748,817	78,778	1,631,496
Changes Associated with CY 2026 Updates	239,400	28,967	599,915
Changes Associated with CY 2027 Updates	No changes	No changes	No changes
Totals	2,491,356	124,349	2,575,271

Table 39 summarizes the total annual change in burden associated with the IPFQR Program's finalized policies in this final rule. These figures are calculated by adding the annual changes in Table 37 with the annual changes in Table 38. We note that these figures represent the changes to our previously approved burden (set forth in Table 26 of this final rule).

TABLE 39: TOTAL ANNUAL CHANGES IN BURDEN ASSOCIATED WITH THE IPFQR PROGRAM

	Total Responses	Total Annual Time (hours)	Total Annual Cost (\$)
CY 2024 Facility	(2,502,832)	(625,746)	(16,131,359)
Changes			
CY 2024 Patient Changes	503,139	16,604	343,860
CY 2024 Subtotal	(1,999,693)	(609,142)	(15,787,499)
CY 2025 Facility Changes	3,192	534	23,911
CY 2025 Patient Changes	1,748,817	78,778	1,631,496
CY 2025 Subtotal	1,752,009	79,312	1,655,407
CY 2026 Facility	240,996	60,116	2,696,827
Changes			
CY 2026 Patient Changes	239,400	28,967	599,915
CY 2026 Subtotal	480,396	89,083	3,296,742
CY 2027 Facility	239,400	59,850	2,684,871
Changes			
CY 2027 Patient Changes	0	0	0
CY 2027 Subtotal	239,400	59,850	2,684,871
Total	472,112	(380,897)	(8,150,479)

We solicited public comment on our estimated burden associated with the information collection requirements.

The following comments were received.

<u>Comment</u>: Several commenters expressed concern that the policies under the IPFQR Program will be burdensome, and some commenters specifically noted burden related to the PIX survey. One commenter expressed the belief that removing two measures while adopting four measures would increase overall burden.

Response: We understand commenters' concerns that some of the policies under the IPFQR Program may contribute to IPF reporting burden. With respect to the PIX survey, we do not believe that administering a patient experience of care survey will be unduly burdensome for the majority of IPFs that previously self-reported that they already administer such a survey when responding to the IPFQR Program's former Assessment of Patient Experience of Care measure. We recognize that there will be some non-recurring burden for these IPFs to transition to the newly adopted survey. With respect to the concern that removing two measures while adopting four measures would increase the overall burden, we note that the measures we are removing are chart-abstracted measures with high reporting burden. We estimate that the newly adopted measures require less time to calculate and report. Therefore, we believe that our estimate that the overall burden of the IPFQR Program will be decreased by these policies is accurate.

VIII. 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 2024 (October 1, 2023 through September 30, 2024). We are finalizing our proposal to apply a 2021-based IPF market basket increase for FY 2024 of 3.5 percent, less the productivity adjustment of 0.2 percentage point as required by 1886(s)(2)(A)(i) of the Act for a final total FY 2024 payment rate update of

3.3 percent. In this final rule, we are finalizing our proposal to update the outlier fixed dollar loss threshold amount, update the IPF labor-related share, and update the IPF wage index to reflect the FY 2024 hospital inpatient wage index. Section 1886(s)(3)(4) of the Act requires IPFs to report data in accordance with the requirements of the IPFQR Program for purposes of measuring and making publicly available information on health care quality, and links the quality data submission to the annual applicable percentage increase.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), Executive Order 14094 entitled "Modernizing Regulatory Review" (April 6, 2023), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). The Executive Order 14094 entitled "Modernizing Regulatory Review" (hereinafter, the Modernizing E.O.) amends section 3(f)(1) of Executive Order 12866 (Regulatory Planning and Review). The amended section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action that is likely to result in a rule: (1) having an annual effect on the economy of \$200 million or more in any 1 year (adjusted every 3 years by the Administrator of OIRA for changes in gross domestic product), or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities; (2) creating a serious inconsistency or

otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in the order, as specifically authorized in a timely manner by the Administrator of OIRA in each case.

A regulatory impact analysis (RIA) must be prepared for major rules with significant regulatory action(s) and/or with significant effects as per section 3(f)(1) (\$200 million or more in any 1 year). We estimate that the total impact of these changes for FY 2024 payments compared to FY 2023 payments will be a net increase of approximately \$70 million. This reflects a \$95 million increase from the update to the payment rates (+\$100 million due to the FY 2024IPF market basket update of 3.5 percent, and -\$5 million for the productivity adjustment of 0.2 percentage point), as well as a \$25 million decrease as a result of the update to the outlier threshold amount. Outlier payments are estimated to change from 2.9 percent in FY 2023 to 2.0 percent of total estimated IPF payments in FY 2024.

Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined that this rulemaking is not significant per section 3(f)(1) as measured by the \$200 million threshold or more in any 1 year. Nevertheless, this rule is a major rule, and accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking. Therefore, OMB has reviewed this final regulation, and we have provided the following assessment of its impact.

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 will equal the amount that would have been paid if the IPF PPS had not been implemented. This Budget neutrality factor included 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 proposed to update 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 IPF market basket update for FY 2024 of 3.5 percent (see section IV.A.2 of this final rule) reduced by the productivity adjustment of 0.2 percentage point as 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 2024 impact will be a net increase of \$70 million in payments to IPF providers. This reflects an estimated \$95 million increase from the update to the payment rates and a \$25 million decrease 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 2024. This estimate does not include the implementation of the mandatory 2.0 percentage point reduction of the productivity-adjusted IPF market basket update factor for any IPF that fails to meet the IPF quality reporting requirements (as discussed in section IV.B.2. 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 proposed IPF PPS rates and factors for FY 2024 versus those under FY 2023. We determined the percent change in the estimated FY 2024 IPF PPS payments compared to the estimated FY 2023 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 final update to the outlier fixed dollar loss threshold amount; the

updated wage index data including the final labor-related share; and the final IPF market basket update for FY 2024, as reduced by the final productivity adjustment according to section 1886(s)(2)(A)(i) of the Act.

To illustrate the impacts of the FY 2024 changes in this final rule, our analysis begins with FY 2022 IPF PPS claims (based on the 2022 MedPAR claims, March 2023 update). We estimate FY 2023 IPF PPS payments using these 2022 claims, the finalized FY 2023 IPF PPS Federal per diem base rates, and the finalized FY 2023 IPF PPS patient and facility level adjustment factors (as published in the FY 2023 IPF PPS final rule (87 FR 46846)). We then estimate the FY 2024 outlier payments based on these simulated FY 2023 IPF PPS payments using 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 2022, where total outlier payments are maintained at 2 percent of total estimated FY 2023 IPF PPS payments. We note that in the FY 2023 final rule (87 FR 46862 through 46864) we excluded providers from our simulation of IPF PPS payments for FY 2022 and FY 2023 if their change in estimated average cost per day was outside 3 standard deviations from the mean. As discussed in section IV.E.2 of this final rule, we did not propose to apply this methodology for FY 2024.

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

- The update to the outlier fixed dollar loss threshold amount.
- The FY 2024 IPF wage index and the FY 2024 labor-related share.
- The IPF market basket update for FY 2024 of 3.5 percent less the productivity adjustment of 0.2 percentage point in accordance with section 1886(s)(2)(A)(i) of the Act for a final IPF payment rate update of 3.3 percent.

Our column comparison in Table 40 illustrates the percent change in payments from

FY 2023 (that is, October 1, 2022, to September 30, 2023) to FY 2024 (that is, October 1, 2023,

to September 30, 2024) including all the payment policy changes.

TABLE 40: FY 2024 IPF PPS Payment Impacts
[Percent Change in columns 3 through 5]

[Percei	nt Change in columns 3 t	hrough 5]	·	<u> </u>
Facility by Type	Number of Facilities	Outlier	Wage Index FY24, LRS, and 5% Cap	Total Percent Change*
(1)	(2)	(3)	(4)	(5)
All Facilities	1,479	-0.9	0.0	2.3
Total Urban	1,204	-1.0	0.1	2.4
Urban unit	687	-1.5	0.2	2.0
Urban hospital	517	-0.4	0.0	2.9
Total Rural	275	-0.6	-0.7	2.0
Rural unit	214	-0.6	-0.7	2.0
Rural hospital	61	-0.5	-0.8	1.9
By Type of Ownership:				
Freestanding IPFs				
Urban Psychiatric Hospitals				
Government	119	-1.4	0.1	2.0
Non-Profit	98	-0.5	0.5	3.4
For-Profit	300	-0.2	-0.2	2.9
Rural Psychiatric Hospitals				
Government	31	-0.7	-0.3	2.3
Non-Profit	13	-2.1	-0.1	0.9
For-Profit	17	0.0	-1.3	2.0
IPF Units				
Urban				
Government	99	-2.6	0.7	1.3
Non-Profit	449	-1.4	0.3	2.1
For-Profit	139	-0.6	-0.5	2.2
Rural				
Government	51	-0.4	-0.6	2.2
Non-Profit	120	-0.7	-0.6	1.9
For-Profit	43	-0.4	-0.9	2.0
By Teaching Status:				
Non-teaching	1,282	-0.7	-0.2	2.4
Less than 10% interns and residents to beds	97	-1.7	0.9	2.5
10% to 30% interns and residents to beds	70	-1.9	0.3	1.7
More than 30% interns and residents to beds	30	-2.0	0.7	2.0
By Region:				
New England	105	-1.3	-0.6	1.4
Mid-Atlantic	202	-1.5	1.1	2.9
South Atlantic	229	-0.5	0.2	3.0

Facility by Type	Number of Facilities	Outlier	Wage Index FY24, LRS, and 5% Cap	Total Percent Change*
East North Central	240	-0.6	-0.7	2.0
East South Central	149	-0.6	-0.7	1.9
West North Central	105	-1.8	0.0	1.4
West South Central	215	-0.6	0.0	2.7
Mountain	106	-0.7	-1.0	1.6
Pacific	128	-1.1	0.4	2.7
By Bed Size:				
Psychiatric Hospitals				
Beds: 0-24	91	-0.8	-0.3	2.2
Beds: 25-49	84	-0.1	-0.7	2.4
Beds: 50-75	87	-0.1	-0.2	3.0
Beds: 76 +	316	-0.5	0.2	3.0
Psychiatric Units				
Beds: 0-24	484	-1.0	-0.4	1.9
Beds: 25-49	240	-1.2	0.1	2.3
Beds: 50-75	105	-1.4	0.0	1.8
Beds: 76 +	72	-2.1	0.8	1.9

^{*} This column includes the impact of the updates in columns (3) through (4) above, and of the IPF market basket update for FY 2024 of 3.5 percent, reduced by 0.2 percentage point for the productivity adjustment as required by section 1886(s)(2)(A)(i) of the Act.

3. Impact Results

Table 40 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 1,479 IPFs included in the analysis. In column 2, we present the number of facilities of each type that had information available in the PSF and had claims in the MedPAR dataset for FY 2022.

In column 3, we present the effects of the update to the outlier fixed dollar loss threshold amount. We estimate that IPF outlier payments as a percentage of total IPF payments are

2.9 percent in FY 2023. Therefore, we adjusted the outlier threshold amount to set total estimated outlier payments equal to 2.0 percent of total payments in FY 2024. The estimated change in total IPF payments for FY 2024, therefore, includes an approximate 0.9 percent decrease in payments because we expect the outlier portion of total payments to decrease from approximately 2.9 percent to 2.0 percent.

The overall impact of the estimated decrease to payments due to updating the outlier fixed dollar loss threshold (as shown in column 3 of Table 3), across all hospital groups, is a 0.9 percentage point decrease. The largest decrease in payments due to this change is estimated to be 2.6 percent for urban government unit IPFs.

In column 4, we present the effects of the budget-neutral update to the IPF wage index, the Labor-Related Share (LRS), and the 5-percent cap on any decrease to a provider's wage index from its wage index in the prior year. This represents the effect of using the concurrent hospital wage data as discussed in section IV.D.1.a of this final rule. That is, the impact represented in this column reflects the update from the FY 2023 IPF wage index to the FY 2024 IPF wage index, which includes basing the FY 2024 IPF wage index on the FY 2024 pre-floor, pre-reclassified IPPS hospital wage index data, applying a 5-percent cap on any decrease to a provider's wage index from its wage index in the prior year, and updating the LRS from 77.4 percent in FY 2023 to 78.7 percent in FY 2024. 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. For example, we estimate the largest increase in payments to be 1.1 percent for Mid-Atlantic IPFs, and the largest decrease in payments to be 1.3 percent for freestanding, rural, for-profit IPFs.

Column 5 incorporates the FY 2024 IPF market basket update of 3.5 percent reduced by 0.2 percentage point for the productivity adjustment as required by section 1886(s)(2)(A)(i) of the Act. This includes rebasing the IPF market basket to reflect a 2021 base year.

Overall, IPFs are estimated to experience a net increase in payments as a result of the updates in this final rule. IPF payments are estimated to increase by 2.4 percent in urban areas and 2.0 percent in rural areas. The largest payment increases are estimated at 3.4 percent for freestanding, urban, non-profit IPFs.

4. Effect on Beneficiaries

Under the FY 2024 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 in this final 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 2024 IPF PPS will enhance the efficiency of the Medicare program.

As discussed in sections VI.D.3 and VI.D.4 of this final rule, we expect that additional IPFQR Program measures will support improving care for patients with health-related social needs. We also believe that our data validation pilot is an important step towards ensuring that the data beneficiaries and their caregivers access on Care Compare (or a successor CMS website) are accurate and reliable. Based on the input from patients and their caregivers regarding the importance of having a patient experience of care measure for the IPF setting in which they note many benefits (including, but not limited to helping patients select facilities in which to receive care, providing patients an opportunity to be heard, and increasing alignment between general acute and acute psychiatric settings). We believe that our PIX survey measure will have positive effects on patients and their caregivers. Therefore, we expect that the updates to the IPFQR Program will improve quality for beneficiaries.

5. Effects of the Updates to the IPFQR Program

In section VI.D.3 of this final rule, we are adopting the Screening for Social Drivers of

Health measure for the IPFQR Program beginning with voluntary reporting of CY 2024 data, and with mandatory reporting of CY 2025 data for the FY 2027 payment determination. For IPFs that are not currently administering some screening mechanism and elect to begin doing so as a result of this policy, there will be some non-recurring costs associated with changes in workflow and information systems to collect the data. The extent of these costs is difficult to quantify as different facilities may utilize different modes of data collection (for example, paper-based, electronically patient-directed and clinician-facilitated). In addition, depending on the method of data collection utilized, the time mandatory to complete the survey may add a negligible amount of time to patient visits.

In section VI.D.5 of this final rule, we are adopting the Psychiatric Inpatient Experience (PIX) survey measure. There may be some non-recurring costs associated with changes in workflow and information systems to administer this survey and collect the data. The extent of these costs is difficult to quantify as different facilities currently have different practices for surveying patients to gather information on their experiences of care.

In addition, for the IPFQR Program, we are adopting the Facility Commitment to Health Equity measure and the Screen Positive for Social Drivers of Health measure, as well as to update the COVID-19 Vaccination Coverage Among HCP measure. These updates will not impact providers workflows or information systems to collect or report the data, and because they represent processes of care or structural data that the IPFs will already have in place, we do not believe they will incur costs for providers beyond the recurring information collection costs (described in section VII.B of this final rule).

Finally, we are removing two chart-abstracted measures from the IPFQR Program. We believe that the impact of removing the Tobacco Use Brief Intervention Provided or Offered and Tobacco Use Brief Intervention Provided (TOB- 2/2a) measure will be minimal as we do not believe that IPFs will update their workflow to no longer provide brief tobacco cessation interventions to patients who use tobacco. However, we believe that there may be some

simplification of workflows and clinical documentation associated with the removal of the Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification (HBIPS-5) measure because IPFs will no longer have to ensure the presence of appropriate documentation for the use of multiple antipsychotics. For more information on the updated clinical guidelines regarding polypharmacy for patients with schizophrenia, we refer readers to section VI.F.2.a of this final rule.

As discussed in section IV.B.2 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 2024 market basket update for IPFs that have failed to comply with the IPFQR Program requirements for FY 2024, including reporting on the mandatory measures. In section IV.B.2 of this final rule, we discuss how the 2-percentage point reduction will be applied. For the FY 2023 payment determination, of the 1,596 IPFs eligible for the IPFQR Program, 6 IPFs did not receive the full market basket update because of the IPFQR Program; 2 of these IPFs chose not to participate and 4 did not meet the requirements of the program. Thus, we estimate that the IPFQR Program will have a negligible impact on overall IPF payments for FY 2024.

Based on the IPFQR Program policies in this final rule, we estimate a total decrease in burden of 380,897 hours across all IPFs, resulting in a total decrease in information collection cost of \$8.15 million across all IPFs. Further information on these estimates can be found in section VII.B 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 PPS proposed rule will be the number of reviewers of this final rule. For this FY 2024 IPF PPS final rule, the most recent IPF PPS proposed rule was the FY 2024 IPF PPS proposed rule, and we received 2,506 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 2024 IPF PPS 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 will 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, 2022 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 \$123.06 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 will take approximately 198 minutes (3.3 hours) for the staff to review half of this final rule (49,500), which contains a total of approximately 99,000 words. For each IPF that reviews the final rule, the estimated cost is (3.3 × \$123.06) or \$406.10. Therefore, we estimate that the total cost of reviewing this final rule is \$1,017,686.60 (\$406.10 × 2,506 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; apply the 2021-based IPF market basket update for FY 2024 of 3.5 percent reduced by the productivity adjustment of 0.2 percentage point as required by section 1886(s)(2)(A)(i) of the Act along with the wage index budget neutrality adjustment to update the payment rates; and use a FY 2024 IPF wage index which uses the FY 2024 pre-floor, pre-reclassified IPPS hospital wage index as its basis.

Lastly, we solicited comments on alternative methodologies that could be appropriate for establishing the FY 2024 outlier fixed dollar loss threshold.

E. Accounting Statement

As required by OMB Circular A–4 (https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf), in Table 41, 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 41 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 is based on 1,479 IPFs with data available in the PSF and with claims in our FY 2022 MedPAR claims dataset. Lastly, Table 41 also includes our best estimate of the costs of reviewing and understanding this final rule.

TABLE 41: Accounting Statement: Classification of Estimated Costs and Transfers

	Primary	Units		
Category	estimate (\$million/year)	Year dollars	Period covered	
Regulatory Review Costs	1.0	FY	FY 2024	
		2021		
Annualized Monetized Transfers	70	FY	FY 2024	
from Federal Government to IPF		2024		
Medicare Providers				

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 40, we estimate that the overall revenue impact of this final rule on all IPFs is to increase estimated Medicare payments by 2.3 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 VIII.C.2 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 211 rural excluded psychiatric units and 61 rural psychiatric hospitals in our database of 1,479 IPFs for which data were available. Therefore, the Secretary has determined 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 2023, that threshold is approximately \$177 million. This final rule does not mandate any requirements for state, local, or tribal governments, or for the private sector. This final rule will 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 \$177 million in any 1 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.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on July 24, 2023.

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 amends 42 CFR part 412 as set forth below:

PART 412—PROSPECTIVE PAYMENT SYSTEMS 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 412.25 is amended by revising paragraph (c) to read as follows:

§ 412.25 Excluded hospital units: Common requirements.

* * * * *

(c) The status of a hospital unit may be changed from not excluded to excluded or excluded to not excluded at any time during a cost reporting period, but only if the hospital notifies the fiscal intermediary and the CMS Regional Office in writing of the change at least 30 days before the date of the change, and maintains the information needed to accurately determine costs that are or are not attributable to the hospital unit. A change in the status of a hospital unit from not excluded to excluded or excluded to not excluded that is made during a cost reporting period must remain in effect for the rest of that cost reporting period.

* * * * *

3. Section 412.433 is added to read as follows:

§ 412.433 Procedural requirements under the IPFQR Program.

- (a) Statutory authority. Section 1886(s)(4) of the Act requires the Secretary to implement a quality reporting program for inpatient psychiatric hospitals and psychiatric units. Under section 1886(s)(4) of the Act, for an IPF paid under the IPF PPS that fails to submit data required for the quality measures selected by the Secretary in a form and manner and at a time specified by the Secretary, we reduce the otherwise applicable annual update to the standard Federal rate by 2.0 percentage points with respect to the applicable fiscal year.
 - (b) Participation in the IPFOR Program. To participate in the IPFOR Program, an IPF

(as defined under § 412.402) that is paid under the IPF PPS must:

- (1) Register and maintain an account on the CMS-designated information system before beginning to report data, identification of a security official is necessary to complete such registration; and
 - (2) Submit a notice of participation (NOP).
- (c) Withdrawal from the IPFQR Program. An IPF may withdraw from the IPFQR Program by changing the NOP status in the secure portion of the CMS-designated information system. The IPF may withdraw at any time up to and including August 15 before the beginning of each respective payment determination year. A withdrawn IPF is subject to a reduced annual payment update as specified under paragraph (a) of this section and is mandatory to renew participation as specified in paragraph (b) of this section in order to participate in any future year of the IPFQR Program.
- (d) Submission of IPFQR Program data. In general, except as provided in paragraph (f) of this section, IPFs that participate in the IPFQR Program must submit to CMS data on measures selected under section 1886(s)(4)(D) of the Act and specified non-measure data in a form and manner, and at a time specified by CMS.
- (e) Quality measure updates, retention, and removal. (1) General rule for updates to quality measures. CMS uses rulemaking to make substantive updates to the specifications of measures used in the IPFQR Program
- (2) General rule for the retention of quality measures. Quality measures adopted for the IPFQR Program measure set for a previous payment determination year are retained for use in subsequent payment determination years, except when they are removed, suspended, or modified as set forth in paragraph (3) of this section.
- (3) Measure removal, suspension, or modification through the rulemaking process.

 CMS will use the regular rulemaking process to remove, suspend, or modify quality measures in the IPFQR Program to allow for public comment.

- (i) Factors for consideration in removal or replacement of quality measures. CMS will weigh whether to remove or modify measures based on the following factors:
- (A) Factor 1: Measure performance among IPFs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made;
 - (B) Factor 2: Measure does not align with current clinical guidelines or practice;
- (C) Factor 3: 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 topic;
- (D) Factor 4: Measure performance or improvement does not result in better patient outcomes;
- (E) Factor 5: Measure can be replaced by a measure that is more strongly associated with desired patient outcomes for the particular topic;
- (F) Factor 6: Measure collection or public reporting leads to negative unintended consequences other than patient harm;
 - (G) Factor 7: Measure is not feasible to implement as specified; and
- (H) Factor 8: The costs associated with a measure outweigh the benefit of its continued use in the program.
- (ii) *Retention*. CMS may retain a quality measure that meets one or more of the measure removal factors described in paragraph (i) of this subsection if the continued collection of data on the quality measure would align with other CMS and HHS policy goals, align with other CMS programs, or support efforts to move IPFs toward reporting electronic measures.
- (f) Extraordinary circumstances exception. CMS may grant an exception to one or more data submissions deadlines and requirements in the event of extraordinary circumstances beyond the control of the IPF, such as when an act of nature affects an entire region or locale or a systemic problem with one of CMS's data collection systems directly or indirectly affects data submission. CMS may grant an exception as follows:

(1) Upon request by the IPF.

(2) At the discretion of CMS. CMS may grant exceptions to IPFs that have not requested

them when CMS determines that an extraordinary circumstance has occurred.

(g) Public reporting of IPFQR Program data. Data that an IPF submits to CMS for the

IPFQR Program will be made publicly available on a CMS website after providing the IPF an

opportunity to review the data to be made public. IPFs will have a period of 30 days to review

and submit corrections to errors resulting from CMS calculations prior to the data being made

public.

Xavier Becerra,	

Secretary,

Department of Health and Human Services.

[FR Doc. 2023-16083 Filed: 7/27/2023 4:15 pm; Publication Date: 8/2/2023]