DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 412

[CMS–1806–F]

RIN 0938–AV32

Medicare Program; FY 2025 Inpatient Psychiatric Facilities Prospective Payment System—Rate Update

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final action.

SUMMARY: This final action updates the prospective payment rates, the outlier threshold, and the wage index for Medicare inpatient hospital services provided by Inpatient Psychiatric Facilities (IPF), which include psychiatric hospitals and excluded psychiatric units of an acute care hospital or critical access hospital. This final action also revises the patient-level adjustment factors, the Emergency Department adjustment, and the payment amount for electroconvulsive therapy. These changes will be effective for IPF discharges occurring during the fiscal year (FY) beginning October 1, 2024 through September 30, 2025 (FY 2025). In addition, this final action finalizes the adoption of a new quality measure. It does not finalize modifications to the reporting requirements under the IPF Quality Reporting Program beginning with the FY 2027 payment determination. Furthermore, this final action summarizes comments received through Requests for Information regarding potential future revisions to the IPF PPS facility-level adjustments and regarding the development of a standardized IPF Patient Assessment Instrument.

DATES: This final action is effective on October 1, 2024.

FOR FURTHER INFORMATION CONTACT: The IPF Payment Policy mailbox at *IPFPaymentPolicy@cms.hhs.gov* for general information.

Nick Brock (410) 786–5148, for information regarding the inpatient psychiatric facilities prospective payment system (IPF PPS) and regulatory impact analysis.

Kaleigh Emerson (470) 890–4141, for information regarding the inpatient psychiatric facilities quality reporting program (IPFQR).

SUPPLEMENTARY INFORMATION:

Plain Language Summary: In accordance with 5 U.S.C. 553(b)(4), a plain language summary of this rule may be found at *https://www.regulations.gov/.*

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

Addendum A to this final rule summarizes the fiscal year (FY) 2025 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, Addendum B to this final rule shows the complete listing of ICD–10 Clinical Modification (CM) and Procedure Coding System (PCS) codes, the FY 2025 IPF PPS comorbidity adjustment, and electroconvulsive therapy (ECT) procedure codes. Addenda A and B to this final rule are available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html.* Tables setting forth the FY 2025 Wage Index for Urban Areas Based on Core Based Statistical Area (CBSA) Labor Market Areas, the FY 2025 Wage Index Based on CBSA Labor Market Areas for Rural Areas, and a county-level crosswalk of the FY 2024 CBSA Labor Market Areas to the FY 2025 CBSA Labor Market Areas are available exclusively through the internet, on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/IPFPPS/WageIndex.html.*

I. Executive Summary

A. Purpose

This final rule updates the prospective payment rates, the outlier threshold, and the wage index for Medicare inpatient hospital services provided by Inpatient Psychiatric Facilities (IPFs) for discharges occurring during fiscal year (FY) 2025 (beginning October 1, 2024, through September 30, 2025). This rule also adopts the Core-Based Statistical Area (CBSA) Labor Market Areas for the IPF PPS wage index as defined in the Office of Management and Budget (OMB) Bulletin 23–01. In addition, this rule refines the patient-level adjustment factors and increases the payment amount for electroconvulsive therapy (ECT) treatments. This final rule also clarifies the eligibility criteria for an IPF to be approved to file all-inclusive cost reports. This rule includes a summary of the public comments received to inform revisions to the payment adjustments for rural location and teaching status, along with a potential payment adjustment for safety net population. In addition, this final rule includes a summary of the public comments received in response to our request for information (RFI) regarding the creation of a patient assessment instrument (PAI), as mandated by section 4125 of the Consolidated Appropriations Act (CAA), 2023 (hereafter referred to as CAA, 2023) (Pub. L. 117–328). Lastly, this final rule updates quality measures and discusses reporting requirements under the Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program.

B. Summary of the Major Provisions

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

For the IPF PPS, we are finalizing our proposals to:

- Revise the patient-level IPF PPS adjustment factors and increase the ECT per treatment payment amount.
- Update the IPF PPS wage index to use the CBSAs defined within OMB Bulletin 23–01.
- Clarify the eligibility criteria for an IPF to be approved to file all-inclusive cost reports. Only a government-owned or tribally owned facility satisfies these criteria and is eligible to file its cost report using an all-inclusive rate or no charge structure.
- Make technical rate setting updates: The IPF PPS payment rates will be adjusted annually for input price inflation, as well as statutory and other policy factors.

This rule updates:

++ The IPF PPS Federal per diem base rate from $895.63 to $876.53.

++ The IPF PPS Federal per diem base rate for providers who failed to report quality data to $859.48.

++ The ECT payment per treatment from $385.58 to $661.52.

++ The ECT payment per treatment for providers who failed to report quality data to $648.65.

++ The labor-related share from 78.7 percent to 78.8 percent.

++ The wage index budget neutrality factor to 0.9996. This rule applies a refinement standardization factor of 0.9524.

++ The fixed dollar loss threshold amount from $33,470 to $38,110, 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 proposal to adopt the 30-Day Risk- Standardized All-Cause Emergency Department (ED) Visit Following an IPF Discharge measure

beginning with the FY 2027 payment determination. We are not finalizing our proposal to modify reporting requirements to require IPFs to submit patient-level data on a quarterly basis.

We also refer readers to the summary of the comments to our RFI in which we solicited comments to inform elements to be included in the IPF PAI, which the CAA, 2023 requires the Centers for Medicare & Medicaid Services (CMS) to develop and implement for Rate Year (RY) 2028.

C. Summary of Impacts

Provision Description	Total Transfers & Cost Reductions
FY 2025 IPF PPS payment update	The overall economic impact of this final rule is an estimated $65 million in increased payments to IPFs during FY 2025.
FY 2025 IPFQR Program update	We estimate no economic impact for the policies we are finalizing for the IPFQR Program.

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. 108–17–3) extended the IPF PPS to psychiatric distinct part units of CAHs.

Sections 3401(f) and 10322 of the Patient Protection and Affordable Care Act (Pub. L. 111–148) as amended by section 10319(e) of that Act and by section 1105(d) of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (hereafter referred to jointly as ''the Affordable Care Act'') added subsection (s) to section 1886 of the Act.

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

Section 1886(s)(2)(A)(i) of the Act requires the application of the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act to the IPF PPS for the rate year (RY) beginning in 2012 (that is, a RY that coincides with a FY) and each subsequent RY.

Section 1886(s)(2)(A)(ii) of the Act required the application of an ''other adjustment'' that reduced any update to an IPF PPS base rate by a percentage point amount specified in section 1886(s)(3) of the Act for the RY beginning in 2010 through the RY beginning in 2019. As noted in the FY 2020 Inpatient Psychiatric Facilities Prospective Payment System and Quality Reporting Updates for fiscal year Beginning October 1, 2019 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. Additional information about the specifics of the current IPFQR Program is available in the FY 2020 Inpatient Psychiatric Facilities Prospective Payment System and Quality Reporting Updates for fiscal year beginning October 1, 2019 (FY 2020) final rule (84 FR 38459 through 38468).

Section 4125 of the Consolidated Appropriations Act, 2023 (CAA, 2023) (Pub. L. 117–328), which amended section 1886(s) of the Act, requires CMS to revise the Medicare prospective payment system for psychiatric hospitals and psychiatric units. Specifically, section 4125(a) of the CAA, 2023 added section 1886(s)(5)(A) of the Act to require the Secretary to collect data and information, as the Secretary determines appropriate, to revise payments under the IPF PPS. CMS discussed this data collection last year in the FY 2024 Inpatient Psychiatric Facilities Prospective Payment System—Rate Update (FY 2024 IPF PPS) final rule, as CMS was required to begin collecting this data and information not later than October 1, 2024. As discussed in that rule, the Agency has already been collecting data and information consistent with the types set forth in the CAA, 2023 as part of our extensive and years-long analyses and consideration of potential payment system refinements. We refer readers to the FY 2024 IPF PPS final rule (88 FR 51095 through 51098) where we discussed existing data collection and requested information to inform future IPF PPS revisions.

In addition, section 1886(s)(5)(D) of the Act, as added by section 4125(a) of the CAA, 2023 requires that the Secretary implement revisions to the methodology for determining the payment rates under the IPF PPS for psychiatric hospitals and psychiatric units, effective for RY 2025 (FY 2025). The revisions may be based on a review of the data and information collected under section 1886(s)(5)(A) of the Act.

Sections IV.B, IV.C, and IV.D of this FY 2025 IPF PPS final rule discuss final decisions about our proposed revisions under section 1886(s)(5)(D) of the Act for FY 2025.

Section 4125(b) of the CAA, 2023 amended section 1886(s)(4) of the Act by inserting a new subparagraph (E), which requires IPFs participating in the IPFQR Program to collect and submit to the Secretary standardized patient assessment data, using a standardized patient assessment instrument, for RY 2028 (FY 2028) and each subsequent rate year. IPFs must submit such data with respect to at least the admission and discharge of an individual, or more frequently as the Secretary determines appropriate. For IPFs to meet this new data collection and reporting requirement for RY 2028 and each subsequent rate year, the Secretary must implement a standardized patient assessment instrument that collects data with respect to the following categories: functional status; cognitive function and mental status; special services, treatments, and interventions; medical conditions and comorbidities; impairments; and other categories as determined appropriate by the Secretary. This patient assessment instrument must enable comparison of such patient assessment data that IPFs submit across all such IPFs to which such data are applicable.

Section 4125(b) of the CAA, 2023 further amended section 1886(s) of the Act by adding a new subparagraph (6) that requires the Secretary to implement revisions to the methodology for determining the payment rates for psychiatric hospitals and psychiatric units (that is, payment rates under the IPF PPS), effective for RY 2031 (FY 2031), as the Secretary determines to be appropriate, to take into account the patient assessment data described in paragraph (4)(E)(ii).

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, we refer readers to the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/index.html?redirect=/InpatientPsychFacilPPS/*.

B. Overview of the IPF PPS

We issued the RY 2005 IPF PPS final rule which appeared in the November 15, 2004 **Federal Register** (69 FR 66922). The RY 2005 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 RY 2005 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 RY 2005 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 provides 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. Therefore, in the RY 2005 IPF PPS final rule, we implemented the IPF PPS using the following update strategy:

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

The RY 2005 final rule (69 FR 66922) implemented the IPF PPS. 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 RY 2004 IPF proposed rule (68 FR 66923; 66928 through 66933) and our RY 2005 IPF final rule (69 FR 66933 through 66960). For characteristics with statistically significant cost differences, we used the regression coefficients of those variables to determine the size of the corresponding payment adjustments.

In the RY 2005 IPF 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).

We issued a final rule which appeared in the May 6, 2011 **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 is 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. Beginning October 1, 2012, we finalized that we will refer to the 12-month period from October 1 through September 30 as a ''fiscal year'' (FY) rather than a RY (76 FR 26435). Therefore, in this final rule we refer to rules that took effect after RY 2012 by the FY, rather than the RY, in which they took effect.

CMS issued the most recent IPF PPS annual update, which appeared in a final rule on August 2, 2023, in the **Federal Register** titled, ''Medicare Program; FY 2024 Inpatient Psychiatric Facilities Prospective Payment System—Rate Update'' (88 FR 51054), which updated the IPF PPS payment rates for FY 2024. That final rule updated the IPF PPS Federal per diem base rates that were published in the FY 2023 IPF PPS Rate Update final rule (87 FR 46846) in accordance with our established policies.

Section 902 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) amended section 1871(a) of the Act and requires the Secretary, in consultation with the Director of the Office of Management and Budget, to establish and publish timelines for the publication of Medicare final regulations based on the previous publication of a Medicare proposed or interim final regulation. Section 902 of the MMA also states that the timelines for these regulations may vary but shall not exceed 3 years after publication of the preceding proposed or interim final regulation except under exceptional circumstances.

This final rule finalizes provisions set forth in the April 3, 2024 Medicare Program; FY 2025 Inpatient Psychiatric Facilities Prospective Payment System—Rate Update; Proposed Rule (89 FR 23145). In addition, this final rule has been published within the 3-year time limit imposed by section 902 of the MMA. Therefore, we believe that the final rule is in accordance with the Congress' intent to ensure timely publication of final regulations.

III. Analysis of and Responses to Public Comments

We received 69 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.

In addition, we received a few comments that were out of the scope of the FY 2025 IPF PPS proposed rule. We appreciate these comments but note that, because they fall outside the scope of this rulemaking, we do not address them in this rule. We will consider these comments as we continue to develop policies for future rulemaking.

IV. Provisions of the FY 2025 IPF PPS Final Rule and Responses to Comments

A. FY 2025 Market Basket Update and Productivity Adjustment 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 IPF market basket in the FY 2024 IPF PPS rule, where we adopted a 2021-based IPF market basket, using Medicare cost report data for both Medicare participating freestanding psychiatric hospitals and psychiatric units. We refer readers to the FY 2024 IPF PPS final rule for a detailed discussion of the 2021-based IPF PPS market basket and its development (88 FR 51057 through 51081). References to the historical market baskets used to update IPF PPS payments are listed in the FY 2016 IPF PPS final rule (80 FR 46656).

2. FY 2025 IPF Market Basket Update

For FY 2025 (beginning October 1, 2024 and ending September 30, 2025), we proposed to update the IPF PPS payments by a market basket increase factor with a productivity adjustment as required by section 1886(s)(2)(A)(i) of the Act. Consistent with historical practice, we proposed to estimate the market basket update for the IPF PPS based on the most recent forecast available at the time of rulemaking from IHS Global Inc. (IGI). IGI is a nationally recognized economic and financial forecasting firm with which CMS contracts to forecast the components of the market baskets and productivity adjustment. For the proposed rule, based on IGI's fourth quarter 2023 forecast with historical data through the third quarter of 2023, the 2021-based IPF market basket increase factor for FY 2025 was 3.1 percent.

Section 1886(s)(2)(A)(i) of the Act requires that, after establishing the increase factor for a FY, the Secretary shall reduce such increase factor for FY 2012 and each subsequent FY, by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1886(b)(3)(B)(xi)(II) of the Act sets forth the definition of this productivity adjustment. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable FY, year, cost reporting period, or other annual period) (the ''productivity adjustment''). The 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 MFP. Beginning with the November 18, 2021 release of productivity data, BLS replaced the term ''multifactor productivity'' 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 TFP. However, as mentioned previously, 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/data-research/statistics-trends-and-reports/medicare-program-rates-statistics/market-basket-research-and-information.* In addition, in the FY 2022 IPF 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.

Section 1886(s)(2)(A)(i) of the Act requires the application of the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act to the IPF PPS for the RY beginning in 2012 (a RY that coincides with a FY) and each subsequent RY. For the FY 2025 IPF PPS proposed rule, based on IGI's fourth quarter 2023 forecast, the proposed productivity adjustment for FY 2025 (the 10-year moving average of TFP for the period ending FY 2025) was projected to be 0.4 percent. Accordingly, we proposed to reduce the 3.1 percent IPF market basket increase by this 0.4 percentage point productivity adjustment, as mandated by the Act. This resulted in a proposed FY 2025 IPF PPS payment rate update of 2.7 percent (3.1 − 0.4 = 2.7). We also proposed that if more recent data became available, we would use such data, if appropriate, to determine the FY 2025 IPF market basket increase and productivity adjustment for the final rule.

We solicited comments on the proposed IPF market basket increase and productivity adjustment for FY 2025.

Comment: Several commenters expressed concerns about the proposed 2021-based IPF market basket increase factor for FY 2025 of 3.1 percent suggesting that the proposed rate increases might still be insufficient to meet the growing costs of healthcare provision. They stated that with the significant increase in the costs of labor, pharmaceuticals, and supplies, the payment update is inadequate. Commenters stated that labor-related inflation has been driven in large part by a severe workforce shortage. The commenters also stated that hospitals are turning to costlier contract labor to sustain operations; one commenter noted that they believed that contract labor costs increased 258 percent from 2019 through 2023. The commenters stated these increased costs are felt acutely by IPFs as they struggle to maintain highly skilled technicians, clinical social workers, psychologists, and therapists. They requested that CMS provide a more robust payment update for FY 2025 and in the future, until a more accurate PPS methodology can be adopted. Commenters also stated that the cumulative effect of this inflationary pressure, coupled with the proposed Medicare payment increases for FY 2025, will continue to have negative effects on IPF operating margins. They cited the Medicare Payment Advisory Commission, which determined that Medicare has failed to cover the cost of caring for patients in hospital-based and freestanding nonprofit IPFs since at least 2016. They further stated that when looking at the 2022 Medicare cost reports for freestanding IPFs that included a full of year of data, over half of the hospitals had a negative operating margin. The commenter requested that CMS reassess the data and methodology used to determine the annual market basket update in light of continued inflationary pressures for hospitals.

One commenter stated that the proposed 3.1 percent increase in the market basket is insufficient at this crucial time for many healthcare facilities, especially those in rural and underserved areas. One commenter recommended exploring all options to ensure that provider reimbursement is adequate to meet patient needs. They further stated that in the Medicare behavioral health arena, CMS has leverage to improve financial stability for providers and their patients because the IPF PPS authorizing statute did not specify an annual rate update, giving the Secretary discretion in establishing an update methodology. One commenter noted that in some instances, hospital beds go unused despite increasing demand due to the lack of sufficient staffing. The commenter suggested a 5-percent increase consistent with recently experienced inflation, which they stated would be compounded by the anticipated inflation during the coming year.

One commenter stated that from 2019 to 2023, costs per adjusted discharge rose 25 percent; however, base payment rates for Medicare have failed to keep pace with input price inflation. They recommended CMS use data that better reflects the input price inflation that IPFs have experienced and are projected to experience in 2025.

One commenter generally supported the proposed rate increase; however, they noted that this increase is likely still at a level insufficient to sustain capacity and improve access to high—quality care effectively. One commenter supported increasing the IPF PPS rate by 2.7 percent, noting that increased funding for IPFs would improve access to care and quality of services. One commenter suggested that CMS use more recent data, as proposed, that includes the recent inflationary increases in costs. In absence of such data, they requested that CMS consider an alternative approach to better align the market basket increases with the rising cost of treating patients.

Response: We appreciate the commenters' concern regarding inflationary pressure facing IPFs and the proposed FY 2025 market basket update.

As stated in the FY 2024 IPF final rule (88 FR 51057), the 2021-based IPF market basket 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, consistent with other CMS PPS updates (including for inpatient hospitals, skilled nursing facilities, and home health agencies). CMS established this practice in the RY 2004 IPF PPS final rule (69 FR 66928 through 66930), in accordance with section 1886(b)(3)(B)(ii) of the Act. Because the market basket is designed to measure price inflation for IPF providers, it would 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) or Medicare allowable costs per risk-adjusted discharge.

As is our general practice, we proposed in the FY 2025 IPF proposed rule (89 FR 23150) that if more recent data became available, we would use such data, if appropriate, to derive the final FY 2025 IPF market basket update for the final rule. As noted in that rule and above, the projection of the 2021-based IPF market basket is based on the most recent forecast from IGI, a nationally recognized economic and financial forecasting firm with which CMS contracts to forecast the price proxies of the market baskets. We also note that when developing its forecast for labor prices, IGI considers overall labor market conditions (including rise in contract labor employment due to tight labor market conditions), as well as trends in contract labor wages, which both have an impact on wage pressures for workers employed directly by the hospital. For this final rule, based on the more recent IGI second quarter 2024 forecast with historical data through the first quarter of 2024, the projected 2021-based IPF market basket increase factor for FY 2025 is 3.3 percent, which is 0.2 percentage point higher than the projected FY 2025 market basket increase factor in the proposed rule, and reflects an increase in compensation prices of 3.7 percent. We note that the 10-year historical average (2014 through

2023) growth rate of the 2021-based IPF market basket is 2.7 percent with compensation prices increasing 2.9 percent.

Comment: One commenter recommended that CMS consider reconfiguring how it projects its annual payment updates. They stated that most years, CMS offers modest increases to the payment rates, largely driven by its analysis of cost data from prior years. The commenter stated that CMS payment updates have continued to lag, further expanding the gap between the cost of providing care and the reimbursement received from the public payers. They suggested that CMS work with its Congressional partners to raise awareness and address the underfunding of health care services. One commenter did not understand why the proposed FY 2025 market basket increase is lower than the FY 2024 market basket increase or why the proposed FY 2025 productivity adjustment is higher than the FY 2024 productivity adjustment (88 FR 51076 through 51077).

Response: The projection of the 2021-based IPF market basket is based on the most recent forecast from IGI. The market basket percentage increase is a forecast of the price pressures that IPFs are expected to face in 2025. As projected by IGI and other independent forecasters, upward price pressures are expected to be less significant in 2025 relative to 2022 through 2024. IGI's latest forecast of prices facing hospitals in FY 2025 reflects overall economic and industry-specific influences. We note that these projections do not reflect analysis of cost data from prior years, as stated by the commenter.

Comment: One commenter requested that CMS ensure mechanisms are put in place to capture costs (that is, staffing, capital expense, pharmaceuticals, emerging evidence-based interventions) accurately now and in the future with as little administrative burden as possible.

Response: We appreciate the commenter's suggestion on the topic of data collection. As stated in the FY 2024 IPF final rule, (88 FR 51057 through 51081), the 2021-based IPF market basket major cost weights were derived using the 2021 Medicare cost reports (CMS Form 2552–10, OMB No. 0938–0050) for freestanding and hospital-based IPFs. The Medicare cost report data captures detailed expenses for IPFs (including but not limited to wages and salaries, employee benefits, contract labor, pharmaceuticals, and capital). We continue to encourage all providers to report complete and accurate cost data on the Medicare cost reports—particularly on Worksheet S3, part V, which in prior years has had limited reporting as discussed in the FY 2024 IPF PPS final rule (88 FR 51060), but importantly captures detailed compensation costs.

Comment: One commenter opposed the proposal to reduce the federal per diem base rate from $895.63 to $874.93. They stated with the cost of labor, benefits, pharmacy, and other supplies increasing much greater than inflation, a 2.31 percent decrease is unacceptable. They stated that hospitals are already losing money at the current per diem rate, and anything less than a market basket increase of at least 3 percent, which is comparable to other market basket increases, is insufficient. They stated that there is a shortage of valuable IPF beds, and that cutting reimbursement will exacerbate the issue.

Response: We appreciate the commenter's concern, and we note that although we proposed a decrease to the federal per diem base rate, we estimated that payments under the IPF PPS would increase by approximately 2.6 percent overall after all payment adjustments are applied. As stated in the FY 2025 IPF PPS proposed rule (89 FR 23149), based on IGI's fourth quarter 2023 forecast with historical data through the third quarter of 2023, we proposed a 2021-based IPF market basket increase for FY 2025 of 3.1 percent. As mandated by the Act, we also proposed to reduce the 3.1 percent IPF market basket increase by the proposed 0.4 percentage point productivity adjustment, which was also based on IGI's fourth quarter 2023 forecast. As stated in the FY 2025 IPF PPS proposed rule (89 FR 23153), for the proposed FY 2025 Federal per diem base rate, we applied the payment rate update of 2.7 percent to the FY 2024 Federal per diem base rate of $895.63. Then, we also applied the proposed wage index budget neutrality factor of 0.9998 and a proposed refinement standardization factor of 0.9514 to yield a proposed Federal per diem base rate of $874.93 for FY 2025. As required by section 1886(s)(5)(D)(iii) of the Act, as added by section 4125(a) of the CAA, 2023, proposed revisions to the IPF PPS adjustment factors must be budget neutral. Therefore, we proposed a refinement standardization factor to be applied to the FY 2024 IPF PPS payment rates to maintain budget neutrality for FY 2025. This proposed refinement standardization factor reduced the proposed Federal per diem base rate to account for the overall increase to payments (approximately 5.1 percent) that would otherwise occur under the revised IPF PPS adjustment factors. As indicated in the proposed rule, we note that for this final rule, we are updating the refinement standardization factor to 0.9524 based on more recent data. As proposed (89 FR 23149), we are also updating the projected 2021-based IPF market basket increase for FY 2025 to reflect IGI's more recent second quarter 2024 forecast with historical data through the first quarter of 2024. For the final rule, the projected 2021-based IPF market basket increase for FY 2025 is 3.3 percent. We believe the 2021-based IPF market basket increase for FY 2025 adequately reflects the price increases IPFs are projected to face since the index reflects the mix of inputs used to provide IPF services.

Comment: Several commenters expressed concern about the application of the productivity adjustment stating that the COVID–19 public health emergency (PHE) has had unimaginable impacts on U.S. productivity and that most estimates of labor productivity highlight uncharacteristic reductions. They stated that even before the PHE, the CMS Office of the Actuary (OACT) indicated that hospital productivity will be less than the general economy-wide productivity, though they note the general economy-wide measure is required by law to be used to derive the productivity adjustment. They requested that CMS use its ''special exceptions and adjustments'' authority to eliminate the productivity adjustment for FY 2025.

One commenter stated that hospitals continue to encounter difficulties obtaining nurses and nursing assistants to care for patients, and these struggles could potentially be exacerbated by the recently finalized minimum staffing requirement at nursing facilities. They argued that these issues should be accounted for when determining a productivity factor. One commenter requested CMS lower the productivity adjustment factor to the rate used in FY 2024, which was 0.2 percentage point.

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 2025 productivity adjustment is derived based on the 10-year moving average growth in economy-wide productivity for the period ending FY 2025. We acknowledge the concerns of the commenters regarding the appropriateness of the productivity adjustment and potential impacts of other rulemaking, including minimum nurse staffing requirements; however, we are required pursuant to section 1886(s)(2)(A)(i) of the Act to apply the

specific productivity adjustment. 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.

As stated in the FY 2025 IPF proposed rule (89 FR 23149), the United States Department of Labor's Bureau of Labor Statistics (BLS) publishes the official measures of annual economy-wide, private nonfarm business total factor productivity (previously referred to as annual economy-wide, private nonfarm business multifactor productivity). IGI forecasts total factor productivity consistent with BLS methodology by forecasting the detailed components of TFP. A complete description of IGI's TFP projection methodology is available on the CMS website at *https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-program-rates-statistics/market-basket-research-and-information.*

We believe our methodology for the productivity adjustment is consistent with the statute that states the productivity adjustment is equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multi-factor productivity (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period).

The FY 2025 proposed productivity adjustment of 0.4 percent was based on IGI's forecast of the 10-year moving average of annual economy-wide private nonfarm business TFP, reflecting historical data through 2022 as published by BLS and forecasted TFP for 2023 through 2025. The higher productivity adjustment for FY 2025 (0.4 percent proposed and 0.5 percent for the final rule) compared to FY 2024 (0.2 percent) is primarily a result of incorporating BLS revised historical data through 2022 and preliminary historical growth in TFP for 2023, and an updated forecast for TFP growth for 2024 reflecting higher expected growth in economic output.

Finally, we note that CMS appreciates the concerns that the commenter raised about challenges related to staffing. We remain focused on improving the health and safety of patients seeking care at IPFs, and ensuring access to care.

Comment: Several commenters stated that in FYs 2022, 2023, and 2024, CMS provided market basket updates of 2.7 percent, 4.1 percent, and 3.5 percent, respectively. They claimed that CMS's actual figures have demonstrated the deficiency in these figures, with recent estimates showing the market basket for these years to be 5.3 percent, 4.8 percent, and 3.7 percent, respectively. The commenters argued that the ongoing shortcomings of the market basket perpetuate underpayments to IPFs since future payment adjustments continue to be based on these updates. They stated that given ongoing inflationary pressure, cost increases, and the inadequacy of the prior year market basket updates, they believe CMS's proposed update for FY 2025 will be insufficient to cover costs. They stated that while they appreciate that CMS will update the market basket in the final rule based on more recent data, they are concerned that it will still be inadequate. They noted that when CMS underestimates the market basket update under the Skilled Nursing Facility Prospective Payment System (PPS) and the capital input price index used in the Inpatient Prospective Payment System (IPPS), CMS makes a forecast error adjustment when the error exceeds a threshold. The commenters requested a consistent policy between these payment systems and implementation of a forecast error adjustment. Commenters, anticipating that CMS may respond that rulemaking procedures under section 1871 of the Act would not permit adoption of a forecast error adjustment for the FY 2023 IPF PPS update because such a policy was not proposed, argued that, because the IPF market basket update for FY 2025 has been made subject to public comment in the FY 2025 IPF PPS proposed rule, CMS could finalize a forecast error adjustment.

Several commenters stated that they believed the persistent gap between the forecasted market basket percentage increase and the actual market basket percentage increase is indefensible on policy grounds, particularly when considering what the commenters described as an overwhelming urgency of the behavioral health service shortages facing the United States. The commenters requested that CMS apply a 0.7 percentage point increase to the per diem base rate for FY 2025 to account for the forecast error for FY 2023.

Several commenters requested that CMS make a one-time 3.5 percent adjustment to the IPF market basket in FY 2025 to account for what the commenters consider to be underpayments from FYs 2022 through FY 2024. One commenter requested that CMS adopt a one-time forecast error adjustment to the FY 2025 IPF PPS update based on the 3.9 percentage points difference in the IPF PPS market basket in FYs 2021, 2022, and 2023.

Response: We appreciate the concerns of commenters; however, we did not propose and are not finalizing a forecast error adjustment for the IPF PPS for FY 2025. As we have noted in prior years, 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 2025 market basket update in this final rule reflects historical data through the first quarter of CY 2024 and forecasted data through the third quarter of CY 2025.

While there is no precedent for adjusting for market basket forecast error in the IPF payment update, a forecast error can be calculated for a prior year 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. As of now, the cumulative forecast error since IPF PPS inception (rate year 2007 to FY 2023) is −0.2 percent, which reflects that forecasted market basket updates for each payment year for IPFs were higher than the actual market basket updates from 2012 through 2020 (with the exception of 2018); the opposite was true for 2021 through 2023. Only considering the forecast error for years when the IPF market basket update was lower than the actual market basket update does not consider the full experience and impact of forecast error.

Comment: One commenter stated that the increasing number of beneficiaries who are choosing Medicare Advantage (MA) over Medicare fee-for-service is causing additional strain on overall IPF margins. They stated that MA is increasing the overall cost to care for patients by unilaterally implementing overly restrictive medical necessity and prior authorization processes and increasing the administrative burden of obtaining payments. They stated that although MA plans are receiving higher increases in payment rates than providers, the rate increases paid to MA plans are not actually materializing in the form of higher payments to providers. The commenter recommended CMS adjust Medicare fee-for-service payments to compensate for MA losses incurred.

Response: We appreciate the concerns regarding payment adequacy under the IPF PPS; however, we do not agree that it would be appropriate to adjust IPF PPS payments to compensate providers for losses that IPFs may incur under other payors. Section 124 of the BBRA mandated that the Secretary develop a per diem PPS for inpatient hospital

services furnished in psychiatric hospitals and psychiatric units. As required by § 412.424(c)(6)(ii), the FY 2025 IPF PPS Federal per diem base rate is based on an increase factor to adjust for the most recent estimate of increases in the prices of an appropriate market basket of goods and services provided by inpatient psychiatric facilities. Specifically, we applied the 2021-based IPF market basket increase for FY 2025, reduced by the productivity adjustment, which as noted earlier in this final rule measures expected price inflation for IPF providers in FY 2025.

Final Decision: After consideration of the comments received, we are finalizing our proposal to update IPF PPS payment rates using the latest available productivity-adjusted market basket increase factor. Based on IGI's more recent second quarter 2024 forecast with historical data through the first quarter of 2024, the projected 2021-based IPF market basket increase for FY 2025 rule is 3.3 percent and the projected productivity adjustment is 0.5 percent.

3. FY 2025 IPF Labor-Related Share

Due to variations in geographic wage levels and other labor-related costs, we believe that payment rates under the IPF PPS should continue to be adjusted by a geographic wage index, which will apply to the labor-related portion of the Federal per diem base rate (hereafter referred to as the labor-related share). The labor-related share is determined by identifying the national average proportion of total costs that are related to, influenced by, or vary with the local labor market. We proposed to continue to classify a cost category as labor-related if the costs are labor-intensive and vary with the local labor market.

Based on our definition of the labor-related share and the cost categories in the 2021-based IPF market basket, we proposed to continue to include in the labor-related share the sum of the relative importance of Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-Related Services; and a portion of the Capital-Related relative importance from the 2021-based IPF market basket. For more details regarding the methodology for determining specific cost categories for inclusion in the labor-related share based on the 2021-based IPF market basket, we refer readers to the FY 2024 IPF PPS final rule (88 FR 51078 through 51081).

The relative importance reflects the different rates of price change for these cost categories between the base year (FY 2021) and FY 2025. Based on IGI's fourth quarter 2023 forecast of the 2021-based IPF market basket, the sum of the FY 2025 relative importance moving average 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 was 75.7 percent. We proposed, consistent with prior rulemaking, that the portion of Capital-Related costs that are influenced by the local labor market is 46 percent. Since the relative importance for Capital-Related costs was 6.8 percent of the 2021-based IPF market basket for FY 2025, we proposed to take 46 percent of 6.8 percent to determine a labor-related share of Capital-Related costs for FY 2025 of 3.1 percent. Therefore, we proposed a total labor-related share for FY 2025 of 78.8 percent (the sum of 75.7 percent for the labor-related share of operating costs and 3.1 percent for the labor-related share of Capital-Related costs). We also proposed that if more recent data became available, we would use such data, if appropriate, to determine the FY 2025 labor-related share for the final rule. For more information on the labor-related share and its calculation, we refer readers to the FY 2024 IPF PPS final rule (88 FR 51078 through 51081). We solicited comments on the proposed labor-related share for FY 2025.

Comment: One commenter supported the proposed increase in the labor-related share of the IPF market basket for FY 2025. The commenter expected the increase in the labor-related share given their concerns about labor costs increasing at a higher rate than other hospital costs during the pandemic. They also requested that CMS consider a period less than 5 years for the next rebasing and revising of the IPF market basket, as they believe the current labor share based on FY 2021 cost reports may not fully reflect the increased weight for labor in the overall index that hospital experienced during the COVID–19 PHE.

Response: We appreciate the commenter's request for CMS to consider a shorter period than 5 years for the next rebasing. We generally rebase the IPF market basket every 5 years, in part because the cost weights obtained from the Medicare cost reports generally do not indicate a significant change in the weights over shorter intervals. However, we acknowledge the commenter's concern and the possible impact of the PHE on the cost weights. We regularly monitor the Medicare cost report data to assess whether a rebasing is technically appropriate, and we will continue to do so in the future. Consistent with historical practice, a rebasing of the IPF market basket would be proposed in rulemaking and subject to public comments.

Comment: One commenter encouraged CMS to consider collecting information on staffing. The commenter noted that CMS calculates a labor share for IPFs of 78.8 percent for FY 2025, which they note is higher than other institutional settings (*e.g.,* labor costs comprise less than 70 percent of IPPS hospital costs, 74 percent of inpatient rehabilitation facility costs, and 71 percent of skilled nursing facility costs). However, they noted there was little available information on the mix (and quantity) of staff employed by IPFs and how staff spend their time across various IPF tasks (such as inpatient assessment, counseling, drug management, nursing care, and behavioral monitoring). They further stated that IPF staffing data would provide essential insights into the variation in costs and quality of care across providers, enabling CMS (and Medicare beneficiaries, if data were publicly available) to better understand the services they are purchasing and using. The commenter stated there is a precedent in Medicare for regularly collecting staffing information, as SNFs are required to submit detailed staffing data through the Payroll Based Journal. The commenter stated payroll data are considered the gold standard for measuring staffing; the data are submitted electronically and can be audited by other data sources.

Response: We appreciate the commenter's suggestion to collect more information on staffing at IPFs. We will take these comments into consideration as we explore the possibility of collecting this information in the future.

Final Decision: After consideration of the comments, we are finalizing a FY 2025 labor-related share based on the latest available data. Based on IGI's second quarter 2024 forecast of the 2021-based IPF market basket, the sum of the FY 2025 relative importance moving average 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 is 75.7 percent. Since the relative importance for Capital-Related costs is 6.7 percent of the 2021-based IPF market basket for FY 2025, we take 46 percent of 6.7 percent to determine a labor-related share of Capital-Related costs for FY 2025 of 3.1 percent. Therefore, the total labor-related share for FY 2025 is 78.8

percent (the sum of 75.7 percent for the labor-related share of operating costs and 3.1 percent for the labor-related share of Capital-Related costs).

Table 1 shows the final FY 2025 labor-related share and the final FY 2024 labor-related share using the 2021-based IPF market basket relative importance.

TABLE 1: FY 2025 Final IPF Labor-Related Share and FY 2024 IPF Labor-Related Share

	Relative importance, final labor-related share FY 2025[1]	Relative importance, labor-related share FY 2024[2]
Wages and Salaries	53.6	53.4
Employee Benefits	14.1	14.2
Professional Fees: Labor-Related	4.7	4.7
Administrative and Facilities Support Services	0.6	0.6
Installation, Maintenance and Repair Services	1.2	1.2
All Other Labor-Related Services	1.5	1.5
Subtotal	75.7	75.6
Labor-related portion of Capital-Related (.46)	3.1	3.1
Total Labor-Related Share	78.8	78.7

1. Based on the 2nd quarter 2024 IGI forecast of the 2021-based IPF market basket.
2. Based on the 2nd quarter 2023 IGI forecast of the 2021-based IPF market basket.

B. Revisions to the IPF PPS Rates for FY 2025

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 RY 2005 IPF PPS final rule (69 FR 66926).

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

Section 124(a)(1) of the BBRA requires that we implement the IPF PPS in a budget neutral manner. In other words, the amount of total payments under the IPF PPS, including any payment adjustments, must be projected to be equal to the amount of total payments that will 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 will have been made under the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) (Pub. L. 97–248) methodology had the IPF PPS not been implemented. A step-by-step description of the methodology used to estimate payments under the TEFRA payment system appears in the RY 2005 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 RY 2005 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 RY 2005 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 42 CFR 412.428 through publication of annual notices or proposed and final rules. A detailed discussion on the standardized budget neutral Federal per diem base rate and the Electroconvulsive Therapy (ECT) payment per treatment appears in the FY 2014 IPF PPS update notice (78 FR 46738 through 46740). These documents are available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/index.html.*

As discussed in section IV.B.2 of this final rule, we proposed to revise the patient-level adjustment factors and increase the ECT payment amount for FY 2025. Section 1866(s)(5)(D)(iii) of the Act, as added by section 4125(a) of the CAA, 2023, requires that revisions to the IPF PPS adjustment factors must be made budget-neutrally. Therefore, as discussed in section IV.F of this final rule, we proposed to apply a

standardization factor to the FY 2025 base rate that takes these refinements into account to keep total IPF PPS payments budget neutral.

2. Increase in the Electroconvulsive Therapy (ECT) Payment per Treatment

a. Background

In the RY 2005 IPF PPS final rule (69 FR 66951), we analyzed the costs of IPF stays that included ECT treatment using the FY 2002 MedPAR data based on comments we received on the RY 2005 IPF PPS proposed rule. Consistent with the comments we received about ECT, our analysis and review indicated that cases with ECT treatment are substantially more costly than cases without ECT treatment. Based on this analysis, in that final rule we finalized an additional payment for each ECT treatment furnished during the IPF stay. This ECT payment per treatment is made in addition to the per diem and outlier payments under the IPF PPS. To receive the payment per ECT treatment, IPFs must indicate on their claims the revenue code and procedure code for ECT (Rev Code 901; procedure code 90870) and the number of units of ECT, that is, the number of ECT treatments the patient received during the IPF stay.

To establish the ECT per treatment payment, we used the pre-scaled and pre-adjusted median cost for procedure code 90870 developed for the Hospital Outpatient Prospective Payment System (OPPS), based on hospital claims data. We explained in the RY 2005 IPF PPS final rule that we used OPPS data because after a careful review and analysis of IPF claims, we were unable to separate out the cost of a single ECT treatment (69 FR 66922). We used the unadjusted hospital claims data under the OPPS because we did not want the ECT payment under the IPF PPS to be affected by factors that are relevant to OPPS, but not specifically applicable to IPFs. The median cost was then standardized and adjusted for budget neutrality. We also adjusted the ECT rate for wage differences in the same manner that we adjust the per diem rate.

Since the ECT payment rate was established in the RY 2005 IPF PPS rule, it has been updated annually by application of each year's market basket, productivity adjustment, and wage index budget neutrality factor to the previous year's ECT payment rate (referred to as our ''standard methodology'' in this section). While the ECT payment rate has been updated each year by these factors, we have not recalculated the ECT payment per treatment based on more recent cost data since the establishment of the IPF PPS.

b. Increase to the Electroconvulsive Therapy Payment per Treatment

For the FY 2025 IPF PPS proposed rule, we analyzed data in both the IPF PPS and the OPPS. In the IPF PPS setting, our analysis of recent IPF PPS data indicates that IPF costs have increased for stays that include ECT treatments. As discussed in the next paragraph, our analysis of these costs led us to consider whether the current payment per treatment for ECT is aligned with the additional costs associated with stays that include ECT treatments. We began by analyzing IPF stays with ECT treatment using the CY 2022 Medicare Provider and Analysis Review (MedPAR) data. IPF stays with ECT treatment comprised about 1.7 percent of all stays, which is a decrease from the FY 2002 MedPAR data discussed in the RY 2005 IPF PPS final rule, where stays with ECT treatment were 6.0 percent of all IPF stays. A total of 288 IPF facilities had stays with ECT treatment in 2022, with an average 6.7 units of ECT per stay. We compared the total cost for stays with and without ECT treatment, and found that IPF stays with ECT treatment were approximately three times more costly than IPF stays without ECT treatment ($44,687.50 per stay vs. $15,432.30 per stay). Most of the variance in cost was due to differences in the IPF length of stay (LOS) (28.00 days for stays with ECT treatment vs. 13.43 days for stays without ECT treatment). We note that the IPF PPS makes additional per diem payments for longer lengths of stay, which makes the total payment larger for a longer stay. However, we also observed that there are differences in the per-day cost for stays with and without ECT. We calculated the average cost per day for stays with and without ECT treatment and found that stays with ECT treatment have an average cost per day of $1,595.76, while stays without ECT treatment have an average cost per day of $1,149.51.

Furthermore, as we discuss in section IV.C.3.d.(2) of this final rule, our latest regression analysis includes a control variable to account for the presence of ECT during an IPF stay. That control variable indicates that, holding all other patient-level and facility-level factors constant, there is a statistically significant increase in cost per day for IPF stays that include ECT, further demonstrating that resource use is higher for IPF stays with ECT than those without ECT. As we previously noted in the RY 2005 IPF PPS final rule (69 FR 66922), IPF claims and cost data are not sufficiently granular to identify the per-treatment cost of ECT. Therefore, we examined the difference in ancillary costs for IPF stays with and without ECT treatment. In the CY 2022 MedPAR data, the ancillary costs per IPF stay with ECT treatment were $7,116.85 higher than ancillary costs per IPF stay without ECT treatment. The ancillary costs were calculated as follows: for each ancillary department (for example, drugs or labs), the charges were multiplied by the department-level CCR, and those department-level costs were summed across departments for each stay. The average ancillary costs per stay were calculated accordingly for stays with and without ECT treatment, revealing that average ancillary costs per day are three times higher for stays with ECT treatment: $99.36 for stays without ECT treatment versus $301.77 for stays with ECT treatment. Accounting for differences in length of stay between stays with and without ECT, the average additional ancillary cost per ECT unit was approximately $849.72.

We noted that the application of our standard methodology for updating the ECT payment would have resulted in an FY 2025 payment of $377.54. We note that for this final rule, that figure is $378.23 per ECT treatment, based on the FY 2024 ECT payment amount of $385.58, increased by the market basket update of 2.8 percent and reduced by the FY 2025 wage index budget neutrality factor of 0.9996 and a refinement standardization factor of 0.9546, which is the standardization factor that would account for all other proposed refinements without increasing the ECT per treatment. As we noted above, this ECT payment would be added to the per diem and any applicable outlier payments for the entire stay. CMS considered this rate in proposing to adjust the ECT per treatment rate. However, the analysis of ancillary costs for IPF stays with ECT treatment suggested that a further increase to the current ECT payment amount per treatment could better align IPF PPS payments with the increased costs of furnishing ECT. The ancillary cost data showed that costs for furnishing ECT have risen by a factor greater than the standard methodology for updating the rate will adjust for.

It continues to be the case that, as we discussed in the RY 2005 IPF PPS final rule, current IPF cost and claims data are not sufficiently granular to identify the per-treatment cost of ECT. We believe that using the costs in the OPPS setting are the most accurate for purposes of updating the ECT per treatment rate because we believe this treatment requires comparable resources

when performed in outpatient and inpatient settings. Thus, we analyzed the most recent OPPS cost information to consider changes to the ECT payment per treatment for FY 2025.

The original methodology for determining the ECT payment per treatment was based on the median cost for procedure code 90870 developed for the OPPS, as discussed in the RY 2005 IPF PPS final rule (69 FR 66951). Since that time, the OPPS has adopted certain changes to its methodology for calculating costs. In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68259 through 68270), CMS finalized a methodology for developing the relative payment weights for Ambulatory Payment Classifications using geometric mean costs instead of median costs. We explained that geometric means better capture the range of costs associated with providing services, including those cases where very efficient hospitals have provided services at much lower costs. While medians and geometric means both capture the impact of uniform changes, that is, those changes that influence all providers, only geometric means capture cost changes that are introduced slowly into the system on a case-by-case or hospital-by-hospital basis, allowing us to detect changes in the cost of services earlier.

We believe the rationale for using geometric mean cost in the OPPS setting as the underpinning methodology for establishing payments applies equally to the costs of providing ECT on a per treatment basis under the IPF PPS. Therefore, in considering changes for the IPF PPS ECT payment per treatment for FY 2025, we compared the costs observed in the IPF setting to the geometric mean cost for an ECT treatment posted as part of the CY 2024 OPPS/ASC update, which is based on CY 2022 outpatient hospital claims. Although we proposed to increase the ECT payment with reference to the CY 2024 OPPS ECT geometric mean cost for FY 2025, we did not propose to adopt the OPPS rate (which is distinct from the geometric mean cost) for the ECT payment per treatment for FY 2025 because the final OPPS rates include policy decisions and payment rate updates that are specific to the OPPS. We intend to continue to monitor the costs associated with ECT treatment and may propose adjustments in the future as needed.

The pre-scaled and pre-adjusted CY 2024 OPPS geometric mean cost for ECT is $675.93. Comparatively, the FY 2024 IPF ECT payment rate was $385.58 (88 FR 51054). As discussed in the prior paragraphs, our analysis of updated ancillary cost data indicates that the IPF PPS ECT payment rate per treatment, when updated according to the standard methodology alone, has not kept pace with the cost of furnishing the treatment in the IPF setting. As we stated previously, we believe this treatment requires comparable resources when performed in outpatient and inpatient settings. Therefore, we proposed to use the pre-scaled and pre-adjusted CY 2024 OPPS geometric mean cost of $675.93 as the basis for the IPF PPS ECT payment per treatment in FY 2025, as discussed below. We proposed to update $675.93 by the FY 2025 IPF PPS payment rate update of 2.7 percent (3.1 percent IPF market basket increase, reduced by the 0.4 percentage point productivity adjustment), and the wage index budget neutrality factor of 0.9998 for FY 2025, in alignment with our current standard methodology. We also proposed to update this amount based on more recent data of the market basket, productivity adjustment, and wage index budget neutrality factor.

To account for budget neutrality, as discussed in section IV.F of this final rule, we proposed to apply a refinement standardization factor to the FY 2025 IPF PPS Federal per diem base rate and to the ECT payment amount per treatment to account for this proposed change to the ECT payment amount per treatment and all proposed changes to the patient-level adjustment factors and to the ED adjustment factor for FY 2025. We noted that this proposed increase to the ECT per treatment amount would be associated with a minor decrease to the IPF Federal per diem base rate as a result of the refinement standardization factor (0.9514 instead of 0.9536). We estimated that this change would increase payments for IPFs that provide ECT, and would decrease payments for IPFs that do not provide ECT. However, we explained that the decrease in payments associated with this change would be no more than approximately 0.2 percent, which would be offset by various other proposed changes such as the proposed wage index changes, proposed revisions to the IPF PPS patient-level adjustments, and the proposed market basket increase for FY 2025.

We noted that we have monitored the provision of ECT through analysis of claims data since the beginning of the IPF PPS and have not observed any indicators that payment is inappropriately incentivizing the provision of ECT to IPF patients. We stated that we intend to continue monitoring the provision of ECT through further analysis of IPF PPS claims data. In addition, we presented a detailed discussion of the distributional impacts of this proposed change and we welcomed comments regarding our analysis, including any comments that could inform our understanding of where ECT costs are allocated in cost reports in order to potentially inform improved collection of data on ECT treatment costs in the IPF setting. We also welcomed comments on whether it may be appropriate to collect additional ECT-specific costs on the hospital cost report. Lastly, we proposed that if more recent data became available, we would use such data, if appropriate, to determine the FY 2025 Federal per diem base rate and ECT payment per treatment for the FY 2025 IPF PPS final rule.

Comment: The majority of commenters supported our proposal to increase the ECT payment per treatment, noting that the increased payment would help protect access to this treatment for patients who need it. A few commenters suggested that we could phase in the increase over several years, thus mitigating a reduction to the base rate through the refinement standardization. One of these commenters suggested tying each smaller increase to a quality measure, thus providing additional oversight measures to monitor for unintended consequences, while another advocated for phasing in the increase over three years or phasing in the resulting budget neutrality factor over multiple years. One commenter recommended implementing a smaller increase until more detailed data on ECT costs is available in IPF cost reports.

Response: We appreciate the commenters' support for this proposal regarding the ECT payment per treatment. As we noted in the preamble to the FY 2025 proposed rule, the decrease in payments associated with this change would be no more than approximately 0.2 percent, or a reduction to the IPF federal per diem base rate of approximately $2.03, which we noted would be offset for particular providers by various other proposed changes such as the proposed wage index changes, proposed revisions to the IPF PPS patient-level adjustments, and the proposed market basket increase for FY 2025. We do not agree that the effect of the increase in the ECT payment per treatment on the base rate is substantial enough to warrant phasing in over time. In response to the commenter who suggested tying increases to a quality measure, we thank you for your comment and will consider your suggestion when developing future measures. We will also continue monitoring ECT costs as we receive

more data on ancillary costs in the future.

Comment: One commenter noted that ECT costs are reported on cost report line 76, and requested that the outdated term ''Electroshock Therapy'' in the cost report instructions be changed to ''Electroconvulsive Therapy'' or ECT.

Response: We thank commenters for their suggestion and will consider revising the cost report terminology. We note that the Medicare Claims Processing Manual (CPM) 100–04; chapter 3, § 190.7.3, uses the suggested terminology.

Comment: Two commenters were critical of the use of ECT out of concern for patient safety or concern that the treatment is not sufficiently regulated.

Response: We appreciate commenters expressing their concerns; however, these comments are out of scope of this rule because our proposal did not relate to coverage of ECT or the practice of medicine. Rather, we proposed to refine the payment for a procedure paid for under the IPF PPS. We remind readers that CMS's coverage requirements for ECT can be found at: *https://www.cms.gov/medicare-coverage-database/search-results.aspx?keyword=electroconvulsive+therapy&keywordType=starts&areaId=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all.*

Final Decision: After consideration of the comments received, we are finalizing our proposal to use the pre-scaled and preadjusted CY 2024 OPPS geometric mean cost of $675.93 as the basis for the IPF PPS ECT payment per treatment in FY 2025. Accordingly, we will apply the final FY 2025 IPF PPS payment rate update of 2.8 percent (3.3 percent IPF market basket percentage increase, reduced by the 0.5 percentage point productivity adjustment), the final refinement standardization factor of 0.9524, and the final wage index budget neutrality factor of 0.9996 for FY 2025, in alignment with our current standard methodology. A complete discussion of the final FY 2025 ECT payment per treatment and final refinement standardization factor is found in section II.B.3 of this final rule. A detailed discussion of the distributional impacts of this proposed change is found in section VIII.C of this final rule.

As we stated in the proposed rule, we intend to continue monitoring the provision of ECT through further analysis of IPF PPS claims data. (89 FR 23153)

IPFs must include a valid procedure code for ECT services provided to IPF beneficiaries 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 are no changes to the ECT procedure codes used on IPF claims in the final update to the ICD–10–PCS code set for FY 2025. Addendum B to this proposed rule shows the ECT procedure codes for FY 2025 and is available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html.*

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

The current (FY 2024) Federal per diem base rate is $895.63 and the ECT payment per treatment is $385.58. For the final FY 2025 Federal per diem base rate, we applied the payment rate update of 2.8 percent—that is, the final 2021-based IPF market basket percentage increase for FY 2025 of 3.3 percent reduced by the final productivity adjustment of 0.5 percentage point—the final wage index budget neutrality factor of 0.9996 (as discussed in section IV.D.1 of this final rule), and a final refinement standardization factor of 0.9524 (as discussed in section IV.F of this final rule) to the FY 2024 Federal per diem base rate of $895.63, yielding a final Federal per diem base rate of $876.53 for FY 2025. As discussed in section IV.B.2 of this final rule, we are finalizing our proposal to increase the ECT payment per treatment for FY 2025 in addition to our routine updates to the rate. We applied the 2.8 percent IPF market basket update, the 0.9996 wage index budget neutrality factor, and the 0.9524 refinement standardization factor to the final payment per treatment based on the CY 2024 OPPS geometric mean cost of $675.93, yielding a final ECT payment per treatment of $661.52 for FY 2025.

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

- For IPFs that fail to report required data under the IPFQR Program, we will apply a 0.8 percent payment rate update—that is, the final IPF market basket increase for FY 2025 of 3.3 percent reduced by the productivity adjustment of 0.5 percentage point for an update of 2.8 percent, and further reduced by 2.0 percentage points in accordance with section 1886(s)(4)(A)(i) of the Act. We will also apply the refinement standardization factor of 0.9524 and the wage index budget neutrality factor of 0.9996 to the FY 2024 Federal per diem base rate of $895.63, yielding a Federal per diem base rate of $859.48 for FY 2025.
- For IPFs that fail to report required data under the IPFQR Program, we will apply the 0.8 percent annual payment rate update, the 0.9524 refinement standardization factor, and the 0.9996 wage index budget neutrality factor to the payment per treatment based on the CY 2024 OPPS geometric mean cost of $675.93, yielding an ECT payment per treatment of $648.65 for FY 2025.

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

1. Overview of the IPF PPS Adjustment Factors and Revisions

The current (FY 2024) IPF PPS payment adjustment factors 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, we refer readers to the RY 2005 IPF PPS final rule (69 FR 66935 through 66936).

For FY 2025, we proposed to implement revisions to the methodology for determining payment rates under the IPF PPS. As we noted earlier in this FY 2025 IPF PPS final rule, section 1886(s)(5)(D) of the Act, as added by section 4125(a) of the CAA, 2023 requires that the Secretary implement revisions to the methodology for determining the payment rates under the IPF PPS for psychiatric hospitals and psychiatric units, effective for FY 2025. The revisions may be based on a review of the data and information collected under section 1886(s)(5)(A) of the Act. Accordingly, we proposed to revise the patient-level IPF PPS payment adjustment factors as discussed in section IV.C.4. of this final rule, effective for FY 2025. We explained that we developed proposed adjustment factors based on a regression analysis of IPF cost and claims data, which is discussed in greater detail in the following sections of this final rule. The primary sources of this analysis are CY 2019 through 2021 MedPAR files and Medicare cost report data (CMS

Form 2552–10, OMB No. 0938–0050) [1] from the FY 2019 through 2021 Hospital Cost Report Information System (HCRIS). For each year (2019 through 2021), if a provider did not have a Medicare cost report for that year, we used the provider's most recent available Medicare cost report prior to the year for which a Medicare cost report was missing, going back to as early as 2018. Section IV.C.3 of this final rule discusses the development of the proposed revised case-mix adjustment regression and the final case-mix regression analysis upon which we are basing our final revisions to the FY 2025 IPF PPS patient-level adjustment factors.

2. History of IPF PPS Cost and Claims Analyses

In the FY 2023 IPF PPS proposed rule (87 FR 19428 through 19429), we briefly discussed past analyses and areas of interest for future refinement, about which we previously solicited comments. CMS also released a technical report posted to the CMS website [2] accompanying the rule summarizing these analyses. In that same proposed rule, we described the results of the agency's latest analysis of the IPF PPS and solicited comments on certain topics from the report. We summarized the considerations and findings related to our analyses of the IPF PPS adjustment factors in the FY 2023 IPF PPS final rule (46864 through 46865).

In the FY 2024 IPF PPS proposed rule (88 FR 21269 through 21272), we requested information from the public to inform revisions to the IPF PPS required by the CAA, 2023. Specifically, we sought information about which data and information will be most appropriate and useful for the purposes of refining IPF PPS payments. We requested information related to the specific types of data and information mentioned in the CAA, 2023. We also solicited comments on the reporting of ancillary charges, such as labs and drugs, on IPF claims. Lastly, we presented and solicited comments on the latest results of our analysis of Social Drivers of Health (SDOH).

In response to the requests for information, commenters offered a number of suggestions for further analysis, including recommendations to consider adjusting payment for patients with sleep apnea, violent behavior, and patients that transfer from an acute care unit. We discuss the analysis conducted and our findings as related to patient-level adjustment factors in section IV.C.3 of this final rule.

In the FY 2025 IPF PPS proposed rule, we explained that the primary goal in refining the IPF PPS payment adjustment factors is to pay each IPF an appropriate amount for the efficient delivery of care to Medicare beneficiaries. We stated that the system must be able to account adequately for each IPF's case-mix to allow for both fair distribution of Medicare payments and access to adequate care for those beneficiaries who require more costly care. We also noted that as required by section 1886(s)(5)(D)(iii) of the Act, as added by section 4125(a) of the CAA, 2023, proposed revisions to the IPF PPS adjustment factors must be budget neutral. We explained that we applied a refinement standardization factor to the proposed IPF PPS payment rates to maintain budget neutrality for FY 2025.

3. Development of the Revised Case-Mix Adjustment Regression

In the proposed rule, we explained that to ensure that the IPF PPS continues to account adequately for each IPF's case-mix, we performed an extensive regression analysis of the relationship between the per diem costs and both patient and facility characteristics to identify those characteristics associated with statistically significant cost differences. We discuss the results of this regression analysis in section IV.C.3.e. of this final rule. We further discuss final policies related to the proposed revisions to the IPF PPS patient-level adjustment factors based on this regression analysis in section IV.C.4 of this final rule.

As we discussed in the proposed rule, we computed a per diem cost for each Medicare inpatient psychiatric stay, including routine operating, ancillary, and capital components using information from the CY 2019 through CY 2021 MedPAR files and data from the 2019 through 2021 Medicare cost reports, backfilling with Medicare cost reports from the most recent prior year when necessary.

We began with a 100-percent sample of the CY 2019 through CY 2021 MedPAR data files, which contain a total of 1,111,459 stays from 1,684 IPFs. We explained in the proposed rule that we applied several data restrictions and exclusions to obtain the set of data used for our regression analysis. The MedPAR data files used for this regression analysis contain a total of 806,611 stays from 1,643 IPFs, which reflect the removal of 41 providers and 304,848 stays with missing or erroneous data. To include as many IPFs as possible in the regression, we used the cost report information for each provider corresponding to the year of claims, when available, and substituted the most recent prior available cost report information for routine cost and ancillary cost to charge ratios if the corresponding year's data was not available.

a. Data Sources

For the regression analysis, we stated in the proposed rule that we chose to use a combined set of CY 2019 through 2021 MedPAR data. Our analysis showed that using a combined set of data from multiple years yields the most stable and consistent result. We noted that when we looked at the results for each year individually, we found that some DRGs and comorbidity categories were not statistically significant due in part to small sample size. In addition, we noted that during FY 2020, the U.S. healthcare system undertook an unprecedented response to the Public Health Emergency (PHE) declared by the Secretary of the Department of Health and Human Services on January 31, 2020 in response to the outbreak of respiratory disease caused by a novel (new) coronavirus that has been named ''SARS CoV 2'' and the disease it causes, which has been named ''coronavirus disease 2019'' (abbreviated ''COVID–19''). We stated that we believe the aggregated three-year regression serves to smooth the impact of changes in utilization driven by the COVID–19 PHE, as well as significant changes in staffing and labor costs that commenters noted in response to the FY 2023 and FY 2024 IPF PPS proposed rules. We also explained in the proposed rule that we used 2019 through 2021 Medicare cost report data to retain as many records as possible for analysis.

In addition, we explained that we used several other data sources to identify the IPF population for analysis and to construct variables in the regression model:

- *Provider of Services (POS) File:* The POS file contains facility characteristics including name, address, and types of services provided.
- *Provider Specific Data for Public Use Files for the IPF PPS:* The Provider Specific File (PSF) contains data used to calculate COLA factors and identify the Core-Based Statistical Area (CBSA). CBSA is used to match providers with corresponding wage index data, which is used to adjust the calculation of the Federal per diem base rate to account for geographic differences in costs.
- *Common Working File (CWF) Inpatient Claims Data:* The CWF

[1] *https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202206-0938-017.*

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

contains data regarding ECT treatments provided during an IPF stay.

In the proposed rule, we noted that among the 1,643 providers included in the regression analysis sample, the majority had their most recent Medicare cost report information corresponding to the year of the MedPAR data file. Specifically, for the CY 2019 MedPAR data file, 99.5 percent (1,551 providers) used FY 2019 Medicare cost reports, and 0.5 percent (8 providers) used FY 2018 Medicare cost reports. For CY 2020, 99.7 percent (1,523 providers) used FY 2020 Medicare cost reports, and 0.3 percent (5 providers) used FY 2019 Medicare cost reports. For CY 2021, 97.6 percent (1,435 providers) used FY 2021 Medicare cost reports, and 2.4 percent (35 providers) used FY 2020 Medicare cost reports. We explained that this approach allowed us to use the most current and relevant cost report data, ensuring the robustness and accuracy of our analysis.

b. Trims and Assumptions

In the proposed rule, we explained that to identify the IPF population for analysis, we matched MedPAR records to facility-level information from Medicare cost reports, the POS file, and the PSF. We further explained that we included MedPAR stays that met the following criteria:

- Hospital CMS Certification Number (CCN) contains ''40,'' ''41,'' ''42,'' ''43,'' or ''44'' in the third and fourth position or a special unit code of ''S'' or ''M'' for psychiatric unit or psychiatric unit in a critical access hospital.
- Beneficiary primary payer code is equal to ''Z'' or blank, indicating Medicare is the primary payer.
- Group Health Organization (GHO) paid code is equal to zero or blank, indicating that a GHO has not paid the facility for the stay.
- National Claims History (NCH) claim type code is equal to ''60,'' an inpatient claim.
- Number of utilization days was greater than zero.

We noted in the proposed rule that we completed a series of trimming steps to remove missing and outlier data, to promote the accuracy and completeness of data included in the regression model. We stated that before any trims or exclusions were applied, there were 1,684 providers in the MedPAR data file. We described these trimming steps in detail in the proposed rule.

First, we matched facilities from the MedPAR dataset to the most recent Medicare cost report file available from CY 2018 to CY 2021, and excluded facilities that did not have a Medicare cost report available from 2018 to 2021. If facilities had more than one Medicare cost report in a given year, we used the Medicare cost report representing the longest time span. We identified 1 provider in CY 2019, 5 providers in CY 2020, and 4 providers in CY 2021 that had no available Medicare cost report information. In total, we excluded data from 5 unique providers that had no available Medicare cost report information from CY 2019 to CY 2021.

Next, we trimmed facilities with extraordinarily high or low costs per day. We removed facilities with outlier routine per diem costs, defined as those falling outside of the range of the mean logarithm of routine costs per diem plus or minus 3.00 standard deviations. We also removed stays with outlier total per diem costs, defined as those falling outside the range of the mean per diem cost by facility type (psychiatric hospitals and psychiatric units) plus or minus 3.00 standard deviations. The average and standard deviations of the total per diem cost (routine and ancillary costs) were computed separately for stays in psychiatric hospitals and psychiatric units because we did not want to systematically exclude a larger proportion of cases from one type of facility. In applying these trims across all three data years used in our regression model, there were 104 providers with routine per diem costs outside 3.00 standard deviations from the mean, and 47 providers with total per diem costs outside 3.00 standard deviations from the mean. Specifically, this includes 24 providers in CY 2019, 41 providers in CY 2020, and 39 providers in CY 2021 excluded for outlier routine per diem costs. We identified 25 providers in CY 2019, 1 provider in CY 2020, and 21 providers in CY 2021 that we excluded for outlier total per diem costs. In total, we excluded data from 23 unique providers with outlier routine per diem costs and 8 unique providers with outlier total per diem costs.

We also removed stays at providers without a POS file or PSF. There were 5 providers without a POS file or PSF during the period CY 2019 to CY 2021; therefore, we excluded data from these 5 providers. Only 1 unique provider was entirely excluded with no POS file or PSF from CY 2019 to CY 2021. Additionally, 1 provider was excluded because no stays had one of the recognized IPF PPS DRGs assigned.

In summary, the application of these data preparation steps resulted in excluding 5 providers because they did not have a cost report available from 2018 to 2021, 23 providers with routine per diem costs outside 3.00 standard deviations from the mean, and 8 providers with total per diem costs outside 3.00 standard deviations from the mean. We also excluded 1 provider without a POS file or PSF, 1 provider with no stays with IPF PPS DRGs, and 3 providers based on IPF stays restrictions. In total, the exclusion of these 41 providers resulted in the removal of 304,848 stays from our original total of 1,111,459 stays.

In the proposed rule, we explained that we considered trimming stays from facilities where 95 percent or more of stays had no ancillary charges because we assumed that the cost data from these facilities were inaccurate or incomplete. We noted that this is the trimming methodology that we applied to the analysis described in the technical report released along with the FY 2023 IPF PPS proposed rule. As previously discussed, the IPF PPS regression model uses the sum of routine and ancillary costs as the dependent variable, and we assumed that data from facilities without ancillary charge data will be inadequate to capture variation in costs. We explained that when we examined the claims from 2018, which we used for prior analysis, this trimming step resulted in removing almost one-quarter of total stays from the unrestricted 2018 MedPAR dataset (82,491 out of 364,080 total stays). We stated that this trimming step also resulted in disproportionate exclusion of certain types of facilities, particularly freestanding psychiatric hospitals that were for-profit or government-operated, as well as all-inclusive rate providers. We noted that approximately 55 percent of stays from freestanding facilities would be removed, compared to just 0.3 percent of stays in psychiatric units. In the analysis described in the FY 2023 IPF PPS proposed rule (87 FR 19429), we attempted to address this disproportionate removal of stays by facility type by applying weights by facility type and ownership in the regression model to account for excluded providers and to avoid biasing the sample towards stays from providers in psychiatric units.

We explained that in response to the analysis described in the FY 2023 IPF PPS proposed rule (87 FR 19429), commenters raised concerns about the large number of stays excluded from the regression analysis, and questioned whether the ancillary charge data were truly missing, as all-inclusive rate providers are not required to report separate ancillary charges. We stated that we agree that this trimming step reduces the representativeness of the IPF population used in the regression model and may increase the potential

for bias of the regression coefficients used for payment adjustments. Furthermore, as discussed in section IV.E.4. of this final rule, we are clarifying cost reporting requirements and implementing operational changes that we believe will increase the accuracy of the cost information reported in the future. Specifically, we explain that CMS will issue instructions to the MACs and put in place edits for cost reporting periods beginning on or after October 1, 2024, ensuring that only government-owned or tribally owned IPF hospitals will be permitted to file an all-inclusive cost report. We further explain that all other IPF hospitals will be required to have a charge structure and to report ancillary costs and charges on their cost reports. We expect this change will support increased accuracy of future payment refinements to the IPF PPS.

In this year's proposed rule, we explained that when we examined the claims from CY 2019 to CY 2021, we observed that this trimming step would have resulted in a loss of a significant number of providers (324 providers in CY 2019, 330 providers in CY 2020, and 336 providers in CY 2021). Due to the concerns that commenters previously raised (which we summarized in the FY 2024 IPF PPS final rule (88 FR 51097 through 51098)), and to include as many claims as possible in the regression analysis, we explained that we did not trim stays from facilities with zero or minimal ancillary charges. As a result, we noted that we observed a significant reduction in data loss when comparing our latest regression model with the model described in the FY 2023 IPF PPS proposed rule. We further stated that by including, rather than trimming, facilities with low or no ancillary charge data, we prevented the loss of 288 providers across the three years, allowing for a more inclusive analysis. We noted that these providers accounted for approximately 194,673 stays included in our data set.

We clarified that the regression results presented in the proposed rule did not include the application of any trimming or subsequent weighting to account for the removal of stays from facilities with zero or minimal ancillary charges.

c. Calculation of the Dependent Variable

In the proposed rule, we explained that the IPF PPS regression model uses the natural logarithm of per diem total cost as the dependent variable. We stated that we computed a per diem cost for each Medicare inpatient psychiatric stay, including routine operating, ancillary, and capital components, using information from the combined CY 2019 through 2021 MedPAR file and data from the 2018 through 2021 Medicare cost reports. We explained that for each MedPAR CY, we examined the corresponding Medicare cost report, and if a provider's cost-to-charge ratio was missing from the matching year's cost report, we looked at the provider's cost report from the prior year to obtain the most recent cost-to-charge value for the provider. We noted that we applied a prior-year cost-to-charge ratio to 8 providers from the CY 2019 MedPAR claims, 5 providers from the CY 2020 MedPAR claims, and 35 providers from the CY 2021 MedPAR claims.

We further explained that to calculate the total cost per day for each inpatient psychiatric stay, routine costs were estimated by multiplying the routine cost per day from the IPF's Medicare cost report (Worksheet D–1, Part II, column 1, line 38) by the number of Medicare covered days in the MedPAR stay record. We explained that ancillary costs were estimated by multiplying each departmental cost-to-charge ratio (calculated by dividing the amount obtained from Worksheet C, columns 5, by the sum of Worksheet C, columns 6 and 7) by the corresponding ancillary charges in the MedPAR stay record. We stated that the total cost per day was calculated by summing routine and ancillary costs for the stay and dividing it by the number of Medicare covered days for each day of the stay.

As discussed in the proposed rule, we winsorized the distributions of the 17 ancillary cost centers from Worksheet C of the cost report at the 2nd and 98th percentiles to address extreme cost-to-charge ratios. That is, if the cost-to-charge ratio was missing and there was a charge on the claim, the cost-to-charge ratio was imputed to the calculated median value for each respective cost center.

In addition, we explained that the total cost per day (also referred to as per diem cost) was adjusted for differences in cost across geographic areas using the FY 2019 through 2021 IPF wage indices and COLAs corresponding to each MedPAR data year. We stated that we adjusted the labor-related portion of the per diem cost using the IPF wage index to account for geographic differences in labor cost and adjusted the non-labor portion of the per diem cost by the COLA adjustment factors for IPFs in Alaska and Hawaii. We stated that we used IPF PPS labor-related share and non-labor-related share finalized for each year, FY 2019 through FY 2021, to determine the amount of the per diem cost that is adjusted by the wage index and the COLA, respectively. We explained that we calculated the adjusted cost using the following formula:

Wage adjusted per diem cost = per diem cost/(wage index * labor-related share + COLA * (1-labor-related share)).

d. Independent Variables

In the proposed rule, we stated that the independent variables in the regression model are patient-level and facility-level characteristics that affect the dependent variable in the model, which is per diem cost. As discussed in the following sections, we noted that the updated regression model for the proposed rule included adjustment-related variables and control variables. We explained that adjustment-related variables are used for adjusting payment, and we proposed to revise the IPF PPS patient-level adjustment factors based on the regression results for many of the adjustment-related variables in the model. We further explained that control variables are used to account for variation in the dependent variable that is associated with factors outside the adjustment factors of the payment model.

(1) Adjustment-Related Variables

Patient-level adjustment-related variables included in the regression model are variables for DRG assignment, comorbidity categories, age, and length of stay. We note that facility-level adjustment-related variables for rural status and teaching status are also included in the model; however, we did not propose revisions to the rural or teaching adjustments for FY 2025. We discuss the latest results of the regression analysis for facility-level adjustments in greater detail in section IV.A. of this final rule.

(2) Control Variables

The regression model used to determine IPF PPS payment adjustments in the RY 2005 IPF PPS final rule (69 FR 66922) included control variables to account for facilities' occupancy rate, a control variable to indicate if the patient received ECT, and a control variable for IPFs that do not bill for ancillary charges. In the proposed rule, we explained that the updated regression model for the FY 2025 IPF PPS proposed rule removed the occupancy control variables and the control variable for IPFs that do not bill for ancillary charges. In addition, we explained that we retained the control variable for patients receiving ECT and added control variables for the data year. We also explained that we added a control variable for the presence of ED

charges on the claim. We discuss considerations related to these control variables and others in the following paragraphs.

The 2004 regression model included two control variables for occupancy rate. One was a continuous variable for the facility's logarithmic-transformed occupancy rate. The other was a categorical variable indicating a facility had an occupancy rate below 30 percent. Both of these variables were found to be associated with statistically significant increases in cost. In the RY 2005 IPF PPS final rule, we adopted the structural approach and included these control variables in the regression. We explained that it was appropriate to control for variations in the occupancy rate in estimating the effects of the payment variables on per diem cost to avoid compensating facilities for inefficiency associated with underutilized fixed costs (69 FR 66934). As we discussed in the FY 2023 IPF PPS proposed rule, our analysis found that the occupancy control variables were associated with rural status. We solicited comments on the potential removal of the occupancy control variables from the model (87 FR 19429). In response, we received several comments in support of removing the occupancy control variables, due to the relationship between these control variables and the rural adjustment (87 FR 46865). Commenters cited the importance of rural IPFs as the primary points of care and access for many Medicare beneficiaries who cannot travel to urban areas for mental health services. As we discussed in the FY 2025 IPF PPS proposed rule, we considered the potential negative impact to rural facilities of retaining the occupancy control variables in the regression model. We stated that we agree with the commenters who noted the importance of maintaining stability in payments for rural IPFs; therefore, we did not include any occupancy control variables in our regression model.

In addition, we stated that we considered including a control variable for IPFs that do not bill for ancillary services. As we discussed in the RY 2005 IPF PPS final rule (69 FR 66936), we included variables in the regression to control for psychiatric hospitals that do not bill ancillary costs. However, at that time, the number of IPFs who did not bill for ancillary costs was relatively small and consisted mostly of government-operated facilities. As we discuss later in section IV.E.4 of this final rule, an increasing number of IPFs have stopped reporting ancillary charges on their claims, which means that ancillary cost information is not available for stays at these IPFs.

We explained in the proposed rule that we considered whether to include a control variable for facilities that do not report ancillary charges. We stated that we considered that the inclusion of a control variable would only account for differences in the level of cost between IPFs with and without reported ancillary costs and would not facilitate comparison of costs between all IPFs in our sample. In addition, we noted that facilities that did not report ancillary charges also tended to have lower routine costs; that is, our analysis showed that these facilities will have overall lower costs per day, regardless of whether ancillary costs were considered in the cost variable. We explained that the inclusion of a control variable in the regression model would account for these differences in overall cost, which would impact the size of payment-related adjustment factors that are correlated with the prevalence of missing ancillary charge data. We stated that for this reason, in developing a regression model for proposing revisions to the IPF PPS, we did not include a control variable to account for facilities that report zero or minimal ancillary charges.

As noted earlier, the original model also included a control variable for the presence of ECT. This is because ECT is paid on a per-treatment basis under the IPF PPS. As discussed in more detail in section IV.B.2. of this FY 2025 IPF PPS final rule, we continue to observe that IPF stays with ECT have significantly higher costs per day. We proposed to continue paying for ECT on a per-treatment basis; therefore, we explained that we included a control variable to account for the additional costs associated with ECT, which will continue to be paid for outside the regression model.

Similarly, we stated that we included a control variable for stays with emergency department (ED)-related charges. The original model did not include an ED control variable, because ED costs were excluded from the dependent variable of IPF per diem costs. We explained that our regression model for the FY 2025 IPF PPS proposed rule includes all costs associated with each IPF stay, including ED costs. As we explained in the proposed rule, we proposed to calculate the ED adjustment in accordance with our longstanding methodology, separate from the regression model. However, we included a control variable for stays with ED charges to control for the additional costs associated with ED admissions, which are paid under the ED adjustment outside the regression model.

Lastly, we stated that we included control variables for the data year. We stated that because the model used a combined set of data from 3 years, these control variables are included in the model to account for differences in cost levels between 2019, 2020, and 2021, which would be driven by economic inflation and other external factors unrelated to the independent variables in the regression model.

e. Regression Results

In the proposed rule, we presented the results of our regression model, which we noted includes a total of 806,611 stays, and had an r-squared value of 0.32340, meaning that the independent variables included in the regression model were able to explain approximately 32.3 percent of the variation in per diem cost among IPF stays.

In the proposed rule, we explained that except for the teaching variable, each of the adjustment factors we presented was the exponentiated regression coefficient of our regression model, which as we previously noted uses the natural logarithm of per diem total cost as the dependent variable. We stated that we presented the exponentiated regression results, as these most directly translate to the way that IPF PPS adjustment factors are calculated for payment purposes. That is, the exponentiated adjustment factors presented in the proposed rule represent a percentage increase or decrease in per diem cost for IPF stays with each characteristic. In the case of the teaching variable, we noted that the result presented in the proposed rule is the un-exponentiated regression coefficient. As discussed in section IV.D of this final rule, the current IPF PPS teaching adjustment is calculated as 1 + a facility's ratio of interns and residents to beds, raised to the power of 0.5150. We explained that the coefficient for teaching status presented in the proposed rule can be interpreted in the same way.

We explained that for certain categorical variables, including DRG, age, length of stay, and the year control variables, results for the reference groups were not shown. We stated that the DRG reference group is DRG 885, because this DRG represents the majority of IPF PPS stays. In addition, we explained that the age reference group is the Under 45 category, because this group is associated with the lowest costs after accounting for all other patient characteristics in the model. We further explained that the reference

group for length of stay is 10 days, which corresponds to the reference group used in the original regression model from the RY 2005 IPF PPS final rule. Lastly, we stated that the year control reference group is CY 2021. We stated that each of these reference groups effectively has an adjustment factor of 1.00 in the regression model.

Lastly, we stated that we considered the regression factors to be statistically significant when the p-value was less than or equal to the significance level of 0.05 (*), 0.01 (**), and 0.001 (***), as notated in the table presented in the proposed rule.

We received several comments regarding the regression methodology discussed in the proposed rule.

Comment: Two commenters expressed support for the regression methodology used to develop revised adjustment factors for the IPF PPS. In particular, MedPAC expressed support for the proposal to include stays at facilities with low or no ancillary charge information, as well as including multiple years of data, in the calculation of the updated patient-level adjustments for FY 2025. MedPAC further encouraged CMS to continue to monitor and update the weights as needed using the most recent data available.

Response: We appreciate the support from these commenters, and we intend to continue to monitor IPF PPS payments and costs to consider potential future updates as appropriate.

Comment: One commenter expressed concerns about CMS's piecemeal approach to implementing the updated coefficients. This commenter stated that CMS should update not only the patient-level adjustment factors as proposed but also the updated facility-level coefficients (*i.e.,* the teaching and rural adjustments) that were derived from the same regression model. This commenter further stated that if CMS did not plan to use these updated facility-level adjustments, it should have run a constrained regression, which would have resulted in different patient-level adjustment factors. From a technical perspective, this commenter stated that it is inappropriate to use patient-level and facility-level adjustments that were derived from separate regression analyses.

Response: We appreciate these methodological concerns from the commenter; however, we do not agree that the proposed approach is technically inappropriate. Although the commenter asserted that CMS would not be using the regression-derived facility-level adjustments, this is not an accurate assertion. As we discussed in the proposed rule, we proposed a number of revisions to the patient-level adjustment factors as well as changes to the CBSA delineations. We proposed to maintain the existing facility-level adjustment factors for FY 2025 because we believe it is important to minimize the scope of changes that would impact payments to facilities in any single year. However, as we discussed in the proposed rule, CMS is considering using the regression-derived facility-level adjustment factors for payment in future years, and we solicited comments on potentially making such revisions in future rulemaking.

Regarding the suggestion to apply a constrained regression analysis, we do not believe this methodology would be appropriate. We note that a constrained regression analysis of the type the commenter suggested would apply mathematical constraints such that the coefficients for rural status and teaching status would remain at their current levels. A constrained regression analysis would therefore calculate the patient-level and control variables that minimize the sum of squared errors, given the constraints on the rural and teaching coefficients. We agree with the commenter's assertion that a constrained regression analysis would yield different patient-level adjustment factors for FY 2025. As a result, if CMS were to propose revisions to the facility-level adjustment factors in a future year, a constrained regression methodology of the type that the commenter recommended could result in further changes to the patient-level adjustment factors, which would be contrary to the goal of minimizing the impact of revisions in a single year, which CMS articulated in the proposed rule. Rather, in the case of the application of the regression-derived adjustment factors to the IPF PPS, we have controlled for aggregate changes in spending by applying a refinement standardization factor to the IPF PPS Federal per diem base rate. We believe that our proposed regression analysis appropriately incorporates the relevant payment variables and control variables into the regression model and produces results that can be implemented in accordance with our stated goals. We will take the commenter's methodological suggestions into consideration to potentially inform future changes to the IPF PPS, if appropriate.

Final Decision: After consideration of the comments, we are finalizing our proposed regression methodology as discussed in the proposed rule.

We note that the regression results for this final rule have been updated based on more recent available data, as proposed. Specifically, we note that in reviewing the methodology used to calculate the IPF PPS regression model presented in the proposed rule, we discovered that the computer code incorrectly failed to assign several sleep apnea codes to the proposed Chronic Obstructive Pulmonary Disease and Sleep Apnea comorbidity category. As a result, our regression model underestimated the magnitude of the adjustment factor for this comorbidity category and slightly overestimated the magnitude of the adjustment factor for other independent variables in the model. We note that most of the changes in the adjustment factors in Table 2 are within the threshold of rounding, and therefore do not result in differences to the proposed adjustment factors for payment. We further discuss the impact of these changes to the adjustment factors in section IV.C.4 of this final rule.

This revised final model has an r-squared value of 0.32490, meaning that the independent variables included in the regression model were able to explain approximately 32.5 percent of the variation in per diem cost among IPF stays. We discuss the results of these changes to the final adjustment factors in section IV.C.4 of this final rule, and we discuss the final refinement standardization factor in section IV.F of this final rule.

Table 2 below shows the final calculated adjustment factors and significance level, as well as the number and percent of stays associated with each independent variable. Columns 6 and 7 of Table 2 show the lower and upper bounds of the 95-percent confidence interval (CI). For this final rule, we continue to consider the regression factors to be statistically significant when the p-value was less than or equal to the significance level of 0.05 (*), 0.01 (**), and 0.001 (***).

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Table 2: Final IPF PPS Per Diem Cost Regression Results with Data from CY 2019 through CY 2021

Description	Number of Stays	% of Stays	Adjustment Factors	Significance[1]	CI Lower Bound	CI Upper Bound
Degenerative nervous system disorders w MCC	4,287	0.5%	1.12489	***	1.08938	1.16156
Degenerative nervous system disorders w/out MCC	40,584	5.0%	1.11097	***	1.07794	1.14501
OR procedures with principal diagnosis of mental health	751	0.1%	1.28644	***	1.24458	1.32971
Acute adjustment reaction and psychosocial dysfunction	7,529	0.9%	1.07575	**	1.02333	1.13085
Depressive neuroses	23,566	2.9%	1.06118	***	1.03557	1.08742
Neuroses except depressive	10,143	1.3%	1.02063		0.96702	1.07722
Disorders of personality and impulse control	5,804	0.7%	1.16887	***	1.12856	1.21062
Organic disturbances and intellectual disability	55,842	6.9%	1.08295	***	1.05565	1.11096
Behavioral and developmental disorders	1,582	0.2%	1.07018	***	1.03507	1.10648
Other mental disorder diagnoses	321	0.0%	1.11902		0.92491	1.35388
Alcohol, Drug Abuse or Dependence, Left AMA	3,060	0.4%	0.86120	***	0.81681	0.90800
Alcohol, Drug Abuse or Dependence w rehab therapy	12,361	1.5%	0.89530	***	0.84211	0.95184
Alcohol, Drug Abuse or Dependence w/out rehab therapy w MCC	891	0.1%	1.01859		0.97787	1.06100
Alcohol, Drug Abuse or Dependence w/out rehab therapy w/out MCC	34,767	4.3%	0.94599	**	0.91487	0.97816
Poisoning and toxic effects of drugs w MCC	137	0.0%	1.19038	***	1.12466	1.25995

Description	Number of Stays	% of Stays	Adjustment Factors	Significance[1]	CI Lower Bound	CI Upper Bound
Poisoning and toxic effects of drugs w/out MCC	843	0.1%	1.11541	***	1.08072	1.15122
Signs and Symptoms w MCC	58	0.0%	1.12458	*	1.02823	1.22994
Signs and Symptoms w/out MCC	805	0.1%	1.09079	**	1.02257	1.16356
Age 45 to 54 years	121,498	15.1%	1.01879	***	1.01259	1.02503
Age 55 to 59 years	74,512	9.2%	1.04592	***	1.03588	1.05606
Age 60 to 64 years	68,136	8.4%	1.06370	***	1.05046	1.07711
Age 65 to 69 years	94,473	11.7%	1.08579	***	1.06899	1.10285
Age 70 to 79 years	126,280	15.7%	1.11488	***	1.09114	1.13913
Age over 79 years	87,442	10.8%	1.12706	***	1.09820	1.15668
Acute Renal Failure	19,064	2.4%	1.06069	***	1.03715	1.08476
Artificial Openings - Digestive & Urinary	3,713	0.5%	1.07499	***	1.05586	1.09448
Cardiac conditions	22,152	2.7%	1.04322	***	1.02774	1.05894
Conduct Disorder	5,113	0.6%	0.98279		0.93602	1.03189
Chronic Renal Failure	46,274	5.7%	1.07621	***	1.06277	1.08981
Coagulation Factor Deficit	492	0.1%	1.01240		0.97685	1.04925
Chronic Obstructive Pulmonary Disease	38,159	4.7%	1.08974	***	1.07602	1.10364
Developmental Disabilities	27,020	3.3%	1.01986		0.99450	1.04585
Uncontrolled Diabetes	21,939	2.7%	1.05120	***	1.03307	1.06964
Drug/Alcohol Induced Mental Disorders	59,437	7.4%	0.96118	**	0.93726	0.98571
Eating Disorder	2,812	0.3%	1.09375	***	1.05313	1.13594
Gangrene	223	0.0%	1.11914	***	1.05793	1.18389
Infectious diseases	38,562	4.8%	1.01603	.	0.99984	1.03247
Severe Protein Malnutrition	5,119	0.6%	1.16879	***	1.12359	1.21579
Oncology Treatment	12	0.0%	1.44281	***	1.20615	1.72590
Poisoning	5,966	0.7%	1.16022	***	1.13841	1.18245
Severe Musculoskeletal & Connective Tissue Disease	4,272	0.5%	1.04719	***	1.03039	1.06426
Tracheostomy	304	0.0%	1.09071	***	1.04508	1.13834
Intensive Management for High-Risk Behavior	19,884	2.5%	1.06991	***	1.03016	1.11119

Description	Number of Stays	% of Stays	Adjustment Factors	Significance[1]	CI Lower Bound	CI Upper Bound
ECT Indicator	12,654	1.6%	1.32498	***	1.27045	1.38186
ER Indicator	261,643	32.4%	1.38856	***	1.34548	1.43302
Rural	101,483	12.6%	1.19121	***	1.12331	1.26322
Teaching Status	155,458	19.3%	0.72479	***	0.57528	0.87430
Length of stay - 1 day	16,891	2.1%	1.27513	***	1.24347	1.30760
Length of stay - 2 days	28,370	3.5%	1.20144	***	1.17685	1.22655
Length of stay - 3 days	42,298	5.2%	1.14822	***	1.12761	1.16922
Length of stay - 4 days	48,187	6.0%	1.11626	***	1.09942	1.13336
Length of stay - 5 days	54,187	6.7%	1.08310	***	1.06794	1.09848
Length of stay - 6 days	59,215	7.3%	1.06029	***	1.04785	1.07288
Length of stay - 7 days	63,095	7.8%	1.02618	***	1.01510	1.03738
Length of stay - 8 days	51,491	6.4%	1.01666	***	1.00752	1.02589
Length of stay - 9 days	42,855	5.3%	1.00898	**	1.00215	1.01585
Length of stay - 11 days	35,092	4.4%	0.99518		0.98910	1.00130
Length of stay - 12 days	32,030	4.0%	0.99597		0.98951	1.00247
Length of stay - 13 days	32,356	4.0%	0.99852		0.98922	1.00792
Length of stay - 14 days	34,727	4.3%	0.99927		0.98427	1.01450
Length of stay - 15 days	24,919	3.1%	0.98916		0.97534	1.00318
Length of stay - 16 days	18,907	2.3%	0.98809		0.97394	1.00245
Length of stay - 17 days	16,128	2.0%	0.98984		0.97630	1.00356
Length of stay - 18 days	14,191	1.8%	0.98595	.	0.97172	1.00038
Length of stay - 19 days	13,085	1.6%	0.98825		0.97235	1.00441
Length of stay - 20 days	13,302	1.6%	0.98485	.	0.96832	1.00166
Length of stay - 21 days	12,628	1.6%	0.98519		0.96410	1.00673
Length of stay - greater or equal to 22 days	113,912	14.1%	0.98809		0.96064	1.01633
CY2019 Stay	330,574	41.0%	0.89868	***	0.88769	0.90982
CY2020 Stay	259,052	32.1%	0.94940	***	0.94054	0.95835

[1] Statistical significance based on p-value less than or equal to the significance level of 0.05 (*), 0.01 (**), and 0.001 (***)

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4. Updates and Revisions to the 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. We proposed to derive updated IPF PPS adjustment factors for FY 2025 using a regression analysis of data from the CY 2019 through 2021 MedPAR data files and Medicare cost report data from the 2018 through FY 2021 Hospital Cost Report Information System (HCRIS). In the proposed rule, however, we noted that we used more recent claims (specifically, the December 2023 update of the FY 2023 IPF PPS MedPAR claims) and cost data from the January 2024 update of the provider-specific file (PSF) to simulate payments to finalize the outlier fixed dollar loss threshold amount and to assess the impact of the IPF PPS updates. More information about the data used for the impact simulations is found in section VIII.C of this FY 2025 IPF PPS final rule. We explained that by adjusting for DRGs, comorbidities, age, and length of the stay, along with the facility-level variables and control variables in the model, we were able to explain approximately 32.3 percent of the variation in per diem cost among IPF stays.

In addition, we proposed routine coding updates for FY 2025 for our longstanding code first and IPF PPS comorbidities. Furthermore, as discussed in section IV.C.4.a.(2) of this final rule, we proposed to adopt a sub-regulatory process for future routine coding updates.

a. Updates and Revisions to MS–DRG Assignment

(1) Background

We believe it is important to maintain for IPFs the same diagnostic coding and 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 RY 2004 IPF proposed rule (68 FR 66923; 66928 through 66933) and the RY 2005 IPF final rule (69 FR 66933 through 66960). Mapping the DRGs to the MS–DRGs resulted in the current 17 IPF MS–DRGs, instead of the original 15 DRGs, for which the IPF PPS provides an adjustment.

In the FY 2015 IPF PPS final rule which appeared in the August 6, 2014 **Federal Register** titled, ''Inpatient Psychiatric Facilities Prospective Payment System—Update for FY Beginning October 1, 2014 (FY 2015)'' (79 FR 45945 through 45947), we finalized conversions of the ICD–9–CM-based MS–DRGs to ICD–10–CM/PCS-based MS–DRGs, which were implemented on October 1, 2015. Further information on the ICD–10–CM/PCS MS–DRG conversion project can be found on the CMS ICD–10–CM website at *https://www.cms.gov/medicare/coding-billing/icd-10-codes/icd-10-ms-drg-conversion-project.*

(2) Adoption of Sub-Regulatory Process for Publication of Coding Changes

As discussed in the FY 2015 IPF PPS proposed rule (79 FR 26047) every year, changes to the ICD–10–CM and the ICD–10–PCS coding system have been 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), we have historically described in the IPF PPS proposed and final rules the ICD–10–CM coding changes and DRG classification changes that have been discussed in the annual proposed and final hospital IPPS regulations. This has typically involved a discussion in the proposed rule about coding updates to be effective October 1 of each year, with a summary of comments in the final rule along with a description of additional finalized codes for October.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 44950 through 44956), we adopted an April 1 implementation date for ICD–10–CM diagnosis and ICD–10–PCS procedure code updates in addition to the annual October 1 update of ICD–10–CM diagnosis and ICD–10–PCS procedure codes, beginning with April 1, 2022. In that rule, we noted the intent of this April 1 implementation date is to allow flexibility in the ICD–10 code update process. Currently, as noted earlier in this final rule, the IPF PPS uses the IPPS DRG assignments, which are applied to IPF PPS claims; these DRG assignments reflect the change in process that the IPPS adopted for FY 2022. To maintain consistency with IPPS policy, we proposed to follow the same process beginning in FY 2025. This means that for routine coding updates that incorporate new or revised codes, we proposed to adopt these changes through a sub-regulatory process. Beginning in FY 2025, we will operationalize such coding changes in a Transmittal/Change Request, which would align with the way coding changes are announced under the IPPS.

For example, we proposed that for April 2025, we would adopt routine coding updates for the IPF PPS comorbidity categories, code first policy, ECT code list, and DRG assignment via sub-regulatory guidance. We stated that these coding updates would take effect April 1, 2025. We explained that in accordance with § 412.428(e), we would describe these coding changes, along with any coding updates that would be effective for October 1, 2025, in the FY 2026 IPF PPS proposed rule. We noted we would summarize and respond to any comments on these April and October coding changes in the FY 2026 IPF PPS final rule.

We further stated that this proposed update aims to allow flexibility in the ICD–10 code update process for the IPF PPS and reduce the lead time for making routine coding updates to the IPF PPS code first list, comorbidities, and ECT coding categories. In addition, we noted that the IPPS sub-regulatory process continues to manage DRG assignment changes which apply to the DRG assignments used in the IPF PPS. Finally, we clarified that we only anticipate applying this sub-regulatory process for routine coding updates. Any future substantive revisions to the IPF PPS DRG adjustments, comorbidities, code first policy, or ECT payment policy would be proposed through notice and comment rulemaking. We solicited public comments on this proposed rule.

We did not receive any comments on our proposal to adopt routine coding updates that incorporate new or revised codes through a sub-regulatory process. We are finalizing the use of a sub-regulatory process, as proposed.

(3) Routine Coding Updates for DRG Assignments

The diagnoses for each IPF MS–DRG will be updated as of October 1, 2024, using the final IPPS FY 2025 ICD–10–CM/PCS code sets. The FY 2025 IPPS/LTCH PPS final rule will include tables of the changes to the ICD–10–CM/PCS code sets that underlie the proposed FY 2025 IPF MS–DRGs. Both the FY 2025 IPPS final rule and the tables of final changes to the ICD–10–CM/PCS code sets, which underlie the FY 2025 MS–DRGs, will be available on the CMS IPPS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps.*

(4) 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 readers to the RY 2005 IPF PPS final rule (69 FR 66945). We also refer readers to sections I.A.13 and I.B.7 of the FY 2020 ICD–10–CM Coding Guidelines, which is available at *https://www.cdc.gov/nchs/data/icd/10cmguidelinesFY2020_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.

We proposed to continue our existing code first policy. We did not receive any comments on our proposal to continue the existing code-first policy, and we are finalizing the policy as proposed. As discussed in section IV.C.4.a.(2) of this final rule, we are also finalizing our proposal to adopt a sub-regulatory approach to handle the coding updates, which will remove the requirement to discuss coding updates in the **Federal Register** during regulatory updates prior to implementation and which will mirror the approach taken by the IPPS. The final FY 2025 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.*

(5) Revisions to MS–DRG Adjustment Factors

For FY 2025, we proposed to revise the payment adjustments for designated psychiatric DRGs assigned to the claim based on the patient's principal diagnosis, following our longstanding policy of using the ICD–10–CM/PCS–based MS–DRG system. As discussed in the following paragraphs, we proposed to maintain DRG adjustments for 15 of the existing 17 IPF MS–DRGs for which we currently adjust payment in FY 2024. We proposed to replace two existing DRGs with two new DRGs to reflect changes in coding practices over time and proposing to add two DRGs that are associated with poisoning. We also proposed to revise the adjustment factors for the DRG adjustments based on the results of the regression analysis described in the proposed rule. In accordance with our longstanding policy, we proposed that psychiatric principal diagnoses that do not group to one of the 19 proposed designated MS–DRGs would still receive the Federal per diem base rate and all other applicable adjustments; however, the payment would not include an MS–DRG adjustment.

We proposed to implement all of these revisions to the DRG adjustments budget-neutrally, and we provided a detailed discussion of the distributional impacts of these proposed changes. Lastly, we proposed that if more recent data become available, we would use such data, if appropriate, to determine the FY 2025 DRG adjustment factors.

(a) Replacement of DRGs

We proposed to remove DRGs 080 (Nontraumatic stupor & coma w MCC) and 081 (Nontraumatic stupor & coma w/o MCC), and to replace these with DRGs 947 (Signs and Symptoms w MCC) and 948 (Signs and Symptoms w/out MCC). As previously discussed, we observed that the number of cases in DRGs 080 and 081 have decreased significantly since 2004. We explained that we selected DRGs 947 and 948 as the most clinically appropriate replacements, because most of the ICD–10–CM codes that previously grouped to DRGs 080 or 081 now group to DRGs 947 or 948. We explained that the proposed adjustment factors for DRGs 947 and 948 would each be greater than the current DRG adjustment for DRGs 080 and 081. Therefore, we proposed that claims with DRGs 080 or 081 would still receive the Federal per diem base rate and all other applicable adjustments; however, the payment would not include an MS–DRG adjustment.

(b) Additions of DRGs

We proposed to recognize DRG adjustments for two DRGs associated with poisoning; specifically, DRGs 917 (Poisoning and toxic effects of drugs w MCC) and 918 (Poisoning and toxic effects of drugs w/out MCC). As we discussed in the proposed rule, we identified that a small but increasing number of IPF stays contain these poisoning-related DRG assignments, and that stays with these DRGs have increased costs per day that are statistically significant.

(c) Revisions to Adjustment Factors for Existing DRG Adjustments

We proposed to revise the adjustment factors for the remaining 15 of the existing 17 DRGs that currently receive a DRG adjustment in FY 2024. We stated that these revisions were based on the results of our latest regression analysis described in section IV.C.3 of the proposed rule.

We also stated that our analysis found that some of the adjustment factors in the regression model for DRGs that currently receive an adjustment are no longer statistically significant. Specifically, we found that the adjustment factors for DRG 882 (Neuroses except depressive), DRG 887 (Other mental disorder diagnoses), and

DRG 896 (Alcohol, Drug Abuse or Dependence w/out rehab therapy w MCC) were not statistically significant. We explained that for each of these DRGs, we examined whether the current adjustment factor falls within the confidence interval for our latest regression analysis. We stated that the current adjustment for DRG 882 is 1.02, and this falls within the confidence interval of 0.96798 to 1.07811 for the regression model discussed in the proposed rule. We stated that we believe it would be appropriate to maintain the current adjustment factor of 1.02 for DRG 882 because the latest regression results indicate that the current adjustment factor would be a reasonable approximation of the increased costs associated with DRG 882. However, we stated that for DRGs 887 and 896, the current adjustment factors (0.92 and 0.88, respectively) did not fall within the confidence interval for each of these DRGs. Therefore, we proposed to apply an adjustment factor of 1.00 for IPF stays with these DRGs.

(d) Summary of Comments on the Proposed MS–DRG Updates for FY 2025

We received comments regarding the proposed changes to the MS–DRG adjustments, which are summarized in the following paragraphs.

Comment: Several commenters expressed support for revising the DRG adjustments as proposed; however, a number of these commenters urged CMS to consider developing separate adjustment factors for IPF stays that are currently all grouped into DRG 885. Specifically, commenters expressed concern that a single DRG that accounts for 74.79% of stays does not appropriately capture differences in patient resource utilization between patients being treated for Bipolar Disorders and Schizophrenias (ICD 20–F31 diagnoses) and those patients being treated for Depressive Disorders and Unspecified Mood disorders (ICD F32–F39 diagnoses.

Response: We appreciate the support that commenters expressed for the proposed DRG revisions. Likewise, we appreciate concerns that commenters raised regarding subcategories of conditions within DRG 885. We agree with commenters about the importance of adjusting IPF PPS payment to recognize differences in resource utilization between patients with different conditions. However, contrary to the commenters' suggestion, our analysis does not find that there are statistically significant differences in resources costs or cost per day when we compare different groups of principal diagnoses within DRG 885.

Using the same regression model described in section IV.C.3 of this final rule, we added the following categorical variables:

- Bipolar Disorders and Schizophrenia—Stays with principal diagnosis in the ICD–10–CM code family of F20, F21, F22, F23, F24, F25, F26, F27, F28, F29, F30, or F31
- Depression and Mood Disorders—Stays with principal diagnosis in the ICD–10–CM code family of F32, F33, or F39; or with principal diagnosis of F349 or F3489.
- Other—All other DRG 885 stays.

For this analysis, we applied Bipolar Disorders and Schizophrenia as the reference group; therefore, there is no adjustment factor assigned in Table 3. The adjustment factors for other categories can be interpreted as the cost per day relative to the reference category. Table 3 also presents the significance level and confidence interval for each factor. We note than none of these factors is considered significant because the p-value was not less than or equal to the significance level of 0.05 (*), 0.01 (**), and 0.001 (***) for any of these factors.

Table 3: Analysis of Adjustment Factors for IPF Stays within DRG 885 Subcategories

Description	# of Stays CY 2019–CY 2021	% of Stays CY 2019–CY 2021	Adjustment Factors	Significance	CI Lower Bound	CI Upper Bound
Bipolar Disorders and Schizophrenia	438,269	54.33%	N/A	N/A	N/A	N/A
Depression and Mood Disorders	164,660	20.41%	0.99222		0.97308	1.01173
Other	351	0.04%	1.04685		0.96538	1.13520

Lastly, we acknowledge that even though there may be differences in total cost or differences in cost per day for treating patients with these conditions, other adjustment factors in the IPF PPS, such as the age adjustment or the variable per diem adjustment may account for these differences in cost for such patients.

Final Decision: After consideration of the comments received, we are finalizing our proposal to revise the DRG adjustments based on the latest regression analysis. A detailed discussion of the distributional impacts of this proposed change is found in section VIII.C of this final rule. Tables 4 through 6 summarize the final DRG changes based on the final regression analysis discussed in section IV.C.3.e of this FY 2025 IPF PPS final rule.

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Table 4: Replacements for DRG Adjustments

Description	Current Adjustment Factors	# of Stays CY 2019–CY 2021	% of Stays CY 2019–CY 2021	Final Adjustment Factors
DRG 080- Nontraumatic stupor & coma w MCC	1.07	1	0.00%	N/A
DRG 081-Nontraumatic stupor & coma w/o MCC	1.07	1	0.00%	N/A
DRG 947-Signs and Symptoms w MCC	N/A	58	0.01%	1.12
DRG 948-Signs and Symptoms w/out MCC	N/A	805	0.10%	1.09

Table 5: Additions for DRG Adjustments

Description	Current Adjustment Factors	# of Stays CY 2019–CY 2021	% of Stays CY 2019–CY 2021	Final Adjustment Factors
DRG 917-Poisoning and toxic effects of drugs w MCC	N/A	137	0.02%	1.19
DRG 918-Poisoning and toxic effects of drugs w/out MCC	N/A	843	0.10%	1.12

Table 6: Updates to Existing DRG Adjustments

Description	Current Adjustment Factors	# of Stays CY 2019–CY 2021	% of Stays CY 2019–CY 2021	Final Adjustment Factors
DRG 056-Degenerative nervous system disorders w MCC	1.05	4,287	0.53%	1.12
DRG 057-Degenerative nervous system disorders w/out MCC	1.05	40,584	5.03%	1.11
DRG 876-OR procedure with principal diagnoses of mental illness	1.22	751	0.09%	1.29
DRG 880-Acute adjustment reaction and psychosocial dysfunction	1.05	7,529	0.93%	1.08
DRG 881-Depressive neuroses	0.99	23,566	2.92%	1.06
DRG 882-Neuroses except depressive	1.02	10,143	1.26%	1.02
DRG 883-Disorders of personality and impulse control	1.02	5,804	0.72%	1.17
DRG 884-Organic disturbances and intellectual disabilities	1.03	55,842	6.92%	1.08
DRG 885-Psychoses	1.00	603,280	74.79%	1.00
DRG 886-Behavioral and developmental disorders	0.99	1,582	0.20%	1.07
DRG 887-Other mental disorder diagnoses	0.92	321	0.04%	1.00
DRG 894-Alcohol, Drug Abuse or Dependence, Left AMA	0.97	3,060	0.38%	0.86
DRG 895-Alcohol, Drug Abuse or Dependence w rehab therapy	1.02	12,361	1.53%	0.90
DRG 896-Alcohol, Drug Abuse or Dependence w/out rehab therapy w MCC	0.88	891	0.11%	1.00
DRG 897-Alcohol, Drug Abuse or Dependence w/out rehab therapy w/out MCC	0.88	34,767	4.31%	0.95

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These changes to the DRG adjustments will be included in Addendum A, which is available on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/inpatient-psychiatric-facility/tools-and-worksheets.* The website includes the final DRG adjustment factors for FY 2025.

b. Payment for Comorbid Conditions

(1) Revisions to Comorbidity Adjustments

The intent of the comorbidity adjustments is to recognize the increased costs associated with active comorbid conditions by providing additional payments for certain existing medical or psychiatric conditions that are expensive to treat.

Comorbidities are specific patient conditions that are secondary to the patient's principal diagnosis and that require active 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.

The current 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 identifies the principal diagnosis code as non-psychiatric and searches the secondary codes for a psychiatric code to assign an MS–DRG code for adjustment. The system continues to search the secondary codes for those that are appropriate for a comorbidity adjustment.

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).

As discussed in section IV.C.4.a.(1) of this final rule, 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 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.

As previously discussed in section IV.C.4.a.(2) of this final rule, we proposed to adopt an April 1 implementation date for ICD–10–CM diagnosis and ICD–10–PCS procedure code updates, in addition to the annual October 1 update, beginning with April 1, 2025 for the IPF PPS. For FY 2025 and future years, coding updates related to the IPF PPS comorbidity categories would be adopted following a sub-regulatory process as discussed earlier in this final rule.

For FY 2025, we proposed to revise the comorbidity adjustment factors based on the results of the 2019 through 2021 regression analysis described in section IV.C.3.e. of this final rule. We proposed additions and changes to the comorbidity categories for which we adjust payment based on our analysis of ICD–10–CM codes currently included in each category as well as public comments received in response to the FY 2022 and FY 2023 IPF PPS proposed rules.

Based on analysis of the ICD–10–CM codes, we considered the statistical significance of the adjustment factor and whether the current (FY 2024) adjustment factor fell within the confidence interval in the 2019 through 2021 regression to determine the FY 2025 IPF PPS proposed comorbidity categories and adjustment factors. As previously discussed for the DRG adjustment factors, when the regression factor is not statistically significant, but the current adjustment factor is within the confidence interval, we proposed to maintain the current adjustment factor. When a regression factor is not statistically significant and the current adjustment factor is not within the confidence interval, we proposed to remove the comorbidity category.

Specifically, we proposed to increase the adjustment factors for the Gangrene, Severe Protein Malnutrition, Oncology Treatment, Poisoning, and Tracheostomy comorbidity categories based on the adjustment factors derived from the regression analysis discussed in section IV.C.3 of this final rule. For these comorbidity categories, the regression results produced a statistically significant increase in the adjustment factors.

We did not receive any comments on our proposal to increase the adjustment factors for the Gangrene, Severe Protein Malnutrition, Oncology Treatment, Poisoning, and Tracheostomy comorbidity categories. We are finalizing the increased the adjustment factors for these comorbidity categories as proposed.

We proposed to remove the comorbidity categories for the Coagulation Factor Deficit, Drug/Alcohol Induced Mental Disorders, and Infectious Diseases adjustment factors because the regression factor for the ICD–10–CM codes associated with Coagulation Factor Deficit and Infectious Diseases were not statistically significant, and the current adjustment factors did not fall within the confidence intervals in the 2019 through 2021 regression.

The current adjustment factor for Drug/Alcohol Induced Mental Disorders is 1.03; however, the adjustment factor derived from our latest regression results was statistically significant at 0.96084, meaning payments would be reduced if we applied the regression-derived adjustment factor as a comorbidity adjustment for this category. To understand the drivers of changing costs for the Drug/Alcohol Induced Mental Disorders comorbidity category, we examined a subset of ICD–10–CM codes within the comorbidity category associated with opioid disorders which make up the majority of stays that qualify for the current Drug/Alcohol Induced Mental Disorders comorbidity adjustment. These opioid disorder codes are listed in Table 7. When we separately analyzed these codes associated with opioid disorder, the results suggested that patients with opioid disorder are significantly less expensive than patients without opioid disorder. Because stays with opioid disorders make up the majority of stays in the Drug/Alcohol Induced Mental Disorders comorbidity category, we observe a statistically significant negative adjustment factor for the comorbidity category overall. The application of a comorbidity adjustment derived from our latest regression analysis would result in reduced payments for all stays in this comorbidity category. We do not believe it is appropriate to apply negative adjustment factors (that is, adjustment factors less than 1.00) for comorbidities because that would result in reduced rather than increased payments. Although we apply adjustment factors less than 1.00 for DRGs, this is because the DRG adjustment reflects the cost of stays relative to stays with the baseline DRG 885. In contrast, comorbidity adjustments reflect the cost relative to a stay with no comorbidities. A negative payment adjustment would not be consistent with the intent of a comorbidity adjustment, which is intended to provide additional payments to providers to account for the costs of treating patients with comorbid conditions. Therefore, we have not historically included any negative adjustment factors for comorbid conditions.

Therefore, we proposed to remove the Drug/Alcohol Induced Mental Disorders comorbidity category beginning in FY 2025. IPF stays that include these codes as a non-principal diagnosis would no longer receive the current Drug/Alcohol Induced Mental Disorders comorbidity category adjustment factor of 1.03; nor would they receive a reduction in payment. However, many IPF stays that include these ICD–10–CM diagnosis codes as a principal diagnosis would continue to receive a DRG adjustment. We refer readers to section IV.C.3.a of this final rule for a detailed discussion of proposed DRG adjustments under the IPF PPS.

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Table 7: ICD–10–CM Codes for Opioid Disorder

ICD–10–CM Code	Description
F1123	Opioid dependence with withdrawal
F1120	Opioid dependence, uncomplicated
F1124	Opioid dependence with opioid-induced mood disorder
F11259	Opioid dependence w opioid-induced psychotic disorder, unsp
F11229	Opioid dependence with intoxication, unspecified
F1193	Opioid use, unspecified with withdrawal
F11251	Opioid depend w opioid-induc psychotic disorder w hallucin
F11250	Opioid depend w opioid-induc psychotic disorder w delusions
F1129	Opioid dependence with unspecified opioid-induced disorder
F11288	Opioid dependence with other opioid-induced disorder
F11220	Opioid dependence with intoxication, uncomplicated
F11282	Opioid dependence with opioid-induced sleep disorder
F11921	Opioid use, unspecified with intoxication delirium
F11221	Opioid dependence with intoxication delirium
F11951	Opioid use, unsp w opioid-induc psych disorder w hallucin
F1114	Opioid abuse with opioid-induced mood disorder
F1194	Opioid use, unspecified with opioid-induced mood disorder
F11151	Opioid abuse w opioid-induced psychotic disorder w hallucin
F1113	Opioid abuse with withdrawal
F1110	Opioid abuse, uncomplicated
F1199	Opioid use, unsp with unspecified opioid-induced disorder
F11929	Opioid use, unspecified with intoxication, unspecified
F11922	Opioid use, unsp w intoxication with perceptual disturbance

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We believe removal of the Drug/Alcohol Induced Mental Disorders comorbidity category under the IPF PPS more appropriately aligns payment with resource use, as reflected in the latest regression results. As previously discussed in section IV.F of this final rule, all of these proposed revisions would be applied budget-neutrally. Therefore, we believe the removal of the Drug/Alcohol Induced Mental Disorders comorbidity adjustment would appropriately increase the IPF PPS Federal per diem base rate and thereby increase payment for IPF stays that are costlier. However, we solicited comments on whether a lack of ancillary charge data may be contributing to the results of our regression analysis as it relates to opioid disorders. We note that our analysis of the ICD–10–CM codes associated with opioid disorder also indicates that there is significant overlap between facility characteristics and stays including opioid disorder diagnoses. In particular, for-profit freestanding IPFs were found to serve the majority of patients with opioid disorders. As discussed in section IV.E.4 of this final rule, our ongoing analysis has found an increase in the number of for-profit freestanding IPFs that are consistently reporting no ancillary charges or very minimal ancillary charges on their cost report. As a result, we noted that these IPFs do not report complete information on patient-level cost for the patients treated in these hospitals.

As stated previously, the regression factor for Drug/Alcohol Induced Mental Disorders was statistically significant, but is less than 1, meaning payments would be reduced if we applied it as a comorbidity adjustment. We stated that we were interested in understanding whether there is data and information that could better inform our understanding of the costs of treating these conditions. In addition, we stated that we were interested in understanding whether commenters believe it may be more appropriate to maintain the existing Drug/Alcohol Induced Mental Disorders comorbidity category adjustment factor of 1.03, given that many providers that treat these patients also report minimal or no ancillary charges on their claims and cost reports. We noted that if we were to maintain the adjustment factor of 1.03 for these IPF stays, we expected it would have a negative impact on the refinement standardization factor, thereby slightly reducing the IPF PPS Federal per diem base rate and ECT per treatment amount.

Comment: Two commenters opposed the proposed removal of the Coagulation Factor Deficit and Infectious Disease comorbidity categories, stating that these comorbidities do result in increased resource use. Commenters explained that when patients test positive for infectious diseases after admission, the facility cannot discharge the patient due to the infectious disease. The commenters noted additional

resources are needed in these cases not only to treat the infected patient, but to prevent the spread of the infection to the rest of the patient population.

Response: We thank commenters for their feedback. However, the results of our regression analysis do not support a payment adjustment for coagulation factor deficit or infectious disease. As shown in Table 2, the adjustment factor derived from the regression is not statistically significant. This suggests that the cost of treating IPF patients with these conditions is not significantly different than treating IPF patients without these conditions. Therefore, removing these comorbidity categories more appropriately aligns payment with resource use.

Comment: A few commenters opposed the proposed removal of the Drug/Alcohol Induced Mental Disorders comorbidity category. The commenters stated that patients with drug- and alcohol-induced mental conditions are more complex to care for and therefore often require increased levels of care and medical management. One commenter expressed concern in regard to the proposed removal of the Drug/Alcohol Induced Mental Disorders comorbidity category, considering the prevalence of substance use disorders in society. Additionally, commenters expressed concern with CMS correlating a lack of ancillary cost data with lower cost associated with treating IPF patients with drug- and alcohol-induced mental disorders.

Response: We understand the commenters' concern for the overall prevalence of substance abuse disorders, and how patients with substance use disorder may require increased levels of care. As shown in Table 2, the adjustment factor derived from the regression is statistically significant, but is less than 1. This suggests that the cost of treating IPF patients with these conditions is lower than treating patients without these conditions, and therefore, removing this comorbidity category more appropriately aligns payment with resource use.

Additionally, we did not receive any public comments regarding data and information that could better inform our understanding of the costs of treating these conditions. We believe the best available data was used in the regression. We anticipate that CMS will gain additional cost information on the treatment of IPF patients with substance abuse disorders and we intend to analyze such data for consideration in future refinements of the IPF PPS.

Final Decision: After consideration of the comments received, we are finalizing our proposal for FY 2025 to remove the Coagulation Factor Deficit, Infectious Disease, and Drug/Alcohol Induced Mental Disorders comorbidity categories. We note that we will continue to collect data on these comorbidity categories for consideration in future refinements of the IPF PPS. We encourage providers to report complete cost information for future analyses.

We also proposed to modify the Eating and Conduct Disorders comorbidity category and redesignate it as the Eating Disorders comorbidity category. That is, we proposed to remove conduct disorders from the codes eligible for a comorbidity adjustment. When we separately analyzed the ICD–10–CM codes for eating disorders (specifically, *F5000 Anorexia nervosa, unspecified, F5001 Anorexia nervosa, restricting type, F5002 Anorexia nervosa, binge eating/purging type,* and *F509 Eating disorder, unspecified*) and conduct disorders (*F631 Pyromania, F6381 Intermittent explosive disorder,* and *F911 Conduct disorder, childhood-onset type*), our regression results identified a positive, statistically significant adjustment factor associated with eating disorders. In contrast, conduct disorders had a negative and non-significant factor. These results suggest that eating disorders are associated with an increased level of resource, unlike conduct disorders, and that only eating disorders have an increase resource use at a level that is statistically significant. Based on these findings, we proposed to remove conduct disorders from the proposed newly designated Eating Disorders comorbidity category.

We did not receive any comments on our proposal to remove conduct disorders from the current Eating and Conduct Disorders comorbidity category. We are finalizing the newly designated Eating Disorders comorbidity category as proposed.

In addition, we proposed to modify the Chronic Obstructive Pulmonary Disease comorbidity category to include ICD–10–CM and ICD–10–PCS codes associated with sleep apnea (specifically, G*4733 Obstructive sleep apnea (adult) (pediatric), 5A09357 Assistance with Respiratory Ventilation, <24 Hrs, CPAP, Z9981 Dependence on supplemental oxygen,* and *Z9989 Dependence on other enabling machines and devices*). In response to the FY 2023 and FY 2024 IPF PPS proposed rules, commenters requested that CMS analyze the additional cost associated with patients with sleep apnea. Patients with sleep apnea often need to use a continuous positive airway pressure (CPAP) machine with a cord to manage their condition. Based on the clinical expertise of CMS Medical Officers, we determined that patients with sleep apnea in the IPF setting would have increased ligature risk (that is, anything that could be used to attach a cord, rope, or other material for the purpose of hanging or strangulation), similar to the risk associated with patients in the IPF setting that have chronic obstructive pulmonary disease. We stated that we expect the additional staffing resources involved in treating IPF patients with sleep apnea would be similar to the resources involved in treating IPF patients with chronic obstructive pulmonary disease, as patients with chronic obstructive pulmonary disease may also require the presence of an additional device with a cord in the patient's room, such as a bilevel positive airway pressure (BiPAP) machine. We evaluated adding codes associated with sleep apnea to our regression model, on the basis of our expectation that we would observe higher costs associated with these codes that would be comparable to the costs associated with chronic obstructive pulmonary disease. The results of our 2019 through 2021 regression model suggest that sleep apnea is in fact associated with an increased level of resource use. Therefore, we proposed to redesignate the Chronic Obstructive Pulmonary Disease category as the Chronic Obstructive Pulmonary Disease and Sleep Apnea comorbidity category.

Comment: One commenter supported redesignating the Chronic Obstructive Pulmonary Disease category as the Chronic Obstructive Pulmonary Disease and Sleep Apnea comorbidity category. The commenter noted that patients using a CPAP machine require increased care and medical management due to the need for 1:1 staffing to prevent ligature issues.

Response: We appreciate the commenter's support for adding codes associated with sleep apnea to the Chronic Obstructive Pulmonary Disease comorbidity category. As discussed in section IV.C.4.b.(1), when including sleep apnea codes to the Chronic Pulmonary Disease comorbidity category, the adjustment factor was higher than the number published in the proposed rule. This further supports the commenters' assertion that the resource use for treating sleep apnea is higher than for patients without sleep apnea.

Final Decision: After consideration of the comment received, we are finalizing our proposal for FY 2025 to redesignate the Chronic Obstructive Pulmonary Disease category as the Chronic Obstructive Pulmonary Disease and Sleep Apnea comorbidity category.

Further, we analyzed costs associated with the ICD–10–CM codes in Table 8 that indicate high-risk behavior. In response to the FY 2023 and FY 2024 IPF PPS proposed rules, commenters requested that CMS analyze the additional cost associated with patients exhibiting violent behavior during their stay in an IPF. We considered these comments in coordination with CMS Medical Officers, and determined that patients exhibiting violent behavior would require more intensive management during an IPF stay. We determined that certain ICD–10–CM codes could describe the types of high-risk behaviors that require intensive management during an IPF stay. These could include patients exhibiting violent behavior as well as other high-risk, non-violent behaviors. We examined ICD–10–CM codes in the R45 code family (Symptoms and Signs Related to Emotional State) that could indicate high-risk behavior during an IPF stay, which would lead to increased resource use. The regression analysis found that several codes, *R451 Restlessness and agitation, R454 Irritability and anger,* and *R4584 Anhedonia* codes are associated with a statistically significant adjustment factor. In other words, patients presenting with restlessness and agitation, irritability and anger, or anhedonia are more costly than patients who do not present these conditions. Therefore, we proposed to add a new comorbidity category recognizing the costs associated with Intensive Management for High-Risk Behavior.

Comment: Two commenters supported the proposed addition of a new comorbidity category recognizing the costs associated with Intensive Management for High-Risk Behavior. One commenter recommended that CMS include codes for *R456 Violent Behavior, R4585 Homicidal and suicidal ideations, R45850 Homicidal ideation,* and *R45851 Suicidal ideation* into the proposed Intensive Management for High-Risk Behavior comorbidity category.

Response: We appreciate the commenters' support regarding adding a new comorbidity category recognizing the costs associated with Intensive Management for High-Risk Behavior. As discussed in the proposed rule, we analyzed costs associated with the ICD–10–CM codes including *R456 Violent Behavior, R4585 Homicidal and suicidal ideations, R45850 Homicidal ideation,* and *R45851 Suicidal ideation.* The results of our regression analysis, as presented in the table below, found that these codes are not associated with a statistically significant positive adjustment factor, meaning, the cost of treating IPF patients with these conditions is not significantly higher than treating IPF patients without these conditions. Therefore, adding these codes to the Intensive Management for High-Risk Behavior comorbidity category would not align payment with resource use.

Table 8: Analysis of Adjustment Factors for Additional High Risk Behavior Codes

Description	# of Stays CY 2019–CY 2021	% of Stays CY 2019–CY 2021	Adjustment Factors	Significance	CI Lower Bound	CI Upper Bound
R456 Violent Behavior	6,184	0.8%	0.97869		0.92757	1.03261
R45850 Homicidal ideation	39,856	4.9%	0.92641	***	0.91254	0.94049
R45851 Suicidal ideation	264,551	32.8%	0.95828	***	0.94077	0.97612

Final Decision: After consideration of the comments received, we are finalizing our proposal to add a new comorbidity category recognizing the costs associated with Intensive Management for High-Risk Behavior to include the codes indicated in Table 9.

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Table 9: ICD–10–CM Codes for High-Risk Behavior Analyzed

ICD–10–CM Code	Description	Proposed Action for FY 2025 Intensive Management for High-Risk Behavior Comorbidity Category
R45	Symptoms and signs involving emotional state	
R450	Nervousness	
R451	Restlessness and agitation	Add
R452	Unhappiness	
R453	Demoralization and apathy	
R454	Irritability and anger	Add
R455	Hostility	
R456	Violent behavior	
R457	State of emotional shock and stress, unspecified	
R458	Other symptoms and signs involving emotional state	
R4581	Low self-esteem	
R4582	Worries	
R4583	Excessive crying of child, adolescent or adult	
R4584	Anhedonia	Add
R4585	Homicidal and suicidal ideations	
R45850	Homicidal ideations	
R45851	Suicidal ideations	
R4586	Emotional lability	
R4587	Impulsiveness	
R4589	Other symptoms and signs involving emotional state	

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Lastly, we proposed to maintain the adjustment factors for the Developmental Disabilities and Uncontrolled Diabetes comorbidity categories. Based on the regression analysis, the Developmental Disabilities comorbidity category adjustment factor was not statistically significant; however, the current adjustment factor is within the confidence interval. As discussed in section IV.C.3.a of this final rule, a non-statistically significant adjustment factor within the confidence interval indicates that the current adjustment factor would be a reasonable approximation of the increased costs. The Uncontrolled Diabetes comorbidity category adjustment factor did not change from the current adjustment factor based on the 2019 through 2021 regression.

We did not receive any comments on our proposal to maintain the adjustment factors for the Developmental Disabilities and Uncontrolled Diabetes comorbidity categories. We are finalizing maintaining these adjustment factors, as proposed.

We also proposed to decrease the adjustment factors for the following comorbidity categories: Renal Failure—Acute, Artificial Openings—Digestive & Urinary, Cardiac conditions, Renal Failure—Chronic, Chronic Obstructive Pulmonary Disease, and Severe Musculoskeletal & Connective Tissue Diseases.

The regression analysis found the Renal Failure—Acute, Artificial Openings—Digestive & Urinary, Cardiac conditions, Renal Failure—Chronic, Chronic Obstructive Pulmonary Disease, and Severe Musculoskeletal & Connective Tissue Diseases comorbidity categories resulted in a statistically significant adjustment factor. While payment would still be increased when the claim includes one of these comorbidity categories, the proposed adjustment factors for FY 2025 would be less than the current adjustment factors for these categories.

We did not receive any comments on our proposal to decrease the adjustment factors for the following comorbidity categories: Renal Failure—Acute, Artificial Openings—Digestive & Urinary, Cardiac conditions, Renal Failure—Chronic, Chronic Obstructive Pulmonary Disease, and Severe Musculoskeletal & Connective Tissue Diseases. We are finalizing a decrease to these adjustment factors, as proposed.

The FY 2025 comorbidity adjustment factors are displayed in Table 10, and can be found in Addendum A, available on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/inpatient-psychiatric-facility/tools-and-worksheets.*

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Table 10: Comparison of FY 2024 and FY 2025 IPF PPS Comorbidity Category Adjustments

Description	Current Adjustment Factor	FY 2025 Adjustment Factor
Renal Failure, Acute	1.11	1.06
Artificial Openings – Digestive & Urinary	1.08	1.07
Cardiac Conditions	1.11	1.04
Renal Failure, Chronic	1.11	1.08
Coagulation Factor Deficit	1.13	N/A
Chronic Obstructive Pulmonary Disease	1.12	N/A
Chronic Obstructive Pulmonary Disease and Sleep Apnea	N/A	1.09
Developmental Disabilities	1.04	1.04
Uncontrolled Diabetes	1.05	1.05
Drug/Alcohol Induced Mental Disorders	1.03	N/A
Eating and Conduct Disorders	1.12	N/A
Eating Disorders	N/A	1.09
Gangrene	1.10	1.12
Infectious Diseases	1.07	N/A
Severe Protein Malnutrition	1.13	1.17
Oncology Treatment	1.07	1.44
Poisoning	1.11	1.16
Severe Musculoskeletal & Connective Tissue Diseases	1.09	1.05
Tracheostomy	1.06	1.09
Intensive Management for High-Risk Behavior	N/A	1.07

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As discussed in section IV.F of this final rule, we proposed to implement revisions to the comorbidity category adjustments budget-neutrally. A detailed discussion of the distributional impacts of these changes is found in section VIII.C of this final rule.

(2) Coding Updates for FY 2025

For FY 2025, we proposed to add 2 ICD–10–CM/PCS codes to the Oncology Treatment comorbidity category. The FY 2025 comorbidity codes are shown in Addenda B, available on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/inpatient-psychiatric-facility/tools-and-worksheets.*

In accordance with the policy established in the FY 2015 IPF PPS final rule (79 FR 45949 through 45952), we reviewed all new FY 2025 ICD–10–CM codes to remove codes that were site ''unspecified'' in terms of laterality from the FY 2023 ICD–10–CM/PCS codes in instances where more specific codes are available. As we stated in the FY 2015 IPF PPS final rule, we believe that specific diagnosis codes that narrowly identify anatomical sites where disease, injury, or a condition exists should be used when coding patients' diagnoses whenever these codes are available. We finalized in the FY 2015 IPF PPS rule, that we would remove site ''unspecified'' codes from the IPF PPS ICD–10–CM/PCS codes in instances when laterality codes (site specified codes) are available, as the clinician should be able to identify a more specific diagnosis based on clinical assessment at the medical encounter. There were no proposed changes to the FY 2025 ICD–10–CM/PCS codes, therefore, we did not propose to remove any of the new codes.

c. Patient Age Adjustments

As explained in the RY 2005 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. While our regression analysis of CY 2019 through CY 2021 data supports maintaining a payment adjustment factor based on age as was established in the RY 2005 IPF PPS final rule, the results suggest that revisions to the adjustment factor for age are warranted.

For FY 2025, we proposed to revise the patient age adjustments as shown in Addendum A of this final rule, which is available on the CMS website at (see *https://www.cms.gov/medicare/payment/prospective-payment-systems/inpatient-psychiatric-facility/tools-and-worksheets*). We proposed to adopt the patient age adjustments derived from the regression model using a blended set of 2019 through 2021 data, as discussed in section IV.C.3 of this final rule. Table 11 summarizes the current and proposed patient age adjustment factors for FY 2025. As discussed in section IV.F of this final rule, we proposed to implement this revision to the patient age adjustments budget-neutrally. A detailed discussion of the distributional impacts of this change is found in section VIII.C of this final rule.

We solicited comments on these proposed revisions to the patient age adjustment factors. Lastly, we proposed that if more recent data become available, we would use such data, if appropriate, to determine the final FY 2025 patient age adjustment factors.

We did not receive any comments on our proposal. We are finalizing the revisions to the patient age adjustment factors as proposed.

Table 11: Updates to Patient Age Adjustments

Age (in years)	Current Adjustment Factors	# of Stays CY 2019-CY 2021	% of Stays CY 2019-CY 2021	Adjustment Factors
Under 45	1.00	234,270	29.04%	1.00
45 and under 50	1.01			
50 and under 55	1.02			
45 and under 55	*N/A*	121,498	15.06%	1.02
55 and under 60	1.04	74,512	9.24%	1.05
60 and under 65	1.07	68,136	8.45%	1.06
65 and under 70	1.10	94,473	11.71%	1.09
70 and under 75	1.13			
75 and under 80	1.15			
70 and under 80	*N/A*	126,280	15.66%	1.11
80 and over	1.17	87,442	10.84%	1.13

d. Variable per Diem Adjustments

We explained in the RY 2005 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 RY 2005 IPF PPS final rule, where a complete discussion of the variable per diem adjustments can be found, 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 2025, we proposed to revise the variable per diem adjustment factors as indicated in the table below, and shown in Addendum A to this rule, which is available on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/inpatient-psychiatric-facility/tools-and-worksheets.* We proposed to increase the adjustment factors for days 1 through 9. As shown in Table 12, the results of the latest regression analysis indicate that there is not a statistically significant decrease in cost per day after day 10; therefore, we proposed that days 10 and above will receive a 1.00 adjustment. Table 12 summarizes the current and proposed variable per diem adjustment factors for FY 2025. As discussed in section IV.F of this final rule, we proposed to implement this revision to the variable per diem adjustments budget-neutrally. A detailed discussion of the distributional impacts of this proposed change is found in section VIII.C of this final rule.

We solicited comments on these proposed revisions to the variable per diem adjustment factors. Lastly, we proposed that if more recent data become available, we will use such data, if appropriate, to determine the final FY 2025 variable per diem adjustment factors.

Comment: Two commenters supported the proposed revisions to the variable per diem adjustments, noting that these revisions reflect increased costs early in a stay.

Response: We thank the commenters for their support. As discussed in section IV.C.4.b.(1) of this final rule, we have updated our regression analysis to account for a programming error that inadvertently excluded certain sleep apnea codes from the regression model. The results of the latest regression analysis increase the adjustment factor for the first day of the stay. This result further supports the commenters' assertion that there are increased costs early in an IPF stay.

Final Decision: After consideration of the comments received, we are finalizing the revision of the IPF variable per diem adjustment factors as shown in Table 12.

Table 12: Updates to Variable Per Diem Adjustments

Description	Current Adjustment Factors	# of Stays CY 2019–CY 2021	% of Stays CY 2019–CY 2021	Adjustment Factors
Length of stay - 1 day without ED	1.19	17,141	2.09%	1.28
Length of stay - 1 day *with a qualified ED*	1.31	N/A	N/A	1.54
Length of stay - 2 days	1.12	28,370	3.52%	1.20
Length of stay - 3 days	1.08	42,298	5.24%	1.15
Length of stay - 4 days	1.05	48,187	5.97%	1.12
Length of stay - 5 days	1.04	54,187	6.72%	1.08
Length of stay - 6 days	1.02	59,215	7.34%	1.06
Length of stay - 7 days	1.01	63,095	7.82%	1.03
Length of stay - 8 days	1.01	51,491	6.38%	1.02
Length of stay - 9 days	1.00	42,855	5.31%	1.01
Length of stay – greater than or equal to 10 days	1.00 – 0.92	400,022	49.59%	1.00

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. We proposed to use the existing regression-derived facility-level adjustment factors established in the RY 2005 IPF final rule and did not propose changes to the facility-level adjustment factors for rural location and teaching status for FY 2025. As discussed in the following sections, we proposed updates to the FY 2025 IPF PPS wage index. In addition, we proposed to update the ED adjustment for FY 2025 to reflect more recent cost and claims data.

1. Wage Index Adjustment

a. Background

As discussed in the RY 2007 IPF PPS final rule (71 FR 27061), and the RY 2009 IPF PPS (73 FR 25719) and 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 § 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 RY 2005 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, and therefore, 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 (71FR 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) provides 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 RY 2005 IPF PPS final rule, with an effective date of January 1, 2005, the pre-floor, pre-reclassified IPPS hospital wage index that was available at the time was the FY 2005 pre-floor, pre-reclassified IPPS hospital wage index. Historically, the IPF wage index for a given RY has used the pre-floor, pre-reclassified IPPS hospital wage index from the prior FY as its basis. This has been due in part to the pre-floor, pre-reclassified IPPS hospital wage index data that were available during the IPF rulemaking cycle, where an annual IPF notice or IPF final rule was usually published in early May. This publication timeframe was relatively early compared to other Medicare payment rules because the IPF PPS follows a RY, which was defined in the implementation of the IPF PPS as the 12-month period from July 1 to June 30 (69 FR 66927). Therefore, the best available data at the time the IPF PPS was implemented was the pre-floor, pre-reclassified IPPS hospital wage index from the prior FY (for example, the RY 2006 IPF wage index was based on the FY 2005 pre-floor, pre-reclassified IPPS hospital wage index).

In the RY 2012 IPF PPS final rule, we changed the reporting year timeframe for IPFs from a RY to FY, which begins October 1 and ends September 30 (76 FR 26434 through 26435). In that FY 2012 IPF PPS final rule, we continued

our established policy of using the pre-floor, pre-reclassified IPPS hospital wage index from the prior year (that is, from FY 2011) as the basis for the FY 2012 IPF wage index. This policy of basing a wage index on the prior year's pre-floor, pre-reclassified IPPS hospital wage index has been followed by other Medicare payment systems, such as hospice and inpatient rehabilitation facilities. By continuing with our established policy, we remained consistent with other Medicare payment systems.

In FY 2020, we finalized the IPF wage index methodology to align the IPF PPS wage index with the same wage data timeframe used by the IPPS for FY 2020 and subsequent years. Specifically, we finalized the use of 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. We noted that it would also result in more consistency and parity in the wage index methodology used by other Medicare payment systems. We indicated that the Medicare skilled nursing facility (SNF) PPS already used the concurrent IPPS hospital wage index data as the basis for the SNF PPS wage index. We proposed and finalized 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. Thus, the wage adjusted Medicare payments of various provider types are based upon wage index data from the same timeframe. For FY 2025, we proposed to continue to use the concurrent pre-floor, pre-reclassified IPPS hospital wage index as the basis for the IPF wage index.

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 will apply this cap in a budget neutral manner. In addition, we finalized a policy that a new IPF will 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 will 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.

For FY 2025, we proposed to apply the IPF wage index adjustment to the labor-related share of the national IPF PPS base rate and ECT payment per treatment. The proposed labor-related share of the IPF PPS national base rate and ECT payment per treatment is 78.8 percent in FY 2025. This percentage reflects the labor-related share of the 2021-based IPF market basket for FY 2025 and is 0.1 percentage point higher than the FY 2024 labor-related share (see section IV.A.3 of this final rule). We received several comments on this proposal, which are discussed in the following paragraphs.

Comment: Several commenters requested CMS 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 noted 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. One commenter urged CMS to apply an out-migration adjustment (OMA) to IPFs to account for the employment of hospital employees who reside in one county but commute to work in a county with a higher wage index.

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 pre-reclassification 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 are a variety of reasons why our longstanding IPF wage index policy have 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, 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 budget-neutrally 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 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 critical access hospital. 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 Medicare program as hospitals, as long as those data did not fail any of our edits for reasonableness. These edits excluded providers with aberrant data that should not be included in the wage index. 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.

We appreciate the commenter's suggestion to apply an out-migration adjustment to IPFs to account for employment of hospital staff who commute to work in counties with a higher wage index. However, we note that the out-migration adjustment is applied to the IPPS hospital wage index under section 1886(d)(13) of the Act, which is a statutory provision that specifically applies to subsection (d) hospitals paid under the IPPS. As discussed in the prior paragraph, CMS does not believe it is appropriate for the IPF PPS to apply an out-migration adjustment that is not statutorily required, because such a policy would increase administrative burden and have distributional impacts on IPFs.

Comment: One commenter encouraged CMS to consider developing and applying a low wage index hospital policy for rural and low wage index IPFs similar to the policy in place for the IPPS wage index to ensure that IPFs in low wage index and rural areas, which typically draw from the same labor pool as IPPS hospitals, have adequate resources to continue to provide access to care.

Response: We appreciate the suggestions from commenters; however, we did not propose to apply a low-wage index policy for the IPF PPS wage index and are not finalizing such a methodology. As we noted in the FY 2025 IPF PPS proposed rule, our longstanding methodology for the IPF wage index is derived from IPPS wage data, that is, the pre-reclassified and pre-floor IPPS wage index. Thus, to the extent that increasing wage index values under the IPPS for low-wage index hospitals results in those hospitals increasing employee compensation, this increase would be reflected in the IPPS wage data upon which the IPF wage index is based and would be expected to result in higher wage indices for these areas under the IPF PPS. We further note that IPPS wage index values are based on historical data and typically lag by four years. As a result, the hospital cost report data for FY 2021 would reflect any changes in employee compensation driven by the IPPS low-wage index hospital policy, and under our proposal, this data would become the basis for the IPF wage index in FY 2025. Therefore, any effects of these changes would be extended to the IPF setting.

Final Decision: After consideration of the comments received, we are finalizing our proposal for FY 2025 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 78.7 percent in FY 2024 to 78.8 percent in FY 2025. This percentage reflects the labor-related share of the 2021-based IPF market basket for FY 2025 (see section IV.A.5 of this final rule).

b. Office of Management and Budget (OMB) Bulletins

(1) 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 based on the labor market area in which the IPF is geographically located. IPF labor market areas are delineated based on the Core-Based Statistical Area (CBSAs) established by the OMB.

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

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

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

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

As discussed in the FY 2023 IPF PPS final rule, we did not adopt OMB Bulletin 20–01, which was issued March 6, 2020, because we determined this bulletin had no material impact on the IPF PPS wage index. This bulletin creates only one Micropolitan statistical area, and Micropolitan areas are considered rural for 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.

Finally, on July 21, 2023, OMB issued Bulletin 23–01, which revises the CBSA delineations based on the latest available data from the 2020 census. This bulletin contains information regarding updates of statistical area changes to CBSA titles, numbers, and county or county equivalents.

(2) Proposed Implementation of New Labor Market Area Delineations

We believe it is important for the IPF PPS to use, as soon as is reasonably possible, the latest available labor market area delineations to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions. We believe that using the most current delineations will increase the integrity of the IPF PPS wage index system by creating a more accurate representation of geographic variations in wage levels. In the FY 2025 IPF PPS proposed rule, we explained that we have carefully analyzed the impacts of adopting the new OMB delineations and find no compelling reason to delay implementation. Therefore, we proposed to implement the new OMB delineations as described in the July 21, 2023, OMB Bulletin No. 23–01, effective beginning with the FY 2025 IPF PPS wage index. We proposed to adopt the updates to the OMB delineations announced in OMB Bulletin No. 23–01 effective for FY 2025 under the IPF PPS.

As previously discussed, we finalized a 5-percent permanent cap on any decrease to a provider's wage index from its wage index in the prior year. For more information on the permanent 5-percent cap policy, we refer readers to the FY 2023 IPF PPS final rule (87 FR 46856 through 46859). In addition, we proposed to phase out the rural adjustment for IPFs that are transitioning from rural to urban based on these CBSA revisions, as discussed in section IV.D.1.c. of this final rule.

(a) Micropolitan Statistical Areas

OMB defines a ''Micropolitan Statistical Area'' as a CBSA associated with at least one urban cluster that has a population of at least 10,000, but less than 50,000 (75 FR 37252). We refer to these as Micropolitan Areas. After extensive impact analysis, consistent with the treatment of these areas under the IPPS as discussed in the FY 2005 IPPS final rule (69 FR 49029 through 49032), we determined the best course of action was to treat Micropolitan Areas as ''rural'' and include them in the calculation of each state's IPF PPS rural wage index. We refer readers to the FY 2007 IPF PPS final rule (71 FR 27064 through 27065) for a complete discussion regarding treating Micropolitan Areas as rural. We did not propose any changes to this policy for FY 2025.

(b) Change to County-Equivalents in the State of Connecticut

The June 6, 2022, Census Bureau Notice (87 FR 34235 through 34240), OMB Bulletin No. 23–01 replaced the 8 counties in Connecticut with 9 new ''Planning Regions.'' Planning regions now serve as county-equivalents within the CBSA system. In the proposed rule, we explained that we have evaluated the changes and are proposed to adopt the planning regions as county equivalents for wage index purposes. We stated that we believe it is necessary to adopt this migration from counties to planning region county-equivalents to maintain consistency with OMB updates. We provided the following crosswalk for each county in Connecticut with the current and proposed FIPS county and county-equivalent codes and CBSA assignments.

Table 13: Change to County-Equivalents in the State of Connecticut

FIPS	Current County	Current CBSA	Proposed FIPS	Proposed Planning Region Area (County Equivalent)	Proposed CBSA
09003	HARTFORD	25540	09110	CAPITOL	25540
09015	WINDHAM	49340	09150	NORTHEASTERN CONNECTICUT	7
09005	LITCHFIELD	7	09160	NORTHWEST HILLS	7
09001	FAIRFIELD	14860	09190	WESTERN CONNECTICUT	14860
09001	FAIRFIELD	14860	09120	GREATER BRIDGEPORT	14860
09011	NEW LONDON	35980	09180	SOUTHEASTERN CONNECTICUT	35980
09013	TOLLAND	25540	09110	CAPITOL	25540
09009	NEW HAVEN	35300	09140	NAUGATUCK VALLEY	47930
09009	NEW HAVEN	35300	09170	SOUTH CENTRAL CONNECTICUT	35300
09007	MIDDLESEX	25540	09130	LOWER CONNECTICUT RIVER VALLEY	25540

(c) Urban Counties That Will Become Rural Under the Revised OMB Delineations

As previously discussed, we proposed to implement the new OMB labor market area delineations (based upon OMB Bulletin No. 23–01) beginning in FY 2025. We stated that our analysis shows a total of 53 counties (and county equivalents) and 15 providers are located in areas that were previously considered part of an urban CBSA but would be considered rural beginning in FY 2025 under these revised OMB delineations. Table 14 lists the 53 urban counties that we noted would be rural if we finalized our proposal to implement the revised OMB delineations.

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Table 14: Counties Previously Considered Part of an Urban CBSA that Would Become Rural Areas Under Revised OMB Delineations

County Code	County/County Equivalent	State	Current CBSA	Labor Market Area
01129	WASHINGTON	AL	33660	Mobile, AL
05025	CLEVELAND	AR	38220	Pine Bluff, AR
05047	FRANKLIN	AR	22900	Fort Smith, AR-OK
05069	JEFFERSON	AR	38220	Pine Bluff, AR
05079	LINCOLN	AR	38220	Pine Bluff, AR
10005	SUSSEX	DE	41540	Salisbury, MD-DE
13171	LAMAR	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA
16077	POWER	ID	38540	Pocatello, ID
17057	FULTON	IL	37900	Peoria, IL
17077	JACKSON	IL	16060	Carbondale-Marion, IL
17087	JOHNSON	IL	16060	Carbondale-Marion, IL
17183	VERMILION	IL	19180	Danville, IL
17199	WILLIAMSON	IL	16060	Carbondale-Marion, IL
18121	PARKE	IN	45460	Terre Haute, IN
18133	PUTNAM	IN	26900	Indianapolis-Carmel-Anderson, IN
18161	UNION	IN	17140	Cincinnati, OH-KY-IN
21091	HANCOCK	KY	36980	Owensboro, KY
21101	HENDERSON	KY	21780	Evansville, IN-KY
22045	IBERIA	LA	29180	Lafayette, LA
24001	ALLEGANY	MD	19060	Cumberland, MD-WV
24047	WORCESTER	MD	41540	Salisbury, MD-DE
25011	FRANKLIN	MA	44140	Springfield, MA
26155	SHIAWASSEE	MI	29620	Lansing-East Lansing, MI
27075	LAKE	MN	20260	Duluth, MN-WI
28031	COVINGTON	MS	25620	Hattiesburg, MS
31051	DIXON	NE	43580	Sioux City, IA-NE-SD
36123	YATES	NY	40380	Rochester, NY
37049	CRAVEN	NC	35100	New Bern, NC
37077	GRANVILLE	NC	20500	Durham-Chapel Hill, NC
37085	HARNETT	NC	22180	Fayetteville, NC
37087	HAYWOOD	NC	11700	Asheville, NC
37103	JONES	NC	35100	New Bern, NC
37137	PAMLICO	NC	35100	New Bern, NC
42037	COLUMBIA	PA	14100	Bloomsburg-Berwick, PA
42085	MERCER	PA	49660	Youngstown-Warren-Boardman, OH-PA
42089	MONROE	PA	20700	East Stroudsburg, PA
42093	MONTOUR	PA	14100	Bloomsburg-Berwick, PA

County Code	County/County Equivalent	State	Current CBSA	Labor Market Area
42103	PIKE	PA	35084	Newark, NJ-PA
45027	CLARENDON	SC	44940	Sumter, SC
48431	STERLING	TX	41660	San Angelo, TX
49003	BOX ELDER	UT	36260	Ogden-Clearfield, UT
51113	MADISON	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV
51175	SOUTHAMPTON	VA	47260	Virginia Beach-Norfolk-Newport News, VA-NC
51620	FRANKLIN CITY	VA	47260	Virginia Beach-Norfolk-Newport News, VA-NC
54035	JACKSON	WV	16620	Charleston, WV
54043	LINCOLN	WV	16620	Charleston, WV
54057	MINERAL	WV	19060	Cumberland, MD-WV
55069	LINCOLN	WI	48140	Wausau-Weston, WI
72001	ADJUNTAS	PR	38660	Ponce, PR
72055	GUANICA	PR	49500	Yauco, PR
72081	LARES	PR	10380	Aguadilla-Isabela, PR
72083	LAS MARIAS	PR	32420	Mayagüez, PR
72141	UTUADO	PR	10380	Aguadilla-Isabela, PR

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We proposed that the wage data for all providers located in the counties listed above would now be considered rural, beginning in FY 2025, when calculating their respective state's rural wage index. This rural wage index value would also be used under the IPF PPS. We recognize that rural areas typically have lower area wage index values than urban areas, and providers located in these counties may experience a negative impact in their IPF payment due to the proposed adoption of the revised OMB delineations. However, we noted that providers located in these counties would receive a rural adjustment beginning in FY 2025, which would mitigate the impact of decreases to the wage index for these providers. In addition, we explained that the permanent 5-percent cap on wage index decreases under the IPF PPS would further mitigate large wage index decreases for providers in these areas.

(d) Rural Counties That Would Become Urban Under the Revised OMB Delineations

As previously discussed, we proposed to implement the new OMB labor market area delineations (based upon OMB Bulletin No. 23–01) beginning in FY 2025. We stated that analysis of these OMB labor market area delineations shows that a total of 54 counties (and county equivalents) and 10 providers are located in areas that were previously considered rural but will now be considered urban under the revised OMB delineations. Table 15 lists the 54 rural counties that we stated would be urban if we finalized our proposal to implement the revised OMB delineations.

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Table 15: Counties that Would Gain Urban Status Under Revised OMB Delineations

County Code	County/County Equivalent	State	New CBSA	Labor Market Area
01087	Macon	AL	12220	Auburn-Opelika, AL
01127	Walker	AL	13820	Birmingham, AL
12133	Washington	FL	37460	Panama City-Panama City Beach, FL
13187	Lumpkin	GA	12054	Atlanta-Sandy Springs-Roswell, GA
15005	Kalawao	HI	27980	Kahului-Wailuku, HI
17053	Ford	IL	16580	Champaign-Urbana, IL
17127	Massac	IL	37140	Paducah, KY-IL
18159	Tipton	IN	26900	Indianapolis-Carmel-Greenwood, IN
18179	Wells	IN	23060	Fort Wayne, IN
20021	Cherokee	KS	27900	Joplin, MO-KS
21007	Ballard	KY	37140	Paducah, KY-IL
21039	Carlisle	KY	37140	Paducah, KY-IL
21127	Lawrence	KY	26580	Huntington-Ashland, WV-KY-OH
21139	Livingston	KY	37140	Paducah, KY-IL
21145	Mc Craken	KY	37140	Paducah, KY-IL
21179	Nelson	KY	31140	Louisville/Jefferson County, KY-IN
22053	Jefferson Davis	LA	29340	Lake Charles, LA
22083	Richland	LA	33740	Monroe, LA
26015	Barry	MI	24340	Grand Rapids-Wyoming-Kentwood, MI
26019	Benzie	MI	45900	Traverse City, MI
26055	Grand Traverse	MI	45900	Traverse City, MI
26079	Kalkaska	MI	45900	Traverse City, MI
26089	Leelanau	MI	45900	Traverse City, MI
27133	Rock	MN	43620	Sioux Falls, SD-MN
28009	Benton	MS	32820	Memphis, TN-MS-AR
28123	Scott	MS	27140	Jackson, MS
30007	Broadwater	MT	25740	Helena, MT
30031	Gallatin	MT	14580	Bozeman, MT
30043	Jefferson	MT	25740	Helena, MT
30049	Lewis and Clark	MT	25740	Helena, MT
30061	Mineral	MT	33540	Missoula, MT
32019	Lyon	NV	39900	Reno, NV
37125	Moore	NC	38240	Pinehurst-Southern Pines, NC
38049	McHenry	ND	33500	Minot, ND
38075	Renville	ND	33500	Minot, ND
38101	Ward	ND	33500	Minot, ND
39007	Ashtabula	OH	17410	Cleveland, OH
39043	Erie	OH	41780	Sandusky, OH
41013	Crook	OR	13460	Bend, OR

County Code	County/County Equivalent	State	New CBSA	Labor Market Area
41031	Jefferson	OR	13460	Bend, OR
42073	Lawrence	PA	38300	Pittsburgh, PA
45087	Union	SC	43900	Spartanburg, SC
46033	Custer	SD	39660	Rapid City, SD
47081	Hickman	TN	34980	Nashville-Davidson--Murfreesboro--Franklin, TN
48007	Aransas	TX	18580	Corpus Christi, TX
48035	Bosque	TX	47380	Waco, TX
48079	Cochran	TX	31180	Lubbock, TX
48169	Garza	TX	31180	Lubbock, TX
48219	Hockley	TX	31180	Lubbock, TX
48323	Maverick	TX	20580	Eagle Pass, TX
48407	San Jacinto	TX	26420	Houston-Pasadena-The Woodlands, TX
51063	Floyd	VA	13980	Blacksburg-Christiansburg-Radford, VA
51181	Surry	VA	47260	Virginia Beach-Chesapeake-Norfolk, VA-NC
55123	Vernon	WI	29100	La Crosse-Onalaska, WI-MN

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We proposed that when calculating the area wage index, beginning with FY 2025, the wage data for providers located in these counties would be included in their new respective urban CBSAs. Typically, providers located in an urban area receive a wage index value higher than or equal to providers located in their state's rural area. We also noted that providers located in these areas would no longer be considered rural beginning in FY 2025. We refer readers to section IV.D.1.c of this final rule for a discussion of the proposed policy to phase out the payment of the rural adjustment for providers in these areas.

(e) Urban Counties That Would Move to a Different Urban CBSA Under the New OMB Delineations

In the proposed rule, we noted that in certain cases adopting the new OMB delineations would involve a change only in CBSA name and/or number, while the CBSA continues to encompass the same constituent counties. For example, CBSA 10540 (Albany-Lebanon, OR) would experience a change to its name, and become CBSA 10540 (Albany, OR), while its one constituent county would remain the same. Table 16 shows the current CBSA code and our proposed CBSA code where we proposed to change either the name or CBSA number only. We did not further discuss these proposed changes in the proposed rule, because they are inconsequential changes with respect to the IPF PPS wage index.

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Table 16: Current CBSAs and their New CBSA Codes and Titles

Current CBSA Code	Current CBSA Title	CBSA Code	CBSA Title
10540	Albany-Lebanon, OR	10540	Albany, OR
12420	Austin-Round Rock-Georgetown, TX	12420	Austin-Round Rock-San Marcos, TX
12540	Bakersfield, CA	12540	Bakersfield-Delano, CA
15260	Brunswick, GA	15260	Brunswick-St. Simons, GA
16540	Chambersburg-Waynesboro, PA	16540	Chambersburg, PA
16984	Chicago-Naperville-Evanston, IL	16984	Chicago-Naperville-Schaumburg, IL
19430	Dayton-Kettering, OH	19430	Dayton-Kettering-Beavercreek, OH
19740	Denver-Aurora-Lakewood, CO	19740	Denver-Aurora-Centennial, CO
21820	Fairbanks, AK	21820	Fairbanks-College, AK
22660	Fort Collins, CO	22660	Fort Collins-Loveland, CO
23224	Frederick-Gaithersburg-Rockville, MD	23224	Frederick-Gaithersburg-Bethesda, MD
24860	Greenville-Anderson, SC	24860	Greenville-Anderson-Greer, SC
25940	Hilton Head Island-Bluffton, SC	25940	Hilton Head Island-Bluffton-Port Royal, SC
26380	Houma-Thibodaux, LA	26380	Houma-Bayou Cane-Thibodaux, LA
29820	Las Vegas-Henderson-Paradise, NV	29820	Las Vegas-Henderson-North Las Vegas, NV
31020	Longview, WA	31020	Longview-Kelso, WA
34740	Muskegon, MI	34740	Muskegon-Norton Shores, MI
35840	North Port-Sarasota-Bradenton, FL	35840	North Port-Bradenton-Sarasota, FL
36084	Oakland-Berkeley-Livermore, CA	36084	Oakland-Fremont-Berkeley, CA
36540	Omaha-Council Bluffs, NE-IA	36540	Omaha, NE-IA
39340	Provo-Orem, UT	39340	Provo-Orem-Lehi, UT
39540	Racine, WI	39540	Racine-Mount Pleasant, WI
41620	Salt Lake City, UT	41620	Salt Lake City-Murray, UT
42680	Sebastian-Vero Beach, FL	42680	Sebastian-Vero Beach-West Vero Corridor, FL
42700	Sebring-Avon Park, FL	42700	Sebring, FL
44420	Staunton, VA	44420	Staunton-Stuarts Draft, VA
44700	Stockton, CA	44700	Stockton-Lodi, CA
47220	Vineland-Bridgeton, NJ	47220	Vineland, NJ
48300	Wenatchee, WA	48300	Wenatchee-East Wenatchee, WA
48424	West Palm Beach-Boca Raton-Boynton Beach, FL	48424	West Palm Beach-Boca Raton-Delray Beach, FL

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We explained that in some cases, if we adopt the new OMB delineations, counties would shift between existing and new CBSAs, changing the constituent makeup of the CBSAs. We stated that we consider this type of change, where CBSAs are split into multiple new CBSAs, or a CBSA loses one or more counties to another urban CBSA to be significant modifications.

Table 17 lists the urban counties that we stated would move from one urban CBSA to another newly proposed or modified CBSA if we adopted the new OMB delineations.

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Table 17: Urban Counties That Would Move to a New or Modified CBSA Under Revised OMB Delineations

County Code	County Name	State	Current CBSA	Current CBSA Name	CBSA Code	CBSA Name
06039	MADERA	CA	31460	Madera, CA	23420	Fresno, CA
11001	THE DISTRICT	DC	47894	Washington -Arlington-Alexandria, DC-VA-MD-WV	47764	Washington, DC-MD
12053	HERNANDO	FL	45300	Tampa-St. Petersburg-Clearwater, FL	45294	Tampa, FL
12057	HILLSBOROUGH	FL	45300	Tampa-St. Petersburg-Clearwater, FL	45294	Tampa, FL
12101	PASCO	FL	45300	Tampa-St. Petersburg-Clearwater, FL	45294	Tampa, FL
12103	PINELLAS	FL	45300	Tampa-St. Petersburg-Clearwater, FL	41304	St. Petersburg-Clearwater-Largo, FL
12119	SUMTER	FL	45540	The Villages, FL	48680	Wildwood-The Villages, FL
13013	BARROW	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13015	BARTOW	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	31924	Marietta, GA
13035	BUTTS	GA	12060	Atlanta-Sandy Springs-	12054	Atlanta-Sandy Springs-Roswell, GA

County Code	County Name	State	Current CBSA	Current CBSA Name	CBSA Code	CBSA Name
				Alpharetta, GA		
13045	CARROLL	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13057	CHEROKEE	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	31924	Marietta, GA
13063	CLAYTON	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13067	COBB	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	31924	Marietta, GA
13077	COWETA	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13085	DAWSON	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13089	DE KALB	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13097	DOUGLAS	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13113	FAYETTE	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13117	FORSYTH	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13121	FULTON	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA

County Code	County Name	State	Current CBSA	Current CBSA Name	CBSA Code	CBSA Name
13135	GWINNETT	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13143	HARALSON	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	31924	Marietta, GA
13149	HEARD	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13151	HENRY	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13159	JASPER	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13199	MERIWETHER	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13211	MORGAN	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13217	NEWTON	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13223	PAULDING	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	31924	Marietta, GA
13227	PICKENS	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13231	PIKE	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA

County Code	County Name	State	Current CBSA	Current CBSA Name	CBSA Code	CBSA Name
13247	ROCKDALE	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13255	SPALDING	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13297	WALTON	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
18073	JASPER	IN	23844	Gary, IN	29414	Lake County-Porter County-Jasper County, IN
18089	LAKE	IN	23844	Gary, IN	29414	Lake County-Porter County-Jasper County, IN
18111	NEWTON	IN	23844	Gary, IN	29414	Lake County-Porter County-Jasper County, IN
18127	PORTER	IN	23844	Gary, IN	29414	Lake County-Porter County-Jasper County, IN
21163	MEADE	KY	21060	Elizabethtown-Fort Knox, KY	31140	Louisville/Jefferson County, KY-IN
22103	ST. TAMMANY	LA	35380	New Orleans-Metairie, LA	43640	Slidell-Mandeville-Covington, LA
25015	HAMPSHIRE	MA	44140	Springfield, MA	11200	Amherst Town-Northampton, MA
24009	CALVERT	MD	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	30500	Lexington Park, MD
24017	CHARLES	MD	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	47764	Washington, DC-MD
24033	PRINCE GEORGES	MD	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	47764	Washington, DC-MD
24037	ST. MARYS	MD	15680	California-Lexington Park, MD	30500	Lexington Park, MD
37019	BRUNSWICK	NC	34820	Myrtle Beach-	48900	Wilmington, NC

County Code	County Name	State	Current CBSA	Current CBSA Name	CBSA Code	CBSA Name
				Conway-North Myrtle Beach, SC-NC		
34009	CAPE MAY	NJ	36140	Ocean City, NJ	12100	Atlantic City-Hammonton, NJ
34023	MIDDLESEX	NJ	35154	New Brunswick-Lakewood, NJ	29484	Lakewood-New Brunswick, NJ
34025	MONMOUTH	NJ	35154	New Brunswick-Lakewood, NJ	29484	Lakewood-New Brunswick, NJ
34029	OCEAN	NJ	35154	New Brunswick-Lakewood, NJ	29484	Lakewood-New Brunswick, NJ
34035	SOMERSET	NJ	35154	New Brunswick-Lakewood, NJ	29484	Lakewood-New Brunswick, NJ
36027	DUTCHESS	NY	39100	Poughkeepsie-Newburgh-Middletown, NY	28880	Kiryas Joel-Poughkeepsie-Newburgh, NY
36071	ORANGE	NY	39100	Poughkeepsie-Newburgh-Middletown, NY	28880	Kiryas Joel-Poughkeepsie-Newburgh, NY
39035	CUYAHOGA	OH	17460	Cleveland-Elyria, OH	17410	Cleveland, OH
39055	GEAUGA	OH	17460	Cleveland-Elyria, OH	17410	Cleveland, OH
39085	LAKE	OH	17460	Cleveland-Elyria, OH	17410	Cleveland, OH
39093	LORAIN	OH	17460	Cleveland-Elyria, OH	17410	Cleveland, OH
39103	MEDINA	OH	17460	Cleveland-Elyria, OH	17410	Cleveland, OH
39123	OTTAWA	OH	45780	Toledo, OH	41780	Sandusky, OH
72023	CABO ROJO	PR	41900	San Germán, PR	32420	Mayagüez, PR
72059	GUAYANILLA	PR	49500	Yauco, PR	38660	Ponce, PR
72079	LAJAS	PR	41900	San Germán, PR	32420	Mayagüez, PR
72111	PENUELAS	PR	49500	Yauco, PR	38660	Ponce, PR
72121	SABANA GRANDE	PR	41900	San Germán, PR	32420	Mayagüez, PR
72125	SAN GERMAN	PR	41900	San Germán, PR	32420	Mayagüez, PR

County Code	County Name	State	Current CBSA	Current CBSA Name	CBSA Code	CBSA Name
72153	YAUCO	PR	49500	Yauco, PR	38660	Ponce, PR
47057	GRAINGER	TN	34100	Morristown, TN	28940	Knoxville, TN
51510	ALEXANDRIA CITY	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51013	ARLINGTON	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51043	CLARKE	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51047	CULPEPER	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51059	FAIRFAX	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51600	FAIRFAX CITY	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51610	FALLS CHURCH CITY	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51061	FAUQUIER	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51630	FREDERICKSBURG CITY	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51107	LOUDOUN	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51683	MANASSAS CITY	VA	47894	Washington-Arlington-Alexandria,	11694	Arlington-Alexandria-Reston, VA-WV

County Code	County Name	State	Current CBSA	Current CBSA Name	CBSA Code	CBSA Name
				DC-VA-MD-WV		
51685	MANASSAS PARK CITY	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51153	PRINCE WILLIAM	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51157	RAPPAHANNOCK	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51177	SPOTSYLVANIA	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51179	STAFFORD	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51187	WARREN	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
53061	SNOHOMISH	WA	42644	Seattle-Bellevue-Kent, WA	21794	Everett, WA
55059	KENOSHA	WI	29404	Lake County-Kenosha County, IL-WI	28450	Kenosha, WI
54037	JEFFERSON	WV	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV

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We stated in the proposed rule that we identified 68 IPF providers located in the affected counties listed in Table 17. We noted that if providers located in these counties move from one CBSA to another under the revised OMB delineations, there may be impacts, either negative or positive, upon their specific wage index values.

(f) Summary of Comments on the Proposed CBSA Updates for FY 2025

We received mixed comments on the proposal to adopt the revised CBSA delineations. Several commenters recognized the impact of these delineation changes, and some commenters were supportive of this action, while others voiced concerns. In addition, we received comments regarding the permanent 5-percent cap on wage index decrease.

Comment: MedPAC agreed with the 5-percent cap policy and additionally recommended applying a cap on wage index increases of more than 5-percent.

Response: We thank MedPAC for their support and appreciate the suggestion to apply a cap on wage index changes of more than 5-percent to increases in the wage index. However, as we noted in

the FY 2023 IPF PPS proposed rule (87 FR 19424), we believe applying a 5-percent cap on all wage index decreases would support increased predictability about IPF PPS payments for providers, enabling them to more effectively budget and plan their operations. That is, we proposed to cap decreases because we believe that a provider would be able to more effectively budget and plan when there is predictability about its expected minimum level of IPF PPS payments in the upcoming fiscal year. We did not propose to limit wage index increases because we do not believe such a policy is needed to enable IPFs to more effectively budget and plan their operations. Therefore, we believe it is appropriate for providers that experience an increase in their wage index value to receive that wage index value.

Comment: One commenter stated that while they appreciate the 5-percent cap, CMS should implement a 3-year transition period to updated OMB CBSA delineations as we have done in previous OMB CBSA updates.

Response: We appreciate the commenter's feedback; however, we do not agree. In FY 2021 (85 FR 47059), we implemented a 2-year transition to mitigate any negative effects of wage index changes by applying a 5-percent cap on any decrease in an IPF's wage index from the IPF's final wage index from FY 2020.

In the FY 2022 IPF PPS final rule (86 FR 42616 through 42617), we stated that we continued to believe that applying the 5-percent cap transition policy in year one provided an adequate safeguard against any significant payment reductions associated with the adoption of the revised CBSA delineations in FY 2021, allowed for sufficient time to make operational changes for future FYs, and provided a reasonable balance between mitigating some short-term instability in IPF payments and improving the accuracy of the payment adjustment for differences in area wage levels.

In FY 2023 (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. Effective for FY 2025, the adoption of the updates to the OMB delineations announced in OMB Bulletin No. 23–01 will be subject to the 5-percent cap on wage index decreases policy.

As discussed in the FY 2023 IPF PPS final rule (87 FR 46856 through 46859), we continue to believe this methodology will maintain the IPF PPS wage index as a relative measure of the value of labor in prescribed labor market areas, increase predictability of IPF PPS payments for providers, and mitigate instability and significant negative impacts to providers resulting from significant changes to the wage index. Therefore, we do not believe implementing a transition period to updated OMB CBSA delineations effective for FY 2025 is appropriate.

Comment: One commenter recommended that CMS apply the wage index 5-percent cap in a non-budget neutral manner.

Response: CMS did not propose any new policies this year pertaining to the 5-percent cap, and accordingly, we are not finalizing any new policies in this final rule. In accordance with our longstanding policy under the IPF PPS, we updated the wage index in such a way that total estimated payments to IPFs for FY 2025 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 applied the wage index cap in a budget-neutral manner in accordance with this overall budget neutrality policy for the IPF PPS wage index so that wage index changes do not increase aggregate Medicare spending. In the FY 2023 IPF PPS proposed rule (87 FR 19423 through 19425), we noted that applying a 5-percent cap on all wage index decreases would have a very small effect on the wage index budget neutrality factor for FY 2023. We explained that we anticipate that in the absence of proposed policy changes, most providers will not experience year to-year wage index declines greater than 5-percent in any given year and that we expect the impact to the wage index budget neutrality factor in future years will continue to be minimal.

Comment: One commenter stated that both OMB guidance and the Metropolitan Areas Protection and Standardization (MAPS) Act (Pub. L. 117–219) support that, if CMS chooses to adopt new OMB delineations, CMS must fully explain why reliance on the updated CBSAs as set forth by OMB is appropriate for purposes of the FY 2025 wage index adjustments. The commenter asserted that CMS has not provided rationale for why relying on the updated CBSAs is appropriate. Rather than simply adopting the OMB CBSAs by default, the commenter stated that CMS must make a fact-specific determination of those CBSAs' suitability for Medicare reimbursement purposes, including whether it would be appropriate to use additional data to modify OMB's delineation to ensure that such changes are appropriate for purposes of defining regional labor markets for IPF workers.

Response: We acknowledge the commenter's concerns about adopting CBSA changes by default. We do not agree with the commenter's assertion that CMS has not provided rationale for the proposed adoption of the revised CBSA delineations for FY 2025. The MAPS Act specifically states that ''this act limits the automatic application of, and directs the Office of Management and Budget (OMB) to provide information about, changes to the standards for designating a core-based statistical area (CBSA) . . .'' We believe our proposed rule meets the requirements of the MAPS Act, because we have not automatically applied the revised CBSAs outlined in OMB Bulletin 23–01. Rather, as we noted in the proposed rule, we proposed the adoption of the revised CBSA delineations because we believe it is important for the IPF PPS to use, as soon as is reasonably possible, the latest available labor market area delineations to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions. We also stated that using the most current delineations would increase the integrity of the IPF PPS wage index system by creating a more accurate representation of geographic variations in wage levels.

With respect to the suggestion that CMS consider whether it would be appropriate to use additional data to modify OMB's delineation to ensure that such changes are appropriate for purposes of defining regional labor markets for IPF workers, we do not believe use of such additional data is appropriate. As we have previously discussed in the RY 2007 final rule (71 FR 27066) and as we noted earlier in this final rule, 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. Accordingly, we do not believe it would be appropriate to use additional data to modify OMB's delineations for the same reasons we previously stated with regard to floors or reclassifications. For example, using additional data to modify OMB's CBSA delineations would significantly increase administrative burden, both for IPFs and for CMS, associated with particular geographical areas or even individual IPFs moving from one CBSA to another, and it would significantly increase the complexity of the methodology.

Furthermore, because all CBSA delineation changes would be applied budget-neutrally 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 be a departure from our longstanding policies that IPFs have relied on for many years. For these reasons, we continue to believe it is important for the IPF PPS to use the latest available labor market area delineations based on the latest available CBSA delineations established by OMB as soon as is reasonably possible in order to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions.

Comment: One commenter requested that CMS provide a wage index table with the FY 2025 IPF final rule that provides the wage index for each hospital by the Hospital CMS Certification Number (CCN), similar to the Case-Mix Index and Wage Index Table by CCN published for the IPPS rule.

Response: We appreciate the commenter's interest in requesting that CMS publish information about wage index changes at the provider level. However, if CMS were to include a provider-level wage index table for the IPF PPS in rulemaking, we would be concerned that it could create confusion if providers' details change after a file has been published alongside the IPF PPS proposed or final rule, as this information can change throughout the year.

We note that the MACs maintain, on an ongoing basis, detailed information about the location, including the applicable wage index, for each IPF. The MACs also have information as to whether the 5-percent cap is applicable for each individual IPF. IPFs can contact their MACs for provider specific wage index information and any related questions. We note that CMS has provided instructions to the MACs on applying the 5-percent cap policy (see publication 100–04 Medicare Claims Processing Manual, chapter 3).

Final Decision: After consideration of the comments received, we are finalizing our proposal to update the IPF PPS wage index for FY 2025 to reflect the CBSA delineations based on OMB Bulletin 23–01. As we did not propose any changes to our established 5-percent wage index cap policy, we are not finalizing any changes to that policy for FY 2025. We refer readers to section IV.D.1.C of this final rule for a discussion about the proposed 3-year transition policy for providers affected by the loss of the IPF PPS rural adjustment in FY 2025.

c. Adjustment for Rural Location

In the RY 2005 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. As discussed earlier in this rule, we proposed a number of revisions to the patient-level adjustment factors as well as changes to the CBSA delineations. In order to minimize the scope of changes that would impact providers in any single year, we proposed to use the existing regression-derived adjustment factor, which was established in RY 2005, for FY 2025 for IPFs located in a rural area as defined at § 412.64(b)(1)(ii)(C). See the RY 2005 IPF PPS final rule (69 FR 66954) for a complete discussion of the adjustment for rural locations. However, as discussed in the section IV.A of this FY 2025 IPF PPS final rule, we have completed analysis of more recent cost and claims and solicited comments on those results in the FY 2025 IPF PPS proposed rule.

As we explained in the proposed rule, the adoption of OMB Bulletin No. 23–01 in accordance with our established methodology would determine whether a facility is classified as urban or rural for purposes of the rural payment adjustment in the IPF PPS. Overall, we stated that we believe implementing updated OMB delineations would result in the rural payment adjustment being applied where it is appropriate to adjust for higher costs incurred by IPFs in rural locations. However, we noted we recognize that implementing these changes would have distributional effects among IPF providers, and that some providers would experience a loss of the rural payment adjustment because of our proposals. Therefore, we explained that we believe it would be appropriate to consider, as we have in the past, whether a transition period should be used to implement these proposed changes.

In the proposed rule, we explained that prior changes to the CBSA delineations have included a phase-out policy for the rural adjustment for IPFs transitioning from rural to urban status. On February 28, 2013, OMB issued OMB Bulletin No. 13–01, which established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas in the United States and Puerto Rico based on the 2010 Census. We adopted these new OMB CBSA delineations in the FY 2016 IPF final rule (80 FR 46682 through 46689), and identified 105 counties and 37 IPFs that will move from rural to urban status due to the new CBSA delineations. To reduce the impact of the loss of the 17-percent rural adjustment, we adopted a budget-neutral 3-year phase-out of the rural adjustment for existing FY 2015 rural IPFs that became urban in FY 2016 and that experienced a loss in payments due to changes from the new CBSA delineations. These IPFs received two-thirds of the rural adjustment for FY 2016 and one-third of the rural adjustment in FY 2017. For FY 2018, these IPFs did not receive a rural adjustment.

For subsequent adoptions of OMB Bulletin No. 15–01 for FY 2018 (82 FR 36779 through 36780), OMB Bulletin 17–01 for FY 2020 (84 FR 38453 through 38454), and OMB Bulletin 18–04 for FY 2021 (85 FR 47053 through 47059), we identified that fewer providers were affected by these changes than by the changes relating to the adoption of OMB Bulletin 13–01. We did not phase out the rural adjustment when adopting these delineation changes.

In the FY 2025 IPF PPS proposed rule, we explained that for facilities located in a county that transitioned from rural to urban in Bulletin 23–01, we considered whether it will be appropriate to phase out the rural adjustment for affected providers consistent with our past practice of using transition policies to help mitigate negative impacts on hospitals of OMB Bulletin proposals that have a material effect on a number of IPFs. We noted that adoption of the updated CBSAs in Bulletin 23–01 would change the status of 10 IPF providers currently designated as ''rural'' to ''urban'' for FY 2025 and subsequent fiscal years. As such, we explained that these 10 newly urban providers would no longer receive the 17-percent rural adjustment. Consistent with the transition policy adopted for IPFs in FY 2016 (80 FR 46682 through 4668980 FR 46682 through 46689), we proposed a 3-year budget neutral phase-out of the rural adjustment for IPFs located in the 54 rural counties that would become urban under the new OMB delineations, given the potentially significant payment impacts for these IPFs. We stated that we believe a phase-out of the rural adjustment transition period for these 10 IPFs specifically is appropriate because we expect these IPFs would experience a steeper and more abrupt reduction in their

payments compared to other IPFs. Therefore, we proposed to phase out the rural adjustment for these providers to reduce the impact of the loss of the FY 2024 rural adjustment of 17-percent over FYs 2025, 2026, and 2027. We explained that this policy would allow IPFs that are classified as rural in FY 2024 and would be classified as urban in FY 2025 to receive two-thirds of the rural adjustment for FY 2025. For FY 2026, these IPFs would receive one-third of the rural adjustment. For FY 2027, these IPFs would not receive a rural adjustment. We explained that we believe a 3-year budget-neutral phase-out of the rural adjustment for IPFs that transition from rural to urban status under the new CBSA delineations would best accomplish the goals of mitigating the loss of the rural adjustment for existing FY 2024 rural IPFs. We stated that the purpose of the gradual phase-out of the rural adjustment for these providers is to mitigate potential payment reductions and promote stability and predictability in payments for existing rural IPFs that may need time to adjust to the loss of their FY 2024 rural payment adjustment or that experience a reduction in payments solely because of this re-designation. We stated that this policy would be specifically for rural IPFs that become urban in FY 2025. We did not propose a transition policy for urban IPFs that become rural in FY 2025 because these IPFs would receive the full rural adjustment of 17-percent beginning October 1, 2024. We solicited comments on this proposed policy.

We received comments on the proposal to maintain the 17-percent rural adjustment for FY 2025, and the proposal to establish a 3-year budget-neutral transition policy for rural IPFs that become urban in FY 2025. We discuss these comments below. In addition, we refer readers to section V.A of this final rule for a discussion of comments received in response to a request for information about potential future revisions to the IPF PPS facility-level adjustments.

Comment: Several commenters expressed support for maintaining the existing 17-percent rural adjustment for FY 2025, with one commenter agreeing with the importance of mitigating the scope of changes in the payment system in one year. In contrast, one commenter suggested CMS update the rural adjustment for FY 2025 to use the regression-derived adjustment factor as discussed in section IV.C of this final rule. This commenter stated that the impact to facilities of revising the rural adjustment would be relatively small and recommended that CMS adopt a transition policy for all changes to mitigate the impact in a single year. This commenter recommended re-running the regression analysis with more current data before proposing a revision of the rural location adjustment in the future.

Response: We appreciate the comments regarding the proposal to maintain the existing 17-percent rural adjustment for FY 2025. Based on the informational impact analysis discussed in section IV.A of the proposed rule, we have identified that potential changes to the rural adjustment for FY 2025 would have distributional impacts for individual providers, although the overall impact would be budget neutral (that is, 0 percent overall impact). We continue to believe that the most appropriate approach to maintain stability in payments for FY 2025 is to maintain the existing rural adjustment factor, as proposed. We appreciate the thoughtful recommendations for methodological considerations and will take them into consideration for potential future revisions to the rural adjustment.

Comment: Two commenters expressed support for phasing in changes related to the revised CBSA delineations, including the proposal to phase out the rural adjustment for IPFs that would become urban in FY 2025.

Response: We appreciate the support from commenters.

Final Decision: After consideration of the comments received, we are finalizing our proposals to maintain the current 17-percent adjustment for IPFs located in rural areas, and to phase out the rural adjustment for IPFs that will become urban in FY 2025 because of the adoption of the revised CBSA delineations based on OMB Bulletin 23–01. We will apply two-thirds of the rural adjustment for these providers for FY 2025 and one-third of the rural adjustment for FY 2026. For FY 2027, these IPFs will not receive a rural adjustment.

d. Wage Index 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 2025, we proposed to continue to apply a budget neutrality adjustment in accordance with our existing budget neutrality policy. This policy requires us to update the wage index in such a way that total estimated payments to IPFs for FY 2025 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 proposed a budget neutrality factor of 0.9998 in to ensure that the rates reflect the FY 2025 update to the wage indexes (based on the FY 2021 hospital cost report data) and the labor-related share in a budget neutral manner.

Finally, we note that in the April 3, 2024 IPF PPS proposed rule (89 FR 23188), there was a technical error in describing the calculation of the FY 2025 proposed wage index budget neutrality factor. We erroneously stated that on that page that the wage index budget neutrality factor was 0.9995; however, the correct wage index budget neutrality factor base rate was 0.9998, as discussed in section I.B of the same proposed rule (89 FR 23147) and in Addendum A to the proposed rule. To be clear, this error only affected the description of the wage index budget neutrality factor in section IV.D.1.d of the FY 2025 IPF PPS proposed rule, 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.

For this FY 2025 IPF PPS final rule, we use the following steps to ensure that the rates reflect the FY 2025 update to the wage indexes (based on FY 2021 hospital cost report data) and the labor-related share in a budget-neutral manner:

Step 1: Simulate estimated IPF PPS payments, using the FY 2024 IPF wage index values (available on the CMS website) and labor-related share (as published in the FY 2024 IPF PPS final rule (88 FR 51054).

Step 2: Simulate estimated IPF PPS payments using the FY 2025 IPF wage index values (available on the CMS website), and the FY 2025 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 2025 budget neutral wage adjustment factor of 0.9996.

Step 4: Apply the FY 2025 budget neutral wage adjustment factor from step 3 to the FY 2024 IPF PPS Federal per diem base rate after the application of the IPF market basket increase reduced by the productivity adjustment described in section IV.A of this final rule to determine the FY 2025 IPF PPS Federal per diem base rate. As discussed in section IV.F of this final rule, we are also applying a refinement standardization factor to determine the FY 2025 IPF PPS Federal per diem base rate.

2. Teaching Adjustment

Background

In the RY 2005 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 RY 2005 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 that informed the RY 2004 IPF PPS final rule, 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 RY 2005 IPF PPS final rule (69 FR 66954 through 66957) and the RY 2009 IPF PPS notice (73 FR 25721).

We proposed to retain the coefficient value of 0.5150 for the teaching adjustment to the Federal per diem base rate as we did not propose refinements to the facility-level payment adjustments for rural location or teaching status for FY 2025. As noted earlier, given the scope of changes to the wage index and patient-level adjustment factors, we believe this will minimize the total impacts to providers in any given year. We refer readers to section V.A of this final rule for a discussion of comments received in response to a request for information about potential future revisions to the IPF PPS facility-level adjustments.

Comment: Several commenters expressed support for maintaining the existing teaching adjustment for FY 2025, with one commenter agreeing with the importance of mitigating the scope of changes in the payment system in one year. In contrast, one commenter recommended CMS update the rural adjustment for FY 2025 to use the regression-derived adjustment factor as discussed in section IV.C of this final rule. This commenter stated that the impact to facilities of revising the rural adjustment would be relatively small, and recommended that CMS adopt a transition policy for all changes to mitigate the impact in a single year. This commenter recommended re-running the regression analysis with more current data before proposing a revision of the teaching adjustment in the future.

Response: We thank the commenters for their support. Based on the informational impact analysis discussed in section IV.A of the proposed rule, we have identified that potential changes to the teaching adjustment for FY 2025 would potentially have distributional impacts for individual providers, although the overall impact would be budget neutral (that is, 0 percent overall impact). We continue to believe that the most appropriate approach to maintain stability in payments for FY 2025 is to maintain the existing teaching adjustment factor, as proposed. We appreciate the thoughtful recommendations for methodological considerations and will take this into consideration for potential future revisions to the teaching adjustment.

Comment: Two commenters requested that CMS allow affiliation agreements for IPFs, which would permit a facility to share its training cap with other facilities, or that CMS revise the definition of a new training program to allow an originating training facility that closes to transfer its existing program to a new facility. One commenter requested CMS provide teaching cap increases to IPFs who receive section 126 and section 4122 psychiatry residency under the CAA, 2021 and CAA, 2023, respectively. This commenter additionally stated that CMS should remove the teaching cap altogether, citing a national shortage of psychiatrists and their analysis of 2021 and 2022 HCRIS data indicating that IPFs nationally are training 600 residents above their caps.

Response: We appreciate the commenter's suggestion regarding potential changes to the IPF teaching adjustment to recognize new residency slots 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. Section 126 of the CAA, 2021 and Section 4122 of the CAA, 2023 specifically pertain to section 1886(h) and section 1886(d)(5)(B) of the Act, which do not pertain to the IPF PPS. 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.

Final Decision: After consideration of the comments received, we are finalizing as proposed to calculate the teaching adjustment according to our existing methodology and to maintain the existing coefficient value for FY 2025.

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

The IPF PPS includes a payment adjustment for IPFs located in Alaska and Hawaii based upon the area in which the IPF is located. As we explained in the RY 2005 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. As a result of this analysis, we provided a COLA in the RY 2005 IPF PPS final rule. We refer readers to the FY 2024 IPF PPS final rule for a complete discussion of the currently applicable COLA factors (88 FR 51088 through 51089).

We adopted a new methodology to update the COLA factors for Alaska and Hawaii for the IPF PPS in the FY 2015 IPF PPS final rule (79 FR 45958 through 45960). For a complete discussion, we refer readers to the FY 2015 IPF PPS final rule.

We also specified that the COLA updates will be determined every 4 years, in alignment with the IPPS market basket labor-related share update (79 FR 45958 through 45960). 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 finalized an update to the IPF PPS COLA factors to reflect the updated COLA factors finalized in the FY 2022 IPPS/LTCH rulemaking effective for FY 2022 through FY 2025 (86 FR 42621 through 42622). This is reflected in Table 18 below. We proposed to maintain the COLA factors in Table 18 for FY 2025 in alignment with the policy described in this paragraph.

We did not receive any comments on our proposal; we are finalizing the COLA factors for IPFs located in Alaska and Hawaii as proposed.

Table 18: 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 final IPF PPS COLA factors for FY 2025 are also shown in Addendum A to this rule, which is available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html.*

4. Adjustment for IPFs With a Qualifying ED

The IPF PPS includes a facility-level adjustment for IPFs with qualifying EDs. As defined in § 412.402, qualifying emergency department means an emergency department that is staffed and equipped to furnish a comprehensive array of emergency services and meets the requirements of 42 CFR 489.24(b) and § 413.65.

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 critical access hospital (CAH), and the overhead cost of maintaining the ED. This payment applies to all IPF admissions (with one exception which we describe in this section), regardless of whether the patient was admitted through the ED. The ED adjustment is made on every qualifying claim except as described in this section of this final rule. As specified at § 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 RY 2005 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.

For FY 2025, we proposed to update the adjustment factor from 1.31 to 1.53 for IPFs with qualifying EDs using the same methodology used to determine ED adjustments in prior years. We proposed that those IPFs with a qualifying ED would receive an adjustment factor of 1.53 as the variable per diem adjustment for day 1 of each patient stay. If an IPF does not have a qualifying ED, we proposed that it would receive an adjustment factor of 1.27 as the variable per diem adjustment for day 1 of each patient stay. We proposed to apply this revision to the ED adjustment budget-neutrally by applying a refinement standardization factor, and we presented a detailed discussion of the distributional impacts

of this proposed change (89 FR 23154 through 23172).

We solicited comment on this proposal. We also discussed alternative analysis of adjustment factors based on source of admission, which we did not propose to adopt. Lastly, we proposed that if more recent data become available, we would use such data, if appropriate, to determine the FY 2025 ED adjustment factor.

Comment: One commenter erroneously stated that CMS proposed to maintain the existing adjustment factor for IPFs with a qualified ED, and expressed support for doing so, but did not provide a rationale.

Response: We appreciate the comment, but we believe the commenter may have misunderstood the proposal. We proposed to increase the variable per diem adjustment factor for IPFs that have a qualified ED to 1.53, which we believe would appropriately adjust IPF PPS payments to account for differences in costs between IPFs without a qualified ED and those with a qualified ED.

Final Decision: After consideration of the comments received, we are finalizing the proposed revision to the ED adjustment factor following the proposed methodology. Thus, we are finalizing our proposal to use the following steps, as used in prior years, to calculate the updated ED adjustment factor. (A complete discussion of the steps involved in the calculation of the ED adjustment factors can be found in the RY 2005 IPF PPS final rule (69 FR 66959 through 66960) and the RY 2007 IPF PPS final rule (71 FR 27070 through 27072).)

Step 1: Estimate the proportion by which the ED costs of a stay will increase the cost of the first day of the stay. Using the IPFs with ED admissions in years 2019 through 2021, we divided the average ED cost per stay when admitted through the ED ($519.97) by the average cost per day ($1,338.93), which equals 0.39.

Step 2: Adjust the factor estimated in step 1 to account for the fact that we will pay the higher first day adjustment for all cases in the qualifying IPFs, not just the cases admitted through the ED. Since on average, 66 percent of the cases in IPFs with ED admissions are admitted through the ED, we multiplied 0.39 by 0.66, which equals 0.26.

Step 3: Add the adjusted factor calculated in the previous 2 steps to the variable per diem adjustment derived from the regression equation that we used to derive our other payment adjustment factors. As discussed in section IV.C.4.d. of this final rule, the first day payment factor for FY 2025 is 1.28. Adding 0.26, we obtained a first day variable per adjustment for IPFs with a qualifying ED equal to 1.54.

The ED adjustment is incorporated into the variable per diem adjustment for the first day of each stay for IPFs with a qualifying ED. A detailed discussion of the distributional impacts of this proposed change is found in section VIII.C of this final rule.

E. Other 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 RY 2005 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; therefore, reduce the incentives for IPFs to under-serve these patients. We make outlier payments for discharges where 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 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. We proposed to maintain the established 2 percent outlier policy for FY 2025.

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. We note that for FY 2022 and FY 2023 only, we made certain methodological changes to our modeling of outlier payments, and we discussed the specific circumstances that led to those changes for those years (86 FR 42623 through 42624; 87 FR 46862 through 46864). We direct readers to the FY 2022 and FY 2023 IPF PPS proposed and final rules for a more complete discussion.

We proposed to update the IPF outlier threshold amount for FY 2025 using FY 2023 claims data and the same methodology that we have used to set the initial outlier threshold amount each year beginning with the RY 2007 IPF PPS final rule (71 FR 27072 and 27073). Based on an analysis of the December 2023 update of FY 2023 IPF claims, we estimated that IPF outlier payments as a percentage of total estimated payments would be approximately 2.1 percent in FY 2024. Therefore, we proposed to update the outlier threshold amount to $35,590 to maintain estimated outlier payments at 2 percent of total estimated aggregate IPF payments for FY 2025. We noted that the proposed rule update would be an increase from the FY 2024 threshold of $33,470. Lastly, we proposed that if more recent data become available for the FY 2025 IPF PPS final rule, we would use such data as appropriate to determine the final outlier fixed dollar loss threshold amount for FY 2025.

Comment: Three commenters wrote that CMS should seek alternatives to the calculation of the outlier fixed dollar loss threshold. Two commenters suggested that CMS remove IPFs with extremely high or low costs per day, as we did in FY 2022 and FY 2023. One commenter suggested that CMS establish a new outlier baseline that increases each year based on the market basket update or using three-year rolling average to calculate the fixed dollar loss threshold.

Response: We appreciate the suggestions from commenters regarding 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 because we believe the proposed methodology, which follows our longstanding methodology, is the most technically appropriate for maintaining outlier payments at 2 percent of total IPF PPS payments in FY 2025.

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 2025 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 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. Moreover, such a policy would increase outlier payments above the 2-percent target for FY 2025. Likewise, a methodology in which CMS would calculate the IPF PPS outlier threshold based on a three-year rolling average would not effectively target outlier payments at 2 percent of total IPF PPS payments. This is because the outlier threshold in FY 2023 and FY 2024 are lower than the threshold level that our payment simulations suggest would most effectively target outlier payments at 2 percent. Therefore, if we were to use a rolling average to calculate the FY 2025 IPF PPS outlier threshold, such a methodology would likely result in outlier payments that exceed the target.

Final Decision: 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. For this FY 2025 IPF PPS rulemaking, consistent with our longstanding practice, based on an analysis of the latest available data (the March 2024 update of FY 2023 IPF claims) and rate increases, we believe it is necessary to update the fixed dollar loss threshold amount to maintain an outlier percentage that equals 2 percent of total estimated IPF PPS payments. Based on an analysis of these updated data, we estimate that IPF outlier payments as a percentage of total estimated payments are approximately 2.3 percent in FY 2024. Therefore, we are finalizing an update to the outlier threshold amount to $38,110 to maintain estimated outlier payments at 2 percent of total estimated aggregate IPF payments for FY 2025.

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. 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 RY 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 RY 2005 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 RY 2005 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 2025, we proposed to continue following this methodology to update the FY 2025 national median and ceiling CCRs for urban and rural IPFs based on the CCRs entered in the latest available IPF PPS PSF, and we proposed that if more recent data became available, we would use such data to calculate the rural and urban national median and ceiling CCRs for FY 2025. We did not receive any comments on this proposal, and we are finalizing it as proposed.

To determine the final 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 final upper threshold CCR for IPFs in FY 2025 is 2.3181 for rural IPFs, and 1.8287 for urban IPFs, based on current 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.

Specifically, for FY 2025, for each of the three situations listed above, using the most recent CCRs entered in the CY 2023 PSF, we estimate a 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 current CBSA-based geographic designations. A complete discussion regarding the national median CCRs appears in the RY 2005

IPF PPS final rule (69 FR 66961 through 66964).

4. Requirements for Reporting Ancillary Charges and All-Inclusive Status Eligibility Under the IPF PPS

a. Background

As discussed in section IV.E.4.b of this final rule, to analyze variation in cost between patients with different characteristics, it is crucial for us to have complete cost information about each patient, including data on ancillary services provided. Currently, IPFs and psychiatric units are required to report ancillary charges on cost reports. 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.

However, our ongoing analysis has found a notable increase in the number of IPFs, specifically for-profit freestanding IPFs, that appear to be erroneously identifying on form CMS–2552–10, Worksheet S–2, Part I, line 115, as eligible for filing all-inclusive cost reports. These hospitals identifying as eligible for filing all-inclusive cost reports (indicating that they have one charge covering all services) are consistently reporting no ancillary charges or very minimal ancillary charges and are not using charge information to apportion costs in their cost report. Generally, based on the nature of IPF services and the conditions of participation applicable to IPFs, we expect to see ancillary services and correlating charges, such as labs and drugs, on most IPF claims.[3]

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 charges, such as laboratory and drug 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 only pay 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 1 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. We 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. This requirement is still currently in place. For details, we refer readers to see these Transmittals, which are available on the CMS website at *https://www.cms.gov/medicare/regulations-guidance/transmittals.*

Under IPF PPS regulations at § 412.404(e), all inpatient psychiatric facilities paid under the IPF PPS must meet the recordkeeping and cost reporting requirements as specified at § 413.24. Historically, in accordance with § 413.24(a)(1), most hospitals that were approved to file all-inclusive cost reports were Indian Health Services (IHS) hospitals, government-owned psychiatric and acute care hospitals, and nominal charge hospitals. Although IPFs are no longer reimbursed on the basis of reasonable costs, we continue to expect that most IPFs, other than government-owned or tribally owned IPFs, should report cost data that is based on an approved method of cost finding and on the accrual basis of accounting. The option to elect to file an all-inclusive rate cost report is limited to providers that do not have a charge structure and that, therefore, must use an alternative statistic to apportion costs associated with services rendered to Medicare beneficiaries.

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. We refer readers to the Provider Reimbursement Manual (PRM) 15–1; chapter 22, § 2208 for detailed information on the requirements to file an alternative method.

b. Challenges Related to Missing IPF Ancillary Cost Data

In general, most providers allocate their Medicare costs using costs and charges as described at § 413.53(a)(1)(i) and referred to as the Departmental Method, which is the ratio of beneficiary charges to total patient charges for the services of each ancillary department. For cost reporting periods beginning on or after October 1, 1982, the cost report uses the Departmental Method to apportion the cost of the department to the Medicare program. Added to this amount is the cost of routine services for Medicare beneficiaries, determined based on 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); and 15–1, chapter 22, § 2200.1.[4]

We use cost-to-charge ratios (CCRs) from Medicare cost reports as the method of establishing reasonable costs for hospital services and as the basis for ratesetting for several hospital prospective payment systems. In general, detailed ancillary cost and charge information is necessary for accurate Medicare ratesetting. When hospitals identify as all-inclusive, they are excluded from ratesetting because they do not have CCRs but use an alternative basis for apportioning costs. When hospitals erroneously identify as all-inclusive but have a charge structure, data that is necessary for accurate Medicare ratesetting is improperly excluded.

Since the issuance of Transmittal 15, we have continued to identify an increase in the number of IPFs, specifically for-profit freestanding IPFs, that appear to be erroneously identifying on form CMS–2552–10, Worksheet S–2, Part I, line 115, as filing all-inclusive cost reports. 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. The report showed that approximately 23 percent of IPF stays were trimmed from the data set used in

[3] 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.''

[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.''

that analysis because they were stays at facilities where fewer than 5-percent of their stays had ancillary charges. The report is available on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/inpatient-psychiatric-facility/ipf-reports-and-educational-resources.*

Section 4125 of the CAA, 2023 authorizes the Secretary to collect data and information, specifically including charges related to ancillary services, as appropriate to inform revisions to the IPF PPS.

In the FY 2024 IPF PPS proposed rule (88 FR 21270 through 21272), we included a request for information (RFI) related to the reporting of charges for ancillary services, such as labs and drugs, on IPF claims. We were interested in better understanding IPF industry practices pertaining to the billing and provision of ancillary services to inform statutorily mandated IPF PPS refinements. We stated that we were 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.

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. MedPAC stated that it is not known: whether IPFs fail to report ancillary charges separately because they were appropriately 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 fails to furnish the kinds of care reflected in ancillary charges when medically necessary; 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 charges and whether IPFs are providing necessary care and appropriately billing for inpatient psychiatric services under the IPF PPS.

MedPAC also encouraged CMS to require the reporting of ancillary charges and clarify the requirements related to IPFs' ''all-inclusive-rate'' hospital status. MedPAC noted that it observed in cost report data that IPFs that previously were not all-inclusive-rate hospitals have recently changed to an all-inclusive-rate status. MedPAC noted that the timing of many of these changes appears to correspond to CMS's transmittals requiring ancillary services to be reported on cost reports for IPFs that do not have an all-inclusive rate.

Other commenters, including IPFs and hospital associations, responded to the RFI stating that the lack of ancillary charges on claims does not indicate a lack of services being provided. The commenters strongly opposed any claim-level editing and stated that reporting ancillary charges at the claim level would be inefficient and burdensome, particularly for government and IHS all-inclusive hospitals.

c. Clarification of Eligibility Criteria for the Option To Elect To File an All-Inclusive Cost Report

After taking into consideration the feedback we received from both MedPAC and IPF providers, for FY 2025 (89 FR 23193 through 23194) we clarified the eligibility criteria to be approved to file all-inclusive cost reports. We explained that only government-owned or tribally owned facilities are able to satisfy these criteria, and thus only these facilities will be permitted to file an all-inclusive cost report for cost reporting periods beginning on or after October 1, 2024.

We reminded readers that in order to be approved to file an all-inclusive cost report, hospitals must either have an all-inclusive rate (one charge covering all services) or a no-charge structure.[5] We clarified that this does not mean any hospital can elect to have an all-inclusive rate or no-charge structure. Our longstanding policy as discussed in the PRM 15–1, chapter 22, § 2208.1, only allows a hospital to use an all-inclusive rate or no charge structure if it has never had a charge structure in place. In addition, we clarified that our expectation is that any new IPF would have the ability to have a charge structure under which it could allocate costs and charges. As previously stated, only a government-owned or tribally owned facility will be able to satisfy these criteria and will be eligible to file its cost report using an all-inclusive rate or no charge structure.

We stated that for cost reporting periods beginning on or after October 1, 2024, we will issue instructions to the MACs and put in place edits to operationalize our longstanding policy that only government-owned or tribally owned IPF hospitals are permitted to file an all-inclusive cost report. We explained that all other IPF hospitals must have a charge structure and must report ancillary costs and charges on their cost reports. IPFs that have previously filed an all—inclusive cost report erroneously will no longer be able to do so. We further noted that to the extent government-owned or tribally owned hospitals can report ancillary charges on their cost reports, we strongly encourage them to do so to allow CMS to review and analyze complete and accurate data.

We stated that we believe clarifying the current eligibility criteria to be approved to file all-inclusive cost reports and implementing these operational changes will appropriately require freestanding IPFs with the ability to have a charge structure, that is, all IPFs other than those which are government-owned or tribally owned, to track and report ancillary charge information. In addition, we stated that we expect that more IPFs reporting ancillary charge information will result in an increase of IPFs having a CCR, which will in turn result in an increased number of IPFs being included in ratesetting. Therefore, we explained that we believe these operational changes will improve the quality of data reported, which will result in increased accuracy of future payment refinements to the IPF PPS.

Furthermore, we explained that we believe collecting charges of ancillary services from freestanding IPFs supports the directive for competition under the Executive Order on Promoting Competition in the American Economy as it facilitates accurate payment, cost efficiency, and transparency.[6] We received several comments regarding this clarification and the operational changes discussed in the FY 2025 IPF PPS proposed rule.

Comment: Overall, commenters understood the clarification that only a government-owned or tribally owned facility will be able to satisfy these criteria and will be eligible to file its cost report using an all-inclusive rate or no charge structure. However, many commenters requested that CMS be lenient with facilities as they transition, and extend the date for compliance to October 1, 2026. A few commenters stated that reporting ancillary costs would require major changes to internal systems to efficiently track ancillary costs.

Response: We appreciate commenters' understanding of the importance of reporting ancillary costs on cost reports. As discussed in the proposed rule, the requirement that cost reports from psychiatric hospitals, except all-inclusive rate providers, include certain

[5] PRM 15–1, chapter 22, § 2208.1.

[6] *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09executive-order-on-promoting-competition-in-the-american-economy/.*

ancillary costs is currently in place. For a hospital to be eligible to file an all-inclusive cost report, they must require the use of an alternative statistic to apportion costs associated with services rendered to Medicare beneficiaries due to not having a charge structure. These requirements have been discussed through prior rulemaking, transmittals, a technical report, and MedPAC meetings and reports.

We remind readers that implementing the proposed operational changes to limited all-inclusive cost reporting would, at the earliest, affect cost reports submitted after October 1, 2025. This means that affected IPFs would have at least one year to make operational changes. While we acknowledge the concerns from commenters regarding systems changes needed to track ancillary costs, we believe putting in place edits for cost reporting periods beginning on or after October 1, 2024, to operationalize our longstanding policy provides IPF hospitals sufficient time to generally track and submit the ancillary cost and charge information.

Comment: Some commenters noted that the absence of ancillary costs on cost reports does not correlate to the assumption that ancillary services were not provided to the patient. The commenters stated that filing all-inclusive cost reports is a matter of efficiency to reduce administrative burden and cost. Commenters also expressed that they do not believe reporting ancillary costs has a direct influence on payment.

Response: We understand the lack of reported ancillary costs may not necessarily correlate with the services not being provided; however, based on the nature of IPF services and the conditions of participation applicable to IPFs, we expect to see ancillary services and correlating charges, such as labs and drugs, on most IPF claims. We believe IPFs are providing these necessary services to patients; however, the information currently reported does not provide evidence to this effect. In regard to commenters who stated that filing all-inclusive cost reports is a business decision for efficiency and to reduce administrative burden, filing correct cost reports should not be a new burden as this has always been required under Medicare. Furthermore, as mentioned above, we believe maintaining an accurate charge structure would be part of a business's accounting for reordering and restocking pharmaceuticals at a minimum, as well as more accurate payment for the purposes of outlier payments. As we mention above, these requirements have been discussed through prior rulemaking, transmittals, a technical report, and MedPAC meetings and reports.

Further, we disagree with the commenters' assertion that reporting ancillary costs does not have a direct influence on payment. As discussed in section IV.C.3.c of this final rule, we analyzed ancillary cost and charge data to inform our proposed FY 2025 refinements to the IPF PPS. In addition, in section and III.C.4.b if this final rule, we solicited comments on whether a lack of ancillary charge data may be contributing to the results of our regression analysis as it relates to opioid use disorders. For future refinements of the IPF PPS, such as those related to the patient assessment instrument as discussed in section V.B. of this final rule, the quality of the analyses of patient-level costs that CMS performs will ultimately depend on the quality of data that IPFs report.

Final Decision: After consideration of the comments received, we are putting in place operational edits to allow only those freestanding IPFs that are government-owned, IHS- or tribally owned facilities, to submit an all-inclusive cost report, effective for cost reporting periods beginning on or after October 1, 2024. Therefore, all other IPFs are required to have a charge structure and must report costs and charges for inpatient psychiatric services. We believe that collecting, and subsequently analyzing, detailed ancillary data from additional IPF hospitals will allow us to increase the accuracy of the IPF PPS.

F. Refinement Standardization Factor

Section 1886(s)(5)(D)(iii) of the Act, as added by section 4125(a) of the CAA, 2023, states that revisions in payment implemented pursuant to section 1886(s)(5)(D)(i) for a rate year shall result in the same estimated amount of aggregate expenditures under this title for psychiatric hospitals and psychiatric units furnished in the rate year as would have been made under this title for such care in such rate year if such revisions had not been implemented. We interpret this to mean that revisions in payment adjustments implemented for FY 2025 (and for any subsequent fiscal year) must be budget neutral.

Historically, we have maintained budget neutrality in the IPF PPS using the application of a standardization factor, which is codified in our regulations at § 412.424(c)(5) to account for the overall positive effects resulting from the facility-level and patient-level adjustments. As discussed in section IV.B.1 of this final rule, section 124(a)(1) of the BBRA required that we implement the IPF PPS in a budget neutral manner. In other words, the amount of total payments under the IPF PPS, including any payment adjustments, must be projected to be equal to the amount of total payments that would have been made if the IPF PPS were not implemented. Therefore, we calculated the standardization factor by setting the total estimated IPF PPS payments, taking into account all of the adjustment factors under the IPF PPS, to be equal to the total estimated payments that would have been made under the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) (Pub. L. 97–248) methodology had the IPF PPS not been implemented. A step-by-step description of the methodology used to estimate payments under the TEFRA payment system appears in the RY 2005 IPF PPS final rule (69 FR 66926).

We believe the budget neutrality requirement of section 4125(a) of the CAA, 2023 is consistent with our longstanding methodology for maintaining budget neutrality under the IPF PPS. Therefore, for FY 2025, we proposed to apply a refinement standardization factor in accordance with our existing policy at § 412.424(c)(5). This policy requires us to update IPF PPS patient-level adjustment factors, ED adjustment, and ECT per treatment amount as proposed in FY 2025 IPF PPS proposed rule, in such a way that total estimated payments to IPFs for FY 2025 are the same with or without the changes (that is, in a budget neutral manner) by applying a refinement standardization factor to the IPF PPS rates. We proposed to apply a refinement standardization factor of 0.9514 to the IPF PPS federal per diem base rate and ECT per treatment amount to maintain budget neutrality.

We did not receive any comments on our proposed methodology for applying a refinement standardization factor. We are finalizing our proposal to use the following steps to ensure that the rates reflect the FY 2025 update to the patient-level adjustment factors (as previously discussed in section IV.C and IV.D of this final rule, and summarized in Addendum A) in a budget neutral manner:

Step 1: Simulate estimated IPF PPS payments using the FY 2024 IPF patient-level and facility-level adjustment factor values and FY 2024 ECT payment per treatment (available on the CMS website).

Step 2: Simulate estimated IPF PPS payments using the FY 2025 IPF patient-level and facility-level adjustment factor values (see Addendum A of this final rule, which

is available on the CMS website) and ECT per treatment amount based on the CY 2022 geometric mean cost for ECT under the OPPS.

Step 3: Divide the amount calculated in step 1 by the amount calculated in step 2. The resulting quotient is the final FY 2025 refinement standardization factor of 0.9524.

Step 4: Apply the FY 2025 refinement standardization factor from step 3 to the FY 2024 IPF PPS Federal per diem base rate and ECT per treatment amount (based on the CY 2022 geometric mean cost for ECT under the OPPS), after the application of the wage index budget neutrality factor and the IPF market basket increase reduced by the productivity adjustment described in section IV.A of this final rule to determine the FY 2025 IPF PPS Federal per diem base rate and FY 2025 ECT payment amount per treatment.

V. Requests for Information (RFI) To Inform Future Revisions to the IPF PPS in Accordance With the CAA, 2023

In the FY 2025 IPF PPS proposed rule, we requested information on two main topics to inform future revisions to the IPF PPS, in accordance with the CAA, 2023. First, we requested information regarding potential revisions to the IPF PPS facility-level adjustments. Second, we requested information regarding the development of a patient assessment instrument under the IPFQR program.

A. Request for Information Regarding Revisions to IPF PPS Facility-Level Adjustments

In section IV of the FY 2025 IPF PPS proposed rule (89 FR 23194 through 23200), we described the results of our latest analysis and requested public comment on them. Specifically, we presented the latest results of our analysis of the adjustments for rural location and teaching status, as well as a potential new adjustment for safety net population. We explained that the potential inclusion of a safety net adjustment could affect the magnitude of the adjustment factors for rural and teaching status, and we noted that future additional data and analysis may produce results that differ from those presented in the proposed rule. Lastly, we presented informational data about the distributional impacts of adopting such adjustment factors for the IPF PPS. We refer readers to the proposed rule for detailed description and explanation of these regression analyses and results.

In the proposed rule, we solicited comments on the following topics:

- Would it be appropriate to consider proposing revisions to the IPF PPS facility-level adjustments for rural location and teaching status in the future based on the results of our latest regression analysis?
- Should we consider adjusting payment using MedPAC's Medicare Safety Net Index (MSNI) formula with adaptations, as described in the proposed rule? What, if any, changes to the methodology should we consider for the IPF setting? For example, should we develop a separate payment adjustment for each component (that is, the low-income ratio, uncompensated care ratio, and Medicare dependency ratio)?
- We note that our construction of the MSNI did not scale or index facility-level variables to a national standard or median value. We anticipate that doing so would result in less of a change to the IPF Federal per diem base rate but would still result in comparable distributional impacts (that is, IPFs with lower MSNIs would receive lower payments, and IPFs with higher MSNIs would receive higher payments). Should we consider scaling or indexing the MSNI to a national average MSNI for all IPFs?
- Is MedPAC's MSNI formula, as adapted, an accurate and appropriate measure of the extent to which an IPF acts as a safety-net hospital for Medicare beneficiaries?
- Should additional data be collected through the cost report to improve the calculation of MSNI, such as collecting UCC and revenue at the IPF unit level?
- Is the current cost report data submitted by IPFs sufficiently valid and complete to support the implementation of an MSNI payment? We note our concerns about the low or non-existent amounts reported for uncompensated care for freestanding IPFs and the use of hospital-level UCC and revenue amounts to calculate the UCC ratio for IPF units.
- What administrative burden or challenges might providers face in reporting their UCC and low-income patient stays?
- Would IPFs have the information necessary to report their low-income patient stays to CMS for the purpose of the MSNI calculation? What challenges might IPFs face in gathering and reporting this information?
- In the FY 2023 IPPS proposed rule, CMS noted that, when calculating the MSNI, the following circumstances may be encountered: new hospitals (for example, hospitals that begin participation in the Medicare program after the available audited cost report data), hospital mergers, hospitals with multiple cost reports and/or cost reporting periods that are shorter or longer than 365 days, cost reporting periods that span fiscal years, and potentially aberrant data. How should CMS consider addressing these circumstances when calculating the MSNI for IPFs?

Comment: Several commenters supported refinements to the rural location and teaching status adjustors as described in the RFI. Some commenters recommended CMS continue to analyze more recent data to ensure that the updated regression model will have similar outcomes.

Response: We appreciate the information and feedback provided and will take these comments into consideration for future rulemaking.

Comment: Several commenters supported the development of a payment adjustment for safety net population. Two of these commenters expressed concerns that the available data is insufficient for implementation of an adjustment for MSNI as described in the RFI.

The majority of commenters who responded to the RFI about a payment adjustment for MSNI opposed the addition of this adjustment factor under the construction presented in the proposed rule because of insufficient data to support the adjustment because of the substantial decrease to the base rate or because of the redistribution of resources away from IPFs with a low MSNI. Several of these commenters, concerned that the adjustment would substantially decrease the base rate, noted that a decrease of this size would have unintended consequences such as further reducing access to care. Some commenters noted concerns that the inclusion of an MSNI adjustment would reduce the size of the rural adjustment, while other commenters noted that the adjustment would reduce the teaching adjustment. A couple of commenters recommended developing a DSH payment for IPFs as an alternative to MSNI. About half of these commenters advocated for an MSNI adjustment that is not budget neutral (*i.e.* that comes from an additional funding source), while one advocated for separate payment adjustments for each factor of MSNI (the low-income ratio, uncompensated care ratio, and Medicare dependency ratio). One of these commenters suggested a bonus value-based payment tied to quality measures for facilities serving high proportions of dually eligible beneficiaries.

MedPAC supported CMS's efforts to develop an adjustment factor based on MSNI. They recommended that CMS analyze whether a facility's low-income subsidy (LIS) and Medicare share of days are correlated with higher costs and lower profit margins, noting that factors that are important for identifying

safety-net acute care hospitals may not be exactly the same for IPFs. They also recommend that CMS require IPFs to report uncompensated care before implementing an adjustment factor including uncompensated care. MedPAC further advocated for investigation of an appropriate cap on changes; they suggest normalizing MSNI and basing each IPF's adjustment on the difference between the IPF's MSNI and the national MSNI.

Response: We appreciate the information and feedback provided and will take these comments into consideration for future rulemaking.

B. Request for Information (RFI)—Patient Assessment Instrument Under IPFQR Program (IPF PAI) To Improve the Accuracy of the PPS

Section 4125(b)(1) of CAA, 2023 amended section 1886(s)(4) of the Act, by inserting a new paragraph (E), to require IPFs participating in the IPFQR Program to collect and submit to the Secretary certain standardized patient assessment data, using a standardized patient assessment instrument (PAI) developed by the Secretary, for RY 2028 (FY 2028) and each subsequent rate year. IPFs must submit such data with respect to at least the admission to and discharge of an individual from the IPF, or more frequently as the Secretary determines appropriate. For IPFs to meet this new data collection and reporting requirement for RY 2028 and each subsequent rate year, the Secretary must implement a standardized PAI that collects data with respect to the following categories: functional status; cognitive function and mental status; special services, treatments, and interventions for psychiatric conditions; medical conditions and comorbidities; impairments; and other categories as determined appropriate by the Secretary. This IPF–PAI must enable comparison of the patient assessment data across all IPFs which submit these data. In other words, the data must be standardized such that data from IPFs participating in the IPFQR Program can be compared; the IPF–PAI each IPF administers must be made up of identical questions and identical sets of response options to which identical standards and definitions apply.

As we develop the IPF–PAI, in accordance with these new statutory requirements, we seek to collect information that will help us achieve the following goals: (1) improve the quality of care in IPFs, (2) improve the accuracy of the IPF PPS in accordance with section 4125(b)(2) of CAA, 2023, and (3) improve health equity.[7] In the Request for Information (RFI) we included in the FY 2025 IPF PPS proposed rule (89 FR 23200 through 23204), we solicited comments for development of this IPF–PAI, in accordance with these new statutory requirements, and to achieve these goals.

The RFI consisted of four sections. The first section discussed a general framework or set of principles for development of the IPF–PAI. The second section outlined potential approaches that could be used to develop the items or data elements that make up the PAI. This section also discussed patient assessment data elements in use in PAIs for skilled nursing facilities and other healthcare settings that could potentially be adapted for use in the IPF–PAI. The third section outlined potential approaches that could be used to collect patient assessment data. Finally, the fourth section solicited public comment on the principles and approaches listed in the first three sections and sought other input regarding the IPF–PAI.

1. Framework for Development of the IPF–PAI

We considered similar legislatively derived PAIs previously implemented for certain post-acute care (PAC) providers to inform the goals and guiding principles for the IPF–PAI because of similarities of section 4125(b) of CAA, 2023 to the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (Pub. L. 113–185, October 6, 2014), codified at section 1899B of the Act. Similar to section 4125(b) of CAA, 2023, section 1899B of the Act requires certain PAC providers, specifically home health agencies (HHAs), skilled nursing facilities (SNFs), inpatient rehabilitation facilities (IRFs), and long-term care hospitals (LTCHs), to submit certain standardized patient assessment data (as set forth at section 1899B(b)(1)(B)) using a standardized PAI under the PAC providers' respective quality reporting programs. While IPFs are acute care providers and not PAC providers, given the similarities between the CAA, 2023 and section 1899B of the Act, we considered the goals and guiding principles that we followed to implement section 1899B of the Act for certain PAC providers and examined their applicability and appropriateness for IPFs.

We previously identified four key considerations when assessing Standardized Patient Assessment Data Elements for the PAC PAIs to collect: (1) Overall clinical relevance; (2) Interoperable exchange to facilitate care coordination during transitions in care; (3) Ability to capture medical complexity and risk factors that can inform both payment and quality; and (4) Scientific reliability and validity, general consensus agreement for its usability.[8] For the reasons discussed in the following subsections, we believe that these considerations are also appropriate for the development of the IPF–PAI. In addition, we seek to balance the need to collect meaningful patient data to improve care with the need to minimize administrative burden. The remainder of this section describes each of these considerations in the context of the IPF–PAI. As we discuss in section V.B.4.a of this final rule, we solicited comment on these considerations.

a. Overall Clinical Relevance

In each category of assessment required by section 1886(s)(4)(E)(ii), as added by section 4125(b) of CAA, 2023, (functional status; cognitive function and mental status; special services, treatments, and interventions for psychiatric conditions; medical conditions and comorbidities; impairments, and other categories as determined appropriate by the Secretary), we seek to establish Standardized Patient Assessment Data Elements that providers can use to support high quality care and outcomes in the IPF setting. As we evaluate Standardized Patient Assessment Data Elements in PAIs designed for other care settings, we intend to work with CMS Medical Officers, including

[7] For more information on our strategic goals to improve health equity by expanding the collection, reporting, and analysis of standardized data, we refer readers to Priority 1 of our Framework for Health Equity at *https://www.cms.gov/priorities/health-equity/minority-health/equity-programs/framework.*

[8] We refer readers to the Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities; Updates to the Quality Reporting Program and Value-Based Purchasing Program for Federal fiscal year 2020 final rule (84 FR 38767); the Medicare Program; Inpatient Rehabilitation Facility (IRF) Prospective Payment System for Federal fiscal year 2020 and Updates to the IRF Quality Reporting Program final rule (84 FR 39110), the Medicare and Medicaid Programs; CY 2020 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; Home Health Quality Reporting Requirements; and Home Infusion Therapy Requirements CY 2020 final rule (84 FR 60567), and the Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and fiscal year 2020 Rates; Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Promoting Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals final rule (84 FR 42537).

psychiatrists, to consider the clinical relevance for IPF patients as a determining factor in whether an item merits inclusion in the IPF–PAI. For an example of a PAI in use in another setting, we refer readers to the IRF–PAI instrument available at *https://www.cms.gov/files/document/irf-pai-version-40-eff-10012022-final.pdf.* We are particularly interested in learning about specific instruments and tools in each area of assessment that have high clinical relevance in the IPF setting and welcomed comments regarding Standardized Patient Assessment Data Elements that may not be clinically relevant to the IPF setting.

To ensure the clinical relevance of the instrument across a diverse group of IPF patients, we are considering structuring the assessment with conditional questions, so that certain sets of questions are only indicated if the questions are relevant to the patient. Furthermore, we note that some data elements may only be appropriate for collection at certain times during the patient's stay (for example, only at admission or only at discharge). We solicited comments regarding the most effective structure to employ in the development of the IPF–PAI.

b. Interoperability

Interoperability is a key priority and initiative at CMS. Across the organization, we aim to promote the secure exchange, access, and use of electronic health information to support better informed decision making and a more efficient healthcare system. As a part of this effort, we make interoperability a priority for standardized data collection. We intend to ensure that the IPF–PAI meets Health Level 7® (HL7®) Fast Healthcare Interoperability Resources® (FHIR®) standards.

As part of our interoperability considerations, we are interested in whether Standardized Patient Assessment Data Elements already in use in the CMS Data Element Library (DEL) [9] are appropriate and clinically relevant for the IPF setting. Based on our analysis of IPF PPS claims submitted in CY 2021, approximately 8,000 admissions to IPFs were individuals transferred from SNFs or IRFs. We are interested in whether Standardized Patient Assessment Data Elements already used in the DEL can be used to better support interoperability between providers, given the high number of transfers.

[9] *https://del.cms.gov/DELWeb/pubHome.*

c. Ability To Capture Medical Complexity and Risk Factors

We intend to expand our efforts to refine the IPF PPS to increase the accuracy of the payment system by better identifying patient characteristics that best predict resource use during an IPF stay. To identify Standardized Patient Assessment Data Elements that would help predict resource use, we intend to evaluate Standardized Patient Assessment Data Elements for their ability to explain medical complexity, the need for special services and treatments, and to measure case-mix differences that impact costs. It is our expectation that an IPF–PAI that effectively differentiates treatment needs between patients will also help IPFs plan and distribute their resources. Our hope is that the IPF–PAI can therefore integrate with IPFs' business practices. In addition, Standardized Patient Assessment Data Elements that capture patient risk factors can contribute to quality of care and patient safety.

d. Scientific Reliability and Validity

Standardized Patient Assessment Data Elements considered for inclusion in the IPF–PAI must be scientifically reliable and valid in IPF settings.[10] We intend to draw on our significant experience in development of quality measures in the IPFQR Program and development of Standardized Patient Assessment Data Elements for other PAIs, such as the IRF–PAI and the Minimum Data Set (MDS) (the PAI for SNFs), in our development of Standardized Patient Assessment Data Elements for the IPF–PAI.[11] It is important to note that the statutorily required timeframe for implementation of the IPF–PAI for RY 2028 limits our ability to develop and test a full battery of new Standardized Patient Assessment Data Elements for the launch of the IPF–PAI. We anticipate the need and opportunity for incremental revisions to the IPF–PAI in the future.

We anticipate that our development process for new Standardized Patient Assessment Data Elements will include working with teams of researchers for each category including a group of advisors made up of clinicians and academic researchers for each team with expertise in IPFs. We expect to convene a Technical Expert Panel (TEP) to provide expert input on new and existing Standardized Patient Assessment Data Elements that merit consideration for inclusion and testing, including environmental scans and reviews of scientific literature. In an ideal scenario, Standardized Patient Assessment Data Elements would be tested in a representative sample of IPFs for appropriateness in different IPF settings and across a range of patients. Standardized Patient Assessment Data Elements would be tested for inter-rater (that is, consistency in results regardless of who is administering the assessment) and inter-organizational reliability, for validity in all IPF settings, for internal consistency, and for breadth of application among a range of IPF patients. We anticipate that Standardized Patient Assessment Data Elements would also need to be tested for their ability to detect differences among patients and costs of treatment. Due to the constraints of the statutorily required implementation timeframe, it may not be possible to complete all testing before launching the IPF–PAI.

The process for scientifically testing each question and set of responses is lengthy and resource-intensive. This process is based on the steps for quality measure development described in the Blueprint Measure Lifecycle,[12] developed by the CMS Measures Management System. These steps include literature review and environmental scanning; various levels of field testing to understand the ''real world'' performance of the data elements; and iterative expert and interested parties engagement to include broader perspectives on topics, candidate data elements, and interpretation of testing results. If appropriate, using data currently collected by IPFs or Standardized Patient Assessment Data Elements that have been tested and validated for use in other clinical settings can reduce these timeframes because test data are already available.

[10] CMS' guidelines for data element identification and evaluation, including definitions of scientific acceptability (*i.e.,* reliability and validity) are described in the Blueprint Measure Lifecycle, available at: *https://mmshub.cms.gov/measure-lifecycle/measure-testing/overview.*

[11] For more information on other PAIs, we refer readers to *https://www.cms.gov/medicare/payment/prospective-payment-systems/inpatient-rehabilitation/pai* (for the IRF–PAI), to *https://www.cms.gov/medicare/quality/home-health/oasis-data-sets* (for the OASIS data set for HHAs), to *https://www.cms.gov/medicare/quality/long-term-care-hospital/ltch-care-data-set-ltch-qrp-manual* (for the CARE data set for LTCHs), and to *https://www.cms.gov/medicare/quality/nursing-home-improvement/resident-assessment-instrument-manual* (for the Minimum Data Set (MDS) Resident Assessment Instrument (RAI)).

[12] *https://mmshub.cms.gov/blueprint-measure-lifecycle-overview.*

e. Administrative Burden

In evaluating Standardized Patient Assessment Data Elements for inclusion in the IPF–PAI, we are considering the burden of data collection through the PAI and aiming to minimize additional burden by considering whether any data that is currently collected through IPFQR Program measures or on IPF claims could be collected as Standardized Patient Assessment Data Elements to avoid duplication of data that IPFs are already reporting. We are also considering how collecting some data for some IPFQR Program measures through the IPF–PAI and collecting other data through the Hospital Quality Reporting (HQR) system would affect the reporting burden for participating IPFs. Licensing, permissions costs, or copyright restrictions that would add to administrative costs and burdens are also a consideration as we evaluate existing PAIs and mechanisms or tools for submitting IPF–PAI data.

As we develop the IPF–PAI, we are interested in receiving information about how to find a balance between collecting the most relevant and useful information and the administrative burden of administering the assessment and submitting the assessment data.

2. Elements of the IPF–PAI

Section 1886(s)(4)(E)(ii) of the Act, added by section 4125(b)(1)(C) of the CAA, 2023, requires that the standardized patient assessment data to be collected in the IPF–PAI must be with respect to six enumerated categories.

a. Functional Status

The first enumerated category of data for the IPF–PAI is functional status. Section 1886(s)(4)(E)(ii)(I) of the Act provides that functional status may include mobility and self-care at admission to a psychiatric hospital or unit and before discharge from a psychiatric hospital or unit. We note that information in this category is generally found in a patient's discharge summary and are interested in learning about standardized elements that correspond to functional status as relevant to IPFs. In the FY 2025 IPF PPS proposed rule, we stated our interest in learning about assessments that may be currently in use in the IPF setting and meet criteria for inclusion in the IPF–PAI (89 FR 23202).

b. Cognitive Function and Mental Status

The second enumerated category of data for the IPF–PAI is cognitive function and mental status. Section 1886(s)(4)(E)(ii)(II) of the Act provides that cognitive function may include the ability to express ideas and to understand, and mental status may include depression and dementia. We note that in the IPF setting, a patient's diagnoses, which can be abstracted from their medical chart, provide some information related to this category. We are aware that IPFs may be currently assessing cognitive function using existing instruments. In the FY 2025 IPF PPS proposed rule, we stated our interest in hearing from IPFs about which instruments are currently in use to measure cognitive function in IPFs and which have high clinical relevance for the IPF setting (89 FR 23202).

c. Special Services, Treatments, and Interventions

The third enumerated category of data for the IPF–PAI is special services, treatments, and interventions for psychiatric conditions. Section 1886(s)(4)(E)(ii)(III) of the Act neither addresses what these terms mean nor provides any illustrative examples. As discussed in section VII.C. of this rule, the IPFQR Program already collects information about the use of restraint and seclusion through quality measures (Hospital Based Inpatient Psychiatric Services (HBIPS)-2, Hours of Physical Restraint, and HBIPS–3, Hours of Seclusion Use), while claims include information about ECT treatments provided. Other areas of interest in this category may include high-cost medications, use of chemical restraints, one-to-one observation, and high-cost technologies. In the FY 2025 IPF PPS proposed rule, we stated our interest in whether these or any other special services, treatments, or interventions should be considered for inclusion in the IPF–PAI (89 FR 23202 through 23203).

d. Medical Conditions and Comorbidities

The fourth enumerated category of data for the IPF–PAI is medical conditions and comorbidities. Section 1886(s)(4)(E)(ii)(IV) of the Act provides that medical conditions and comorbidities may include diabetes, congestive heart failure, and pressure ulcers. We note that IPF claims record a significant number of medical conditions and comorbidities to receive the payment adjustment for comorbidities in the IPF PPS and conditions that are relevant to the IPF stay. In reviewing Standardized Patient Assessment Data Elements listed in this category in PAIs in use in PAC settings, we observed that these PAIs include Standardized Patient Assessment Data Elements regarding pain interference in this category, such as the effect of pain on sleep, pain interference with therapy activities, and pain interference with day-to-day activities. In the FY 2025 IPF PPS proposed rule, we stated our interest in learning from commenters whether these existing data elements from the PAC settings would be clinically relevant for inclusion in this category for the IPF–PAI (89 FR 23203).

e. Impairments

The fifth enumerated category of data for the IPF–PAI is impairments. Section 1886(s)(4)(E)(ii)(V) of the Act provides that impairments may include incontinence and an impaired ability to hear, see, or swallow. PAIs in use in other settings include Standardized Patient Assessment Data Elements regarding hearing and vision (for example, Section B, ''Hearing, Speech, and Vision'' of the IRF–PAI Version 4.2 (Effective October 1, 2024)).[13] In the FY 2025 IPF PPS proposed rule, we stated our interest both in whether Standardized Patient Assessment Data Elements regarding additional impairments merit consideration for the IPF–PAI, and whether the Standardized Patient Assessment Data Elements regarding hearing and vision included in the IRF–PAI are appropriate for the IPF setting (89 FR 23203). We note that the Standardized Patient Assessment Data Element categories are not intended to be duplicative, so we would seek to avoid any overlap in measuring cognitive deficits in the Cognitive Function category with the Impairments category.

f. Other Categories Deemed Appropriate

The sixth enumerated category of data for the IPF–PAI is other categories as determined appropriate by the Secretary. We believe this provision allows for flexibility to include additional areas in the IPF–PAI.

One of our strategic priorities, as laid out in the CMS Strategic Plan,[14] reflects our deep commitment to improvements in health equity by addressing the health disparities that underlie our health system. In line with that strategic priority, in the FY 2025 IPF PPS proposed rule, we stated our interest in Standardized Patient Assessment Data Elements that would provide insight about any demographic factors (for example, race, national origin, primary language, ethnicity, sexual orientation, and gender identity) as well as Social Drivers of Health (SDOH) (for example, housing status and food security)

[13] *https://www.cms.gov/files/document/irf-pai-version-42-effective-10-01-24.pdf.*

[14] The CMS Strategic Plan. Available at *https://www.cms.gov/about-cms/what-we-do/cms-strategic-plan*. Accessed February 20, 2024.

associated with underlying inequities (89 FR 23203). We also stated our interest in whether there are Standardized Patient Assessment Data Elements that would provide insight into special interventions that IPFs are providing to support patients after discharge which could serve to potentially reduce the incidence of readmissions (89 FR 23203).

We note that, beginning with mandatory reporting of CY 2025 data for FY 2027 payment determination, the IPFQR Program includes the Screening for SDOH measure, which assesses the percentage of patients, aged 18 years and over at the time of admission, who are screened for five specific health-related social needs (HRSNs) (food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety) but which does not require reporting of that information at the patient-level (88 FR 51117). Furthermore, we note that PAIs adopted for the PAC settings discussed previously include collection of SDOH data under section 1899B(b)(1)(B)(vi) of the Act, which contains a similar provision for other categories deemed appropriate by the Secretary.[15]

We note that, if we deem it appropriate to add a SDOH category for the IPF–PAI and these SDOH data are included as Standardized Patient Assessment Data Elements in the PAI, they could potentially be used to risk adjust or stratify measures collected for the IPFQR Program. In the FY 2025 IPF PPS proposed rule, we stated our interest in learning whether using some of these SDOH data adopted in other PAIs to risk adjust or stratify these measures would make the measures in the IPFQR Program more meaningful (89 FR 23203).

3. Implementation of the PAI—Data Submission

We plan to develop flexible methods for providers to submit IPF–PAI data to CMS, including batch uploads in specified formats and a portal for submission of files. We welcomed public comment on tools and methods for submission of data that balance administrative burden and ease of use.

4. Request for Information on IPF–PAI

In the FY 2025 IPF PPS proposed rule, we requested information from the public to inform the selection of Standardized Patient Assessment Data Elements to be collected on the IPF–PAI and the implementation process (89 FR 23203). We sought information about PAIs IPFs currently use upon admission and discharge, as well as information about how IPFs estimate resource needs to determine capacity before a patient is admitted. We also sought information about methods for IPFs to submit patient assessment data and the potential administrative burden on IPFs, Medicare Administrative Contractors (MACs), and CMS. Finally, we sought input on the relationship between the IPF–PAI and the measures within the IPFQR Program.

We solicited comment on the following topics:

a. Principles for Selecting Standardized Patient Assessment Data Elements

- To what extent do you agree with the principles for selecting and developing Standardized Patient Assessment Data Elements for the IPF–PAI?
- What, if any, principles should CMS eliminate from the Standardized Patient Assessment Data Element selection criteria?
- What, if any, principles should CMS add to the Standardized Patient Assessment Data Element selection criteria?

Comment: Several commenters were supportive of the idea of implementing a patient assessment for the IPF setting. They saw potential for an IPF–PAI to capture patient characteristics and costs more accurately through standardized assessment and believed that data from the IPF–PAI could support improvement in payment models, quality of care, and health equity. Some commenters expressed general concerns about the IPF–PAI, citing challenges with PAIs used in other provider types and the burden that a standardized patient assessment could place on providers.

Several commenters recommended CMS include data elements that reflect resource use in the IPF–PAI, and a few commenters stated the belief that data elements in the IPF–PAI should be selected with consideration of their ability to capture quality of care or support quality improvement efforts. A commenter stated that CMS should not collect any additional information that would not ultimately impact IPF payments.

Several commenters suggested ways that CMS should approach instrument development to minimize administrative burdens related to the PAI, such as leveraging or aligning with current IPFQR requirements and other common, existing IPF workflows, and focusing on data elements that are easy to collect and assessment instruments that are already in widespread use, rather than developing de novo tools. A commenter recommended that CMS compare the content of the IPF–PAI to other required data submissions in order to reduce duplicative data entry. A commenter recommended that CMS attempt to align data elements, data collection time periods, and measures between the IPFQR Program and The Joint Commission, a national accrediting body that establishes quality and safety standards for health care organizations.[16] To mitigate burden, several commenters recommended that CMS to be judicious when selecting data elements for the IPF–PAI, prioritizing data elements that could be auto-populated from a facility's electronic health record (EHR). A commenter stated that it is important for CMS to only consider standardized tools that are in the public domain and that do not incur costs of utilization for inclusion in the IPF–PAI.

Several commenters agreed with CMS that data elements selected for the IPF–PAI should have demonstrated scientific acceptability, including testing that

[15] For further information detailing the rationale for adopting SDOH Standardized Patient Assessment Data Elements in these settings, we refer readers to the Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities; Updates to the Quality Reporting Program and Value-Based Purchasing Program for Federal fiscal year 2020 final rule (84 FR 38805 through 38817); the Medicare Program; Inpatient Rehabilitation Facility (IRF) Prospective Payment System for Federal fiscal year 2020 and Updates to the IRF Quality Reporting Program final rule (84 FR 39149 through 38161), the Medicare and Medicaid Programs; CY 2020 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; Home Health Quality Reporting Requirements; and Home Infusion Therapy Requirements CY 2020 final rule (84 FR 60597 through 60608), and the Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and fiscal year 2020 Rates; Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Promoting Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals final rule (84 FR 42577 through 42588).

[16] IPFs can receive accreditation from The Joint Commission, formerly known as on The Joint Commission on Accreditation of Healthcare Organizations (JCAHO), through an independent survey process and period reporting of quality measure data. Psychiatric hospitals participating in Medicare that are accredited under The Joint Commission's consolidated standards for adult psychiatric facilities are deemed to meet Medicare's requirements for hospitals (with the exception of the special medical record and staffing requirements). Accreditation by The Joint Commission is not a requirement for participating in Medicare, but many IPFs maintain accredited status and must submit quality measure data to The Joint Commission as well as to CMS. More information on the process of deeming IPFs to have met Medicare's requirements is available in Appendix AA of the State Operations Manual available at: *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/som107ap_aa_psyc_hospitals.pdf*.

shows them to be reliable and valid. A few commenters noted the importance of inter-rater reliability and suggested this could be bolstered during implementation by providing clear guidance to individuals administering the assessment. A commenter recommended ongoing monitoring of IPF–PAI data after the IPF–PAI is implemented, including an audit plan for ensuring accuracy of reported data and periodic reassessment of inter-rater reliability. Several commenters noted the importance of testing the IPF–PAI in IPFs, specifically in a diverse set of IPFs, to ensure relevance, validity, and reliability in this setting.

Several commenters described unique characteristics of IPF patients and limitations of IPFs and recommended that CMS prioritize appropriateness for IPFs when developing the IPF–PAI. Several commenters noted concerns that leveraging data elements used in post-acute care or with geriatric populations would not be appropriate for the majority of IPF patients. A few commenters recommended that CMS select data elements that would be applicable to diverse patient populations and facility types. A commenter noted the importance of using standardized data elements in the IPF–PAI that apply to the broadest range of patients, focusing, for example, on function rather than symptoms, as measures of function apply to all patients while measurement of specific symptomology would need to be tailored to patients' conditions.

Some commenters noted that patients in IPFs may be unwilling or unable to complete any patient interviews to inform data elements. A commenter recommended that testing be conducted with IPFs to understand these dynamics and inform policies on acceptable completion rates.

Several commenters stated concerns about the timeline for development and implementation of the IPF–PAI. To accomplish its goals while minimizing burden to providers, a few commenters recommended that CMS start with a basic tool that is limited in scope while meeting the statutory requirements, then expand the tool as additional data elements are tested for validity and reliability. A commenter suggested that CMS identify what is already being collected by IPFs and require reporting of these data elements, rather than developing a new tool.

Many commenters noted the importance of engaging with experts and other interested parties in the development of the IPF–PAI. A few commenters suggested that CMS engage with specific interested parties, including mental health specialty societies, psychiatric mental health nurses, and software vendors. A commenter recommended that CMS engage with the provider community to solicit their comments before finalizing the IPF–PAI. A commenter suggested that CMS form a working group that meets quarterly in order to incorporate and respond to feedback from interested parties.

Regarding CMS intention to design the IPF–PAI to be interoperable, a commenter recommended that CMS align the IPF–PAI with United States Core Data for Interoperability (USCDI), while another commenter stated support for CMS commitment to interoperability for the IPF–PAI, specifically for data on social risk factors and HRSNs. Several commenters noted that IPFs did not receive funding to adopt certified EHR technology and suggested that CMS consider how the implementation of the IPF–PAI would affect providers without EHRs.

Response: We thank commenters for their responses to this comment solicitation. We will take these comments into consideration in the development of the IPF–PAI.

b. Patient Assessments Recommended for Use in the IPF–PAI

- Are there PAIs currently available for use, or that could be adapted or developed for use in the IPF–PAI, to assess patients': (1) functional status; (2) cognitive function and mental status; (3) special services, treatments, and interventions for psychiatric conditions; (4) medical conditions and comorbidities; (5) impairments; (6) health disparities; or (7) other areas not mentioned in this RFI?

We summarize the comments we received regarding existing assessment instruments or data elements in current use with respect to each patient assessment topic in sections V.B.4.c through V.B.4.h of this rule. We include the names of the instruments that commenters identified in the summaries of comments that pertain to each topic area in sections V.B.4.c through V.B.4.h of this rule.

c. Functional Status Standardized Patient Assessment Data Elements

- What aspects of function are most predictive of medical complexity or increased resource needs to treat a patient in the IPF setting?
- Which of the Standardized Patient Assessment Data Elements related to mobility (that is, the ability to toilet transfer, walk 10 feet, car transfer, walk 10 feet on an uneven surface, 1 step up (that is, a curb), 4 steps up, 12 steps up, and pick up an object) currently collected by PAC settings in their respective PAIs are clinically relevant in the IPF setting? Do they otherwise meet the principles for inclusion in the IPF–PAI?

Comment: A few commenters described aspects of functional status that would be appropriate to capture using the IPF–PAI. These include being wheelchair bound, ability to toilet transfer, ability to walk 10 feet, requiring assistance with walking, being designated as at risk of falls, and requiring 1-on-1 supervision for any reason. A commenter recommended assessing patients' abilities to complete activities of daily living (ADLs) and instrumental activities of daily living (IADLs). We note that ADLs typically refer to ambulating, feeding, dressing, personal hygiene, continence, and toileting and IADLs typically refer to transportation, managing finances, shopping and meal preparation, housekeeping, communication (for example, using the telephone), and managing medications.[17] A commenter offered several examples of public domain measures of physical and social function from the National Institute of Health's Patient-Reported Outcomes Measurement Information System (PROMIS), including Physical Function, Ability to Participate in Social Roles and Activities, Companionship, Friendship, and Social Isolation.[18] A commenter shared two assessments that capture a patient's risk for falls: the Edmonson Fall Risk Assessment Tool [19] and the Morse Fall Scale.[20]

A few commenters stated that the standardized patient assessment data elements on functional status that CMS presented for comment were not relevant to the IPF patient population. They stated that IPF patients are generally younger and have fewer functional impairments than the post-acute and geriatric populations for which these data elements were developed. A commenter suggested that these data elements would only be appropriate for geriatric psychiatry patients, and that the IPF–PAI could

[17] Mlinac, M.E., & Feng, M.C. (2016). Assessment of activities of daily living, self-care, and independence. *Archives of Clinical Neuropsychology, 31*(6), 506–516.

[18] For information about the PROMIS data elements, we refer readers to: *https://www.healthmeasures.net/explore-measurement-systems/promis.*

[19] Edmonson, D., Robinson, S., & Hughes, L. (2011). Development of the Edmonson psychiatric fall risk assessment tool. *Journal of psychosocial nursing and mental health services, 49*(2), 29–36.

[20] Watson, B.J., Salmoni, A.W., & Zecevic, A.A. (2016). The use of the Morse Fall Scale in an acute care hospital. *Clin Nurs Stud, 4*(2), 32–40.

skip these questions for non-geriatric patients.

A commenter stated concerns about the accuracy of provider-assessed functional assessments, in the event that data on functional assessments would be used in payment models (that is, facilities would be paid more for patients with poor functional status), as providers would have an incentive to assess patients as more functionally impaired than they might be. Another commenter stated support for the standardized assessment of functional status, and stated their belief that functional status is the only topic appropriate for standardized patient assessment due to the clinical diversity of IPF patients.

Response: We thank commenters for their responses to this comment solicitation. We will take these comments into consideration in the development of the IPF–PAI.

d. Cognitive Function and Mental Status Standardized Patient Assessment Data Elements

- What aspects of cognitive function and mental status are most predictive of medical complexity or increased resource needs to treat a patient in the IPF setting?
- What components or instruments are used to assess cognitive function, mental status, or a combination thereof upon admission? What, if any, differences are there between assessments administered at admission and at discharge? What are the components of the mental status assessments administered at admission and discharge?

Comment: Several commenters stated that mental status examination is a typical practice in IPFs, with key aspects including appearance and behavior, speech, thought process and content, affect and mood, cognition, perception, judgement, insight, and suicidal ideation and suicide-related behaviors. Several commenters recommended that CMS ensure IPFs and treating clinicians have discretion over the approach to conducting mental status examinations, noting that the mental status examination should be tailored to the patient, and stated concerns about the IPF–PAI introducing a standardized approach to this typically individualized process. Several commenters recommended considering assessment of suicidal ideation and suicide-related behaviors, homicidality and homicidal ideation, aggression, agitation, and unpredictable behavior, as these are markers of patient acuity and predictive of resource use. Additionally, a commenter recommended assessing for psychosis and insomnia, sharing their belief that patients experiencing these states require more resources.

Several commenters stated a belief that assessment of cognitive function is not appropriate for most IPF patients, specifically for patients who do not show signs of cognitive impairment. These commenters stated that cognitive impairment is most common in older adults and questioned the value of universal screening for cognitive impairment for the IPF population.

Commenters shared the names of several assessments on the topics of cognitive function and mental status, including the St. Louis University Mental Status Exam,[21] the Mini-Mental State Exam,[22] the Montreal Cognitive Assessment,[23] the Cohen-Mansfield Agitation Inventory,[24] the Geriatric Depression Scale,[25] the Patient Health Questionnaire (PHQ–9),[26] and the Beck Depression Inventory.[27] A commenter recommended that the IPF–PAI contain only a single item to address the Cognitive Function and Mental Status category, such as ''Does the patient have a co-morbid neurocognitive disorder?'' A commenter recommended including a standardized suicide risk assessment in the IPF–PAI, recommending the Columbia-Suicide Severity Rating Scale.[28]

A commenter stated concerns about the time required to collect standardized assessments of cognitive function and mental status. This commenter noted that, although individual assessments may be brief, when combined with other data elements, this could make the IPF–PAI very long.

Response: We thank commenters for their responses to this comment solicitation. We will take these comments into consideration in the development of the IPF–PAI.

e. Special Services, Treatments, and Interventions for Psychiatric Conditions Standardized Patient Assessment Data Elements

- What special services, treatments, and interventions are most predictive of increased resource intensity during an IPF stay?
- Do data currently collected as part of the IPFQR Program related to special services and treatments (such as HBIPS–2 Hours of Physical Restraint Use and HBIPS–3 Hours of Seclusion Use) meet the criteria for inclusion in the IPF–PAI?

Comment: Several commenters shared thoughts on the special services, treatments, and interventions that they have found to be most predictive of resource intensity. These include supervision or observation needs (for example, one-to-one observation and continuous visual observation), unit restrictions, restraint or seclusion episodes, features of medication (for example, polypharmacy, medication management needs, use of long-acting injectable medication or clozapine, high-cost medications, and emergency medications), fall risk management, the need for any treatments that occur outside of the IPF (for example, dialysis), and the patient being involuntarily hospitalized. Several commenters described the resource intensity impacts of patients who require higher than usual levels of observation at any point during their stay. Regarding medications, a few commenters described how long-acting injectable medications and clozapine are often reserved for patients for whom other medications are not effective or not acceptable, and their use often correlates with patients who are not attaining symptom control quickly, and therefore require more staff attention and supervision. Regarding involuntary hospitalization, a commenter noted the staffing resources required to comply with the administrative and legal processes, such as accompanying the patient to court proceedings. This commenter recommended that CMS include in the IPF–PAI a data element to capture when a patient requires legal hearing(s) related to involuntary hospitalization or treatment over

[21] Shwartz, S.K., Morris, R.D., & Penna, S. (2019). Psychometric properties of the Saint Louis University mental status examination. *Applied Neuropsychology: Adult, 26*(2), 101–110.

[22] Tombaugh, T.N., McDowell, I., Kristjansson, B., & Hubley, A.M. (1996). Mini-Mental State Examination (MMSE) and the Modified MMSE (3MS): a psychometric comparison and normative data. *Psychological Assessment, 8*(1), 48.

[23] Freitas, S., Simões, M.R., Marôco, J., Alves, L., & Santana, I. (2012). Construct validity of the montreal cognitive assessment (MoCA). *Journal of the International Neuropsychological Society, 18*(2), 242–250.

[24] Cohen-Mansfield, J. (1986). Cohen-Mansfield Agitation Inventory. *International Journal of Geriatric Psychiatry*.

[25] Wancata, J., Alexandrowicz, R., Marquart, B., Weiss, M., & Friedrich, F. (2006). The criterion validity of the Geriatric Depression Scale: a systematic review. *Acta Psychiatrica Scandinavica, 114*(6), 398–410.

[26] Löwe, B., Unützer, J., Callahan, C.M., Perkins, A.J., & Kroenke, K. (2004). Monitoring depression treatment outcomes with the Patient Health Questionnaire-9. *Medical care, 42*(12), 1194–1201.

[27] Dozois, D.J., Dobson, K.S., & Ahnberg, J.L. (1998). A psychometric evaluation of the Beck Depression Inventory–II. *Psychological assessment, 10*(2), 83.

[28] Posner, K., Brown, G.K., Stanley, B., Brent, D.A., Yershova, K.V., Oquendo, M.A., . . . & Mann, J. J. (2011). The Columbia–Suicide Severity Rating Scale: initial validity and internal consistency findings from three multisite studies with adolescents and adults. *American journal of psychiatry, 168*(12), 1266–1277.

objection (for example, being administered medication).

A commenter recommended that CMS include recreational therapy as a distinct and separate service to be collected in the IPF–PAI.

A commenter noted concerns that treatments and interventions cannot be assessed in a standardized way in the IPF–PAI because they are different for every patient. Another commenter recommended that CMS not require that minutes of therapy time be tracked on the IPF–PAI, as they believe this would be resource intensive and have little value.

A commenter noted that IPFs already collect and submit patient data relevant to this category through the IPFQR Program's Tobacco Use Treatment Provided or Offered at Discharge measure (TOB–3) [29] and suggested that CMS consider existing data reporting to meet the requirement for patient assessment for this topic.

Response: We thank commenters for their responses to this comment solicitation. We will take these comments into consideration in the development of the IPF–PAI.

f. Medical Conditions and Comorbidities Standardized Patient Assessment Data Elements

- Is the Standardized Patient Assessment Data Element regarding pain interference (effect on sleep, interference with therapy activities, interference with day-to-day activities) currently collected by PAC settings in their respective PAIs clinically relevant in the IPF setting? Does it otherwise meet the criteria for inclusion in the IPF–PAI?
- Do the medical conditions and comorbidities coded on IPF claims meet the criteria for inclusion in the IPF–PAI?

Comment: Commenters provided feedback on the types of medical conditions and comorbidities that would be appropriate to be assessed in the IPF setting.

Commenters shared a list of common comorbidities that could be collected in the IPF–PAI, including chronic lower respiratory diseases, diseases of esophagus/stomach, metabolic disorders, hypertensive diseases, and episodic and paroxysmal disorders (for example, insomnia, migraine). A commenter agreed that the Standardized Patient Assessment Data Element regarding pain interference (effect on sleep, interference with therapy activities, interference with day-to-day activities) [30] is clinically relevant in the IPF setting.

A commenter recommended three topics to include in this domain: presence of medical conditions requiring standing medication, medical/surgical consult required, and need for medical testing/procedure. This commenter described how the need for patients to leave the IPF to receive specialized care creates additional staffing demand. Another commenter recommended that the IPF–PAI include psychiatric diagnoses, medical comorbidities, and levels of intervention required, as these impact resources. Another commenter noted that allowing for the documentation of multiple psychiatric comorbidities would help to capture the resource costs to treat these complex patients.

A few commenters stated concerns or challenges. A commenter noted concerns that standardizing assessment of comorbidities would be difficult, as assessment requires individualized consideration. Another commenter noted that IPFs already collect and submit patient data relevant to this category through the IPFQR Program's Screening for Metabolic Disorders measure [31] and suggested that CMS consider existing data reporting to meet the requirement for patient assessment for this topic.

Response: We thank commenters for their responses to this comment solicitation. We will take these comments into consideration in the development of the IPF–PAI.

g. Impairments Standardized Patient Assessment Data Elements

- Are Standardized Patient Assessment Data Elements related to impairments (that is, the ability to hear and see in adequate light) currently collected PAC settings in their respective PAIs clinically relevant in the IPF setting? Do they otherwise meet the principles for inclusion in the IPF–PAI?
- What impairments are most predictive of increased resource intensity during an IPF stay?

Comment: Several commenters stated agreement with CMS that hearing and vision impairments would be clinically relevant to the IPF setting and are a reason for increased resource use when caring for patients with these impairments. A commenter disagreed that hearing and vision impairments were relevant to the IPF population, arguing that these are conditions that primarily affect older adults. Another commenter, in the context of recommending that CMS minimize data collection burden, suggested a single ''yes/no'' item: Is the patient hard of hearing or visually impaired?

Several commenters suggested assessing more global concepts of impairment, stating that the ability to participate in life and perform daily functions is clinically relevant for the IPF population.

A commenter recommended that the IPF–PAI also assess functional neurologic impairments such as incontinence and dysphagia.

Response: We thank commenters for their responses to this comment solicitation. We will take these comments into consideration in the development of the IPF–PAI.

h. Other Categories of Standardized Patient Assessment Data Elements

- What other assessment elements would contribute to the clinical utility of the IPF–PAI?
- What other assessment elements would best capture medical complexity in the interest of refining and improving the accuracy of the IPF PPS?
- What other assessment elements would inform CMS' understanding of health equity for IPF patients?
- Are there special interventions that IPFs provide which support patients after discharge, and which could serve to reduce the incidence of hospital readmissions for psychiatric conditions? What, if any, assessment elements would inform CMS' understanding of such interventions?

Comment: Regarding assessment elements to inform CMS' understanding of health equity, several commenters suggested that CMS should consider collecting information about a patient's social risk factors in the IPF–PAI. Some commenters provided specific recommendations regarding which social risk factors would be most important to gather information on, or overarching principles to guide selection of social risk factors. However, several commenters cautioned against collecting information pertaining to SDOH through the IPF–PAI.

[29] *https://qualitynet.cms.gov/ipf/ipfqr/measures.*

[30] The Pain Interference standardized patient assessment data elements are currently collected in four other PAIs: the IRF–PAI for IRFs (*https://www.cms.gov/medicare/payment/prospective-payment-systems/inpatient-rehabilitation/pai*), the OASIS data set for HHAs (*https://www.cms.gov/medicare/quality/home-health/oasis-data-sets),* the CARE data set for LTCHs (*https://www.cms.gov/medicare/quality/long-term-care-hospital/ltch-care-data-set-ltch-qrp-manual*), and the Minimum Data Set (MDS) Resident Assessment Instrument (RAI) for SNFs (*https://www.cms.gov/medicare/quality/nursing-home-improvement/resident-assessment-instrument-manual*).

[31] *https://qualitynet.cms.gov/ipf/ipfqr/measures.*

Regarding other topics that could be included in the IPF–PAI, a commenter recommended that the assessment include data elements related to whether an individual has identified and is participating in activities that promote enjoyment, engagement, and social interaction with others. Another commenter recommended that CMS consider quality of life, such as measured by the World Health Organization's Quality-of-Life Scale (WHOQOL–BREF).[32] This commenter also recommended that CMS consider a global measure of psychiatric functioning, such as the Behavior and Symptom Identification Scale (BASIS),[33] which assesses psychosocial symptoms and can be used to measure outcomes.

Response: We thank commenters for their responses to this comment solicitation. We will take these comments into consideration in the development of the IPF–PAI.

i. Implementation

- We anticipate that IPFs will need to make changes to systems and processes and train staff in order to administer the assessment and submit assessment data by the implementation date. What operational or practical limitations would IPFs face in making those necessary changes? Are there particular categories of Standardized Patient Assessment Data Elements that would be more or less feasible for IPFs to operationalize? We are particularly interested in impacts to facilities of varying sizes and ownership characteristics.
- What forms of training and guidance would be most useful for CMS to provide to support IPFs in the implementation of the IPF–PAI?

Comment: Many commenters described challenges that they believe IPFs will face when implementing the IPF–PAI, focusing on workflow, staffing resources, and technological constraints.

Several commenters recommended that CMS engage with the EHR and other software vendors that would be likely to support IPFs' implementation of the IPF–PAI. Two commenters recommended that CMS allow ample time for software vendors to develop data collection and reporting tools for IPFs; a commenter recommended at least 18 months between finalizing technical specifications and implementation, while another recommended 2 years. A commenter recommended that CMS commit to making updates to the IPF–PAI no more than once per year. A commenter recommended that CMS develop the IPF–PAI in such a way that it could be populated from the patient's record in the EHR at the time of discharge.

Regarding implementation at the facility level, a few commenters recommended clarifying what training and guidance that would be provided to IPFs in advance of implementation and suggested that thorough training and clear instructions for completing the IPF–PAI will be important to support data quality.

Response: We thank commenters for their responses to this comment solicitation. We will take these comments into consideration in the development of the IPF–PAI.

j. Relationship to the IPFQR Program

- Would having some measures which require data submission through the HQR system and having other measures, which require data collection and submission through the IPF–PAI increase operational complexity or administrative burden? If so, how would you recommend mitigating this complexity or burden?
- Would any of the current chart-abstracted measures be easier to report through the IPF–PAI? If so, which measures?
- Would any of the current measures in the program be more meaningful if they were stratified or risk-adjusted using data from the required patient assessment categories or other categories not specified by the CAA, 2023 that should be added to the IPF–PAI?
- What new measure concepts, which would use data collected through Standardized Patient Assessment Data Elements in the IPF–PAI, should we consider?

Comment: Several commenters stated concerns about the prospect of needing to submit patient data to two systems, if, for example, IPFs continue using the existing process for submitting patient-level data for the IPFQR Program's measures, but the IPF–PAI data submission is accomplished through a different process. They recommended that CMS incorporate the IPF–PAI into the existing patient level XML submission process. In addition, they recommended against moving current chart-abstracted quality measures to the IPF–PAI, due to concerns that the IPF–PAI is intended to be collected for all patients, not just the sample that are currently the target of chart abstraction.

Another commenter stated concerns about duplication of data collection or data entry between existing IPFQR Program measures and the IPF–PAI. However, that commenter suggested that it would be appropriate to move data reporting to the IPF–PAI for a few of the current IPFQR Program measures.

Response: We thank commenters for their responses to this comment solicitation. We will take these comments into consideration in the development of the IPF–PAI.

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 II.A. of this final rule for a detailed discussion of entities covered under the IPF PPS). Section 1886(s)(4)(A)(i) requires the Secretary to reduce by 2 percentage points the annual update to the standard Federal rate for discharges occurring during such rate year [34] for any IPF that does not comply with quality data submission requirements under IPFQR program, set forth in section 1886(s)(4)(C) of the Act, with respect to an applicable rate 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 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

[32] Whoqol Group. (1998). Development of the World Health Organization WHOQOL–BREF quality of life assessment. *Psychological medicine, 28*(3), 551–558.

[33] Eisen, S.V., Normand, S.L., Belanger, A.J., Spiro III, A., & Esch, D. (2004). The revised behavior and symptom identification scale (BASIS–R): reliability and validity. *Medical care, 42*(12), 1230–1241.

[34] 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).

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.

Section 4125(b)(1) of CAA, 2023 amended section 1886(s)(4) of the Act, by inserting a new paragraph (E), to require IPFs participating in the IPFQR Program to collect and submit to the Secretary certain standardized patient assessment data, using a standardized patient assessment instrument (PAI) developed by the Secretary, for RY 2028 (FY 2028) and each subsequent rate year. We refer readers to section V.B of this final rule in which we discuss responses to our solicitation of public comment on the development of this PAI.

We refer readers to the FY 2019 IPF PPS final rule (83 FR 38589) for a discussion of the background and statutory authority of the IPFQR Program. We have codified procedural requirements and reconsideration and appeals procedures for IPFQR Program decisions in our regulations at 42 CFR 412.433 and 412.434. Consistent with previous IPFQR Program regulations, we refer to both inpatient psychiatric hospitals and psychiatric units as ''facilities'' or ''IPFs.'' This usage follows the terminology in our IPF PPS regulations at § 412.402.

For additional information on procedural requirements related to statutory authority, participation and withdrawal, data submission, quality measure retention and removal, extraordinary circumstances exceptions, and public reporting we refer readers to 42 CFR 412.433 Procedural requirements under the IPFQR Program.

For the IPFQR Program, we refer to the year in which an IPF would receive the 2-percentage 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 for which CY 2025 is the performance period which is required to be submitted in CY 2026 and affects FY 2027 payment determination, if an IPF did not submit the data for this measure as specified during CY 2026 we would reduce by 2-percentage points that IPF's update for the FY 2027 payment determination year (even if the IPF meets all other IPFQR Program requirements for the FY 2027 payment determination).

B. 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,[35] the Behavioral Health Strategy,[36] the Framework for Health Equity,[37] and the Meaningful Measures Framework [38] for information related to our priorities in selecting quality measures.

1. Measure Selection Process

Section 1890A(a) of the Act requires that the Secretary establish and follow a pre-rulemaking process, in coordination with the CBE contracted under 1890(a) of the Act, to solicit input from multi-stakeholder groups on 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. 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. Under the Partnership for Quality Measurement (PQM), which is convened by the entity which currently holds the contract under 1890(a) of the Act, this process is known as the Pre-Rulemaking Measure Review (PRMR). We consider the input and recommendations provided by this multi-stakeholder group in selecting all measures for the IPFQR Program, including the 30-Day Risk-Standardized All-Cause Emergency Department (ED) Visit Following an IPF Discharge measure discussed in this final rule.

2. Adoption of the 30-Day Risk-Standardized All-Cause ED Visit Following an IPF Discharge Measure Beginning With the CY 2025 Performance Period/FY 2027 Payment Determination

a. Background

We have consistently stated our commitment to identifying measures that examine the care continuum for patients with mental health conditions and substance use disorders and to quantify outcomes following IPF-discharge (see for example, the adoption of the Medication Continuation Following Hospitalization in an IPF measure in the FY 2020 IPF PPS Final Rule, 84 FR 38460 through 38462). Post-discharge outcomes are an important part of our measurement strategy because patient-centered discharge planning and coordination of care for patients with any combination of mental health conditions and substance use disorders improves long-term outcomes,

[35] 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.*

[36] CMS. (2022). CMS Behavioral Health Strategy. Available at *https://www.cms.gov/cms-behavioral-health-strategy.*

[37] CMS. (2022). CMS Framework for Health Equity 2022–2032. Available at *https://www.cms.gov/files/document/cms-framework-health-equity-2022.pdf.*

[38] CMS. (2023). Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at *https://www.cms.gov/medicare/quality/meaningful-measures-initiative/meaningful-measures-20.* Accessed on March 20, 2024.

including reducing readmissions and other post-discharge acute care services.[39] [40]

Although not all post-discharge acute care visits are preventable, there are actions that the IPF can take to maximize the chance for patients' successful community reintegration.[41] For example, care transition models to reduce the need for additional acute care following an inpatient stay have been adapted to the inpatient psychiatric setting. To implement these models, IPFs may need to consider how to include the patient and their caregivers, including family, in discharge planning, how to communicate with post-discharge providers, and how to ensure whole-person care for patients during and following their discharge.[42] Specifically, IPFs may need to assist patients in connecting with outpatient providers, such as coordinating with the patient and their caregiver to schedule the patient's first post-discharge follow-up appointment, arranging for the patient's intensive outpatient (IOP) care, or connecting to peer support services. Additionally, IPFs may need to identify and address barriers patients may face in accessing medications and adhering to scheduled post-discharge follow-up appointments. Barriers may include financial factors, transportation, and childcare, which may necessitate support from social services, beginning during hospitalization and continuing after discharge.[43] [44] Barriers may also include the patient's concerns regarding the stigmatization associated with seeking care post-discharge. This can be addressed through treatment provided during the IPF stay.[45] [46] Improvements in patient experience of care and patient-centeredness of care have been associated with improved follow-up post-discharge and a reduction in patients requiring post-discharge acute care.[47] [48] In summary, by proactively addressing potential barriers to post-charge care, improving patient experience of care and patient-centeredness of care, and implementing care transition models, IPFs can reduce the need for post-discharge acute care.

The IPFQR Program currently has three measures that assess post-discharge outcomes: (1) Follow-up After Psychiatric Hospitalization (FAPH); (2) Medication Continuation Following Inpatient Psychiatric Discharge; and (3) Thirty Day All-Cause Unplanned Readmission Following Psychiatric Hospitalization (CBE #2860, the IPF Unplanned Readmission measure). Each of these measures serves a unique role in assessing care coordination and post-discharge outcomes.

The FAPH measure, which we adopted in the FY 2022 IPF PPS Final Rule (86 FR 42640 through 42645), uses Medicare FFS claims to determine the percentage of inpatient discharges from an IPF stay for which the patient received a follow-up visit for treatment of mental illness. The FAPH measure represents an important component of post-discharge care coordination, specifically the transition of care to an outpatient provider. However, this measure does not quantify patient outcomes.

The Medication Continuation Following Inpatient Psychiatric Discharge measure, which we adopted in FY 2020 IPF PPS Final Rule (84 FR 38460 through 38465), assesses whether patients admitted to IPFs with diagnoses of Major Depressive Disorder (MDD), schizophrenia, or bipolar disorder filled at least one evidence-based medication prior to discharge or during the post-discharge period. Medication continuation is important for patients discharged from the IPF setting with these disorders because of significant negative outcomes associated with non-adherence to medication regimes. However, this measure does not quantify patient outcomes with respect to the use of acute care services post-discharge.

The IPF Unplanned Readmission measure, which we adopted in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57241 through 57246), assesses outcomes associated with worsening condition, potentially due to insufficient discharge planning and post-discharge care coordination, by assessing post-discharge use of acute care. The IPF Unplanned Readmission measure estimates the incidence of unplanned, all-cause readmissions to IPFs or short-stay acute care hospitals following discharge from an eligible IPF index admission. A readmission is defined as any admission that occurs within 3 to 30 days after the discharge date from an eligible index admission to an IPF, except those considered planned.[49] However, this measure does not quantify the proportion of patients 18 and older with an ED visit, without subsequent admission, within 30 days of discharge from an IPF. Without collecting this information in a measure, we believe there is a gap in our understanding regarding patients' successful reintegration into their communities following their IPF discharge.

To further understand this gap, we analyzed post-discharge outcomes using claims data. In this analysis, we determined that, for patients discharged from IPFs, the risk-adjusted rate of ED visits after an IPF discharge between June 1, 2019 and July 31, 2021 (excluding the first two quarters of 2020 due to the COVID–19 public health emergency) was 20.7 percent. The rate of readmissions captured under the IPF Unplanned Readmission measure for this same period was 20.1 percent.[50] This means that approximately 40 percent of patients discharged from an IPF had either an ED visit or an

[39] Nelson, E.A. Maruish, M.E., Axler, J.L. Effects of Discharge Planning with Outpatient Appointments on Readmission Rates. *https://ps.psychiatryonline.org/doi/10.1176/appi.ps.51.7.885*.

[40] Steffen S, Kösters M, Becker T, Puschner B. Discharge planning in mental health care: a systematic review of the recent literature. Acta Psychiatr Scand. 2009 Jul;120(1):1–9 doi: 10.1111/j.1600-0447.2009.01373.x. Epub 2009 Apr 8. PMID: 19486329.

[41] Haselden, M., Corbeil, T., Tang, F., Olfson, M., Dixon, L.B., Essock, S.M., Wall, M.M., Radigan, M., Frimpong, E., Wang, R., Lamberti, S., Schneider, M., & Smith, T.E. (2019). Family Involvement in Psychiatric Hospitalizations: Associations With Discharge Planning and Prompt Follow-Up Care. Psychiatric Services, 70(10), 860–866. *https://doi.org/10.1176/appi.ps.201900028*.

[42] Pincus, Harold, Care Transition Interventions to Reduce Psychiatric Re-Hospitalizations. National Association of State Mental Health Program Directors. 2015. Available at *https://nasmhpd.org/sites/default/files/Assessment%20%233_Care%20Transitions%20Interventions%20toReduce%20Psychiatric%20Rehospitalization.pdf*. Accessed on January 23, 2024.

[43] Allen, E.M., Call, K.T., Beebe, T.J., McAlpine, D.D., & Johnson, P.J. (2017). Barriers to Care and Healthcare Utilization among the Publicly Insured. Medical Care, 55(3), 207–214. doi:10.1097/MLR.0000000000000644.

[44] Mutschler, C., Lichtenstein, S., Kidd, S.A., & Davidson, L. (2019). Transition experiences following psychiatric hospitalization: A systematic review of the literature. Community Mental Health Journal, 55(8), 1255–1274. doi:10.1007/s10597–019–00413–9.

[45] Allen, E.M., Call, K.T., Beebe, T.J., McAlpine, D.D., & Johnson, P.J. (2017). Barriers to Care and Healthcare Utilization among the Publicly Insured. Medical Care, 55(3), 207–214. doi:10.1097/MLR.0000000000000644.

[46] Mutschler, C., Lichtenstein, S., Kidd, S.A., & Davidson, L. (2019). Transition experiences following psychiatric hospitalization: A systematic review of the literature. Community Mental Health Journal, 55(8), 1255–1274. doi:10.1007/s10597–019–00413–9.

[47] Donisi V, Tedeschi F, Wahlbeck K, Haaramo P, Amaddeo F. Pre-discharge factors predicting readmissions of psychiatric patients: a systematic review of the literature. BMC Psychiatry. 2016 Dec 16;16(1):449. doi: 10.1186/s12888–016–1114–0. PMID: 27986079; PMCID: PMC5162092.

[48] Morgan C Shields, Mara A G Hollander, Alisa B Busch, Zohra Kantawala, Meredith B Rosenthal, Patient-centered inpatient psychiatry is associated with outcomes, ownership, and national quality measures, Health Affairs Scholar, Volume 1, Issue 1, July 2023, qxad017, *https://doi.org/10.1093/haschl/qxad017*.

[49] *https://p4qm.org/measures/2860*.

[50] As depicted in the April 2023 file available at *https://data.cms.gov/provider-data/archived-data/hospitals*.

unplanned readmission within 30-days of IPF discharge, but only about half of those visits are being captured in the publicly reported IPF Unplanned Readmission measure. Visits to an ED within 30 days of discharge from an IPF (regardless of whether that visit results in a hospital readmission, observation stay, discharge, or patient leaving without being seen) often indicate deteriorating or heightened mental or physical health needs. That is, these visits often represent a patient seeking care for symptoms that were present during the patient's stay in the IPF, regardless of whether the symptom was the reason for the admission, that have become worse for the patient in the time since discharge. Therefore, we believe that IPFs and the public would benefit from having these data made publicly available to inform care decisions and quality improvement efforts. Specifically, members of the public could use these data to inform care decisions and IPFs could use these data to compare their performance to that of similar IPFs. For example, by having these data publicly reported, IPFs could compare their performance with that of other IPFs with similar patient populations, a comparison which is not possible without this measure. If IPFs identified that other IPFs with similar patient populations had better rates of post-discharge ED visits (that is, other IPFs had fewer patients seek care in an ED within 30 days of discharge from the IPF), the IPF could identify a need to evaluate discharge planning and post-discharge care coordination to identify process changes which could improve outcomes.

To address this gap, we developed and proposed the inclusion of the new, claims-based 30-Day Risk-Standardized All-Cause ED Visit Following an IPF Discharge measure (the IPF ED Visit measure) in the IPFQR Program beginning with the CY 2025 performance period/FY 2027 payment determination. The IPF ED Visit measure aims to provide information to patients, caregivers, other members of the public, and IPFs about the proportion of patients who seek care in ED in the 30 days following discharge from an IPF but are not admitted as an inpatient to an acute care hospital or IPF. This measure would assess the proportion of patients 18 and older with an ED visit, including observation stays, for any cause, within 30 days of discharge from an IPF, without subsequent admission.

We recognize that not all post-discharge ED visits are preventable, nor are all post-discharge ED visits associated with the initial IPF admission. However, we developed an all-cause ED visit rate, as opposed to a more narrowly focused measure of ED admissions for mental health or substance use concerns, for three primary reasons. First, such a measure aligns most closely with the IPF Unplanned Readmission measure as this measure is also an all-cause measure. Second, an all-cause measure emphasizes the importance of whole-person care for patients. Whole-person care, during the inpatient stay and through referral at discharge, includes addressing the conditions that may jeopardize a patient's health, but are not the reason for admission to the IPF, if the IPF has reason to identify these conditions during the course of treatment. For example, if an IPF were to identify through metabolic screening that a patient has diabetes, it would be appropriate for that IPF to recommend appropriate follow-up for that patient, such as with a primary care provider, endocrinologist, or dietician. Such post-discharge coordination of care could prevent the patient from seeking acute care after discharge from the IPF for complications of diabetes, such as diabetic ketoacidosis. Third, this measure includes ED visits for all conditions because patients visiting the ED may do so for physical symptoms associated with a mental health condition or substance use disorder. An example is a patient with anxiety that presents to the ED with chest pain and shortness of breath. If the clinician documents the primary diagnosis as chest pain (R07.9) or shortness of breath (R06.02), the patient would not be included in a mental health and substance use-specific IPF ED Visit measure, despite their history of anxiety (F41.9), a potential contributor to their presenting symptoms at the ED. We recognize that it is possible that such a visit may not be related to the patient's anxiety. However, while not all acute care visits after discharge from an IPF are preventable or necessarily related to the quality of care provided by the IPF, there is evidence that improvements in the quality of care for patients in the IPF setting can reduce rates of patients seeking acute care after discharge from an IPF, representing an improved outcome for patients.[51]

Additionally, we considered whether 30 days was an appropriate timeframe for this measure. That is, we sought to identify whether a measure that assessed post-discharge ED visits over a period shorter or longer than 30 days would be more appropriate. Because IPFs are already familiar with interpreting data for the 30-day period in the IPF Unplanned Readmission measure, we determined that it would be appropriate to maintain the 30-day period for the IPF ED Visit measure. Additionally, by maintaining the same timeframe as the IPF Unplanned Readmission measure, we can provide IPFs and patients with a more complete picture of acute care among IPF patients after discharge from the IPF.

Pursuant to the Meaningful Measures 2.0 Framework (a CMS initiative that identifies priority domains for measures within CMS Programs[52]), this measure addresses the ''Seamless Care Coordination'' and the ''Person-Centered Care'' quality domains by encouraging facilities to provide patient-centric discharge planning and support post-discharge care transitions. The IPF ED Visit measure also aligns with the CMS National Quality Strategy Goals[53] of ''Engagement'' and ''Outcomes and Alignment.'' It supports outcomes and alignment because this measure provides a quantified estimate of one post-discharge outcome that patients may experience, that is, a post-discharge acute care visit that does not result in an admission. It also supports the Behavioral Health Strategy[54] domains of ''Quality of Care'' and ''Equity and Engagement'' because engaging patients to improve post-discharge outcomes is an element of providing quality care. Furthermore, similar to the Meaningful Measures domain of ''Person-Centered Care,'' this measure supports the Universal Foundation domain of ''Person-Centered Care.''

b. Overview of Measure

The IPF ED Visit measure was developed with input from clinicians, patients, and policy experts; the measure was subject to the pre-rulemaking process required by section 1890A of the Act, as discussed further in section VI.B.1 of this rule. Consistent

[51] See for instance Chung, D.T., Ryan, C.J., Hadzi-Pavlovic, D., Singh, S.P., Stanton, C., & Large, M.M. (2017). Suicide rates after discharge from psychiatric facilities: A systematic review and meta-analysis. JAMA Psychiatry, 74(7), 694–702. *https://doi.org/10.1001/jamapsychiatry.2017.1044* or Durbin, J., Lin, E., Layne, C., et al. (2007). Is readmission a valid indicator of the quality of inpatient psychiatric care? Journal of Behavioral Health Services Research, 34, 137–150. doi:10.1007/s11414–007–9055–5.

[52] *https://www.cms.gov/medicare/quality/meaningful-measures-initiative/meaningful-measures-20*.

[53] 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*.

[54] CMS. (2022). CMS Behavioral Health Strategy. Available at *https://www.cms.gov/cms-behavioral-health-strategy*.

with the key elements of the CMS Measure Development Lifecycle,[55] we began with measure conceptualization during which we performed a targeted literature review and solicited input from a behavioral health technical expert panel (TEP). This allowed us to ensure that this topic addresses a gap that is important to interested parties. After confirming this, we developed the measure specifications for the IPF ED Visit measure. With these specifications, we issued a 30-day call for public comment [56] and performed empirical testing using claims data, including modeling for risk-adjustment. After refining the measure specifications based on testing and public comment, we performed an equity analysis in which we tested the risk-adjustment methodology to ensure that the measure does not reflect access issues related to patient demographics instead of quality of care. By following the Measure Development Lifecycle, we sought to ensure that this is a vetted, valid, reliable, and ready-to-implement claims-based measure which would assess the proportion of patients 18 and older with an ED visit, including observation stays, for any cause, within 30 days of discharge from an IPF, without subsequent admission. By using the same definitions of index admission and patient populations as those used in the IPF Unplanned Readmission measure, we have designed the IPF ED Visit measure to complement the IPF Unplanned Readmission measure to the extent possible. We have also sought to minimize administrative burden by developing this as a claims-based measure so that it adds no information collection burden to clinicians and staff working in the IPF setting.

(1) Measure Calculation

The focus population for this measure is adult Medicare FFS patients with a discharge from an IPF. The measure is based on all eligible index admissions from the focus population. An eligible index admission is defined as any IPF admission for which the patient meets the following criteria: (1) age 18 or older at admission; (2) discharged alive from an IPF; (3) enrolled in Medicare FFS Parts A and B during the 12 months before the admission date, the month of admission, and at least one month after the month of discharge from the index admission (that is, the original stay in an IPF); and (4) discharged with a principal diagnosis that indicates a psychiatric disorder. Excluded from the measure are patients discharged against medical advice (AMA) from the IPF index admission (because the IPF may not have had the opportunity to conduct full discharge planning for these patients); patients with unreliable data regarding death, demographics, or a combination thereof in their claims record (because these data are unreliable, they may lead to inaccuracies in the measure calculation); patients who expired during the IPF stay (because post-discharge care is not applicable to these patients); patients with a discharge resulting in a transfer to another care facility (because the receiving care facility would be responsible for discharge planning for these patients); and patients discharged but readmitted within 3 days of discharge, also known as an interrupted stay (because interrupted stays are often reflective of patient needs outside of the IPF, such as treatment for another condition).

To calculate the measure, we proposed to use the following data sources which are all available from Medicare administrative records and data submitted by providers through the claims process: (1) Medicare beneficiary and coverage files, which provide information on patient demographic, enrollment, and vital status information to identify the measure population and certain risk factors; (2) Medicare FFS Part A records, which contain final action claims submitted by acute care and critical access hospitals, IPFs, home health agencies, and skilled nursing facilities to identify the measure population, readmissions, and certain risk factors; and (3) Medicare FFS Part B records, which contain final action claims submitted by physicians, physician assistants, clinical social workers, nurse practitioners, and other outpatient providers to identify certain risk factors. To ensure that diagnoses result from encounters with providers trained to establish diagnoses, we proposed that this measure will not use claims for services such as laboratory tests, medical supplies, or other ambulatory services. Index admissions and ED visits would be identified in the Medicare FFS Part A records. Comorbid conditions for risk-adjustment would be identified in the Medicare Part A and Part B records in the 12 months prior to admission, including the index admission. Demographic and FFS enrollment data would be identified in the Medicare beneficiary and coverage files.

To calculate the IPF ED Visit measure, we proposed that CMS would: (1) identify all IPF admissions in the one-year performance period; (2) apply inclusion and exclusion criteria to identify index admissions; (3) identify ED visits and observation stays within 30 days of discharge from each index admission; (4) identify risk factors in the 12 months prior to index admission and during the index admission; and (5) run hierarchical logistic regression to compute the risk-standardized ED visit rate for each IPF.[57] This hierarchical logistic regression would allow us to apply the risk-adjustment factors developed in measure testing to ensure that measure results are comparable across IPFs regardless of the clinical complexity of each IPF's patient population.

(2) Pre-Rulemaking Measure Review and Measure Endorsement

As required under section 1890A of the Act, the CBE established the Partnership for Quality Measurement (PQM) to convene clinicians, patients, measure experts, and health information technology specialists to participate in the pre-rulemaking process and the measure endorsement process. The pre-rulemaking process, also called the Pre-Rulemaking Measure Review (PRMR), includes a review of measures published on the publicly available list of Measures Under Consideration (MUC List) by one of several committees convened by the PQM for the purpose of providing multi-stakeholder input to the Secretary on the selection of quality and efficiency measures under consideration for use in certain Medicare quality programs, including the IPFQR Program. The PRMR process includes opportunities for public comment through a 21-day public comment period, as well as public listening sessions. The PQM posts the compiled comments and listening session inputs received during the public comment period and the listening sessions within five days of the close of the public comment period.[58] More details regarding the PRMR process may be found in the CBE's Guidebook of Policies and Procedures

[55] *https://mmshub.cms.gov/blueprint-measure-lifecycle-overview*.

[56] We note that in the FY 2025 IPF PPS proposed rule we incorrectly stated that this call for comments was issued in the **Federal Register**. It was actually posted on the measure lifecycle's public comment page (available at: *https://mmshub.cms.gov/get-involved/public-comments/overview*) and communicated through subregulatory channels.

[57] For an example of the hierarchal logistic risk-adjustment algorithm, we refer readers to the algorithm for the IPF Unplanned Readmission measure at *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/hospitalqualityinits/downloads/inpatient-psychiatric-facility-readmission-measure.zip*.

[58] These materials are available at the PRMR section of the PQM website: *https://p4qm.org/PRMR*.

for Pre-Rulemaking Measure Review and Measure Set Review, including details of the measure review process in Chapter 3.[59]

The CBE-established PQM also conducts the measure endorsement and maintenance (E&M) process to ensure measures submitted for endorsement are evidence-based, reliable, valid, verifiable, relevant to enhanced health outcomes, actionable at the caregiver-level, feasible to collect and report, and responsive to variations in patient characteristics, such as health status, language capabilities, race or ethnicity, and income level, and are consistent across types of health care providers, including hospitals and physicians (see section 1890(b)(2) of the Act). The PQM convenes several E&M project groups twice yearly, formally called E&M Committees, each comprised of an E&M Advisory Group and an E&M Recommendations Group, to vote on whether a measure meets certain quality measure criteria. More details regarding the E&M process may be found in the E&M Guidebook, including details of the measure endorsement process in the section titled, ''Endorsement and Review Process.'' [60]

As part of the PRMR process, the IPF ED Visit measure was reviewed during the PRMR Hospital Recommendation Group meeting on January 18, 2024. For the voting procedures of the PRMR and E&M process, the PQM utilized the Novel Hybrid Delphi and Nominal Group (NHDNG) multi-step process, which is an iterative consensus-building approach aimed at a minimum of 75 percent agreement among voting members, rather than a simple majority vote, and supports maximizing the time spent to build consensus by focusing discussion on measures where there is disagreement. For example, the PRMR Hospital Recommendation Group can reach consensus and have the following voting results: (A) Recommend, (B) Recommend with conditions (with 75 percent of the votes cast as recommend with conditions or 75 percent between recommend and recommend with conditions), and (C) Do not recommend. If no voting category reaches 75 percent or greater (including the combined [A] Recommend and [B] Recommend with conditions) the PRMR Hospital Recommendation Group is considered not to have come to consensus and the voting result is ''Consensus not reached.'' Consensus not reached signals continued disagreement amongst the committee despite being presented with perspectives from public comment, committee member feedback and discussion, and highlights the multi-faceted assessments of quality measures. More details regarding the PRMR voting procedures may be found in Chapter 4 of the PQM Guidebook of Policies and Procedures for Pre-Rulemaking Measure Review and Measure Set Review.[61] More details regarding the E&M voting procedures may be found in the PQM Endorsement and Maintenance (E&M) Guidebook.[62] The PRMR Hospital Recommendation Group [63] reached consensus and recommended including this measure in the IPFQR Program with conditions.

Seven members of the group recommended adopting the measure into the IPFQR program without conditions; eleven members recommended adoption with conditions; and one committee member voted not to recommend the measure for adoption. Taken together, 94.73 percent of the votes were between recommend & recommend with conditions.

The conditions specified by the PRMR Hospital Recommendation Group were: (1) that the measure be considered for endorsement by a consensus-based entity; and (2) further consideration of how the measure addresses 72-hour transfers to the ED. We have taken those considerations into account and proposed this measure for adoption because we believe we have adequately addressed the concerns raised by those considerations.

To address the first condition, we have submitted the measure to the CBE for consideration. For more information on submission to and consideration by the CBE we refer readers to section VI.B.2.b.(3) of this rule.

The second voting condition requested that we further consider how the measure addresses 72-hour transfers to the ED because of concerns that IPFs may appear to have worse performance if ''interrupted stays'' are not excluded from the measure. An ''interrupted stay'' occurs when a patient is discharged from an IPF and readmitted to the same IPF within 72 hours. This frequently occurs when a patient needs medical treatment that is beyond the scope of the IPF, such as care in an ED for an emergent health issue. We believe that this concern is sufficiently addressed in the ED Visit measure's specifications because these ''interrupted stays'' are excluded from the measure, as described in section VI.B.2.b.(1) of this rule. This exclusion is defined as an index admission with a readmission on Days 0, 1, or 2 post-discharge. In other words, patients transferred to the ED and subsequently readmitted to the IPF within 72 hours are excluded from the measure. Therefore ''interrupted stays'' are excluded from the measure as per the group's recommendation.

(3) CBE Endorsement

Section 1886(s)(4)(D)(i) of the Act generally requires that measures specified by the Secretary shall be endorsed by the entity with a contract under section 1890(a) of the Act (that is, the CBE). After a measure has been submitted to the CBE, the committee responsible for reviewing the measure evaluates the measure on five domains: (1) Importance; (2) Feasibility; (3) Scientific Acceptability (that is, reliability and validity); (4) Equity; and (5) Use and Usability. Committee members evaluate whether the measure the domain is ''Met'', ''Not Met but Addressable'' or ''Not Met'' for each measure using a set of criteria provided by the CBE.[64] When a measure is submitted it is assigned to one of the CBE's projects based on where in the patient's healthcare experience the measure has the most relevance. The five projects are (1) Primary Prevention; (2) Initial Recognition and Management; (3) Management of Acute Events, Chronic Disease, Surgery, Behavioral Health; (4) Advanced Illness and Post-Acute Care; and (5) Cost and Efficiency.

The measure developer submitted the measure for CBE endorsement consideration in the Fall 2023 review cycle. The measure was assigned to the Cost and Efficiency Project. The CBE Cost and Efficiency Endorsement committee met on January 31, 2024 and did not reach consensus regarding the IPF ED Visit measure, with 60.6 percent voting in favor of endorsement or endorsement with conditions and the remaining members voting to not endorse, which is below the 75 percent threshold necessary for the endorsement of the measure, as described in VI.B.2.b. During the Cost and Efficiency Endorsement committee's meeting, members of the committee discussed whether an all-cause measure was appropriate and whether IPFs are able to

[59] *https://p4qm.org/sites/default/files/2023-09/Guidebook-of-Policies-and-Procedures-for-Pre-Rulemaking-Measure-Review-%28PRMR%29-and-Measure-Set-Review-%28MSR%29-Final_0.pdf.*

[60] The Partnership for Quality Measurement. (October 2023). Endorsement and Maintenance (E&M) Guidebook. Available at: *https://p4qm.org/sites/default/files/2023-12/Del-3-6-Endorsement-and-Maintenance-Guidebook-Final_0_0.pdf.*

[63] We note that the PRMR Hospital Recommendation Group was previously the Measure Applications Partnership (MAP) Hospital Workgroup under the pre-rulemaking process followed by the previous CBE.

[64] *https://p4qm.org/EM.*

implement interventions to reduce post-discharge acute care.[65]

As discussed in section VI.B.2.a of this final rule, an all-cause measure complements the IPF Unplanned Readmission measure, emphasizes whole-person care, and captures visits to the ED for patients with physical symptoms associated with mental health conditions. Additionally, evidence shows that there are interventions that reduce post-discharge acute care. These include adopting care transition models, proactively connecting patients with post-discharge providers, identifying and addressing patients' barriers to post-discharge care, and focusing on providing patient-centered care and improving patient experience of care.

Although section 1886(s)(4)(D)(i) of the Act generally requires that measures specified by the Secretary shall 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 have determined that this is an appropriate topic for the adoption of a measure absent CBE endorsement because where possible we focus on measures that assess patient outcomes. Unplanned use of acute care after discharge from an IPF is often associated with worsening condition, potentially due to insufficient discharge planning and post-discharge care coordination. While the IPFQR Program currently has a measure that assesses unplanned readmissions after discharge from an IPF, there is a gap in the measure set with respect to unplanned ED visits without a subsequent admission to an acute care hospital or IPF. The IPF ED Visit measure fills that gap. We also reviewed CBE-endorsed measures and were unable to identify any other CBE-endorsed measures that assess outcomes that solely result in a patient's ED visit after the patient's discharge from an IPF. The only endorsed measure that we identified that addresses an IPF patient seeking acute care after discharge is the IPF Unplanned Readmission measure. As we discussed previously, the IPF Unplanned Readmission measure does not assess ED visits that do not result in an admission. Therefore, we believe that the IPF ED Visit measure is an important complement to the IPF Unplanned Readmission measure. We did not find any other measures that assess post-discharge ED visits without a subsequent admission, and therefore the exception in section 1886(s)(4)(D)(ii) of the Act applies.

c. Data Collection, Submission, and Reporting

Because all data used to calculate the IPF ED Visit measure are available on Medicare claims, this measure requires no additional data collection or submission by IPFs. We proposed to adopt the ED Visit Measure with a reporting period beginning with data from CY 2025 performance period/FY 2027 payment determination year.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported adoption of the IPF ED Visit measure. Some commenters stated that this measure would improve prioritization of discharge planning and provide a more comprehensive understanding of IPF patients' acute care needs following a discharge, which is a critical period for this patient population. Other commenters stated that this measure may serve as an important tool to assess the quality of care in IPFs for beneficiaries, policymakers, and other interested parties. A commenter also noted that these data are not available from the current readmission measure in the IPFQR Program (that is, the Thirty Day All-Cause Unplanned Readmission Following Psychiatric Hospitalization—the IPF Unplanned Readmission measure) because that measure does not capture ED visits. A commenter noted that this measure may promote improved discharge planning, patient engagement, and improved referrals to social services, which could help patients avoid relying on EDs for care for chronic conditions, which could, in turn, reduce overcrowding in EDs. This commenter also stated that this is particularly important for the IPF patient population because they are at high risk of experiencing gaps in the care continuum leading to readmissions and poor outcomes.

Response: We thank these commenters for their support.

Comment: Several commenters expressed concern that this measure does not account for patient characteristics that could affect the likelihood of the patient needing acute care following discharge from the IPF. These commenters were specifically concerned that IPFs that treat patients with high levels of unmet social needs (including inability to afford medication, lack of a home, lack of access to communications technology for accessing less acute care—such as a phone for calling emergency hotlines or other resources) may appear to perform worse on the measure (that is, have more patients seeking care in the ED within 30 days of discharge) than IPFs that treat patients with fewer unmet social needs. A commenter stated that patients who receive care in IPFs have an increased risk for violence and victimization, which may affect their use of EDs.

Response: We agree with commenters that the prevalence of unmet social needs is high among patients receiving care in IPFs, and that the prevalence of these needs may be higher in some IPFs when compared to others. We further agree that patient factors, including unmet social needs and an increased risk for violence or victimization, increase a patient's risk of needing emergency care. We note that data on the Screen Positive Rate for SDOH measure (which includes information about the patient's risk of interpersonal violence), which we finalized in the FY 2024 IPF PPS final rule (88 FR 51117 through 51121), will be publicly reported starting with the FY 2027 payment determination (the same period for which we are adopting the IPF ED Visit measure). With both measures being implemented and publicly reported at same time, IPFs and other interested parties will be able to compare performance on this IPF ED Visit measure across IPFs with similar rates of patients who screen positive for social needs under the Screen Positive Rate for SDOH measure.

We reiterate that the goal of this measure is to reduce rates of 30-day post-discharge ED visits in comparison to other similarly situated IPFs and that we seek to achieve this by publicly reporting IPF performance on this measure. We note that the IPF ED Visit measure is not intended to allow comparisons between post-discharge outcomes of patients discharged from IPFs and patients discharged from other facility types.

We also note that, as part of the measure development and testing process, the measure developer performed an equity analysis in which

[65] For information about the Cost and Efficiency endorsement review we refer readers to the meeting summary, available at *https://p4qm.org/sites/default/files/Cost%20and%20Efficiency/material/EM-Cost-and-Efficiency-Fall2023-Endorsement-Meeting-Summary.pdf.*

they tested the risk-adjustment methodology to ensure that the measure does not reflect access issues related to patient demographics instead of quality of care. The equity analysis involved comparing a model that included both SDOH and clinical risk-factors against a model that included only clinical risk factors. The model that included both SDOH and clinical risk-factors had only marginally better predictive accuracy than the model with only clinical risk-factors, suggesting that the impact of SDOH on the outcome is relatively small compared to the clinical risk-factors.[66] Furthermore, we have concerns about holding IPFs to different standards for the outcomes of their patients of diverse sociodemographic status because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. The measure developer's equity testing verified that the measure provides information about the quality of care provided in the IPF, even for IPFs that treat patients with different demographic characteristics.[67] Therefore, we do not expect results on this measure to be driven by an IPF's patient case-mix or prevalence of unmet social needs within that IPF. However, we will continue to monitor measure results to ensure that they reflect IPF quality of care.

Comment: Several commenters expressed concern that by including an all-cause measure we will not accurately represent the quality of care provided by IPFs. These commenters noted that there are reasons that patients seek emergency care that are unrelated to the care provided by the IPF, including accidents or physical health needs unrelated to the patient's behavioral health condition. Some commenters expressed concern that the use of an all-cause measure, instead of a more narrowly specified measure such as the potentially preventable admissions measures used in post-acute care settings (specifically, IRFs, SNFs, LTCHs, and HHAs) or the ED Visits Following Outpatient Chemotherapy measure in the Hospital Outpatient Quality Reporting Program), implies that IPFs have more accountability for patients than other care settings.

Response: We recognize that not all post-discharge ED visits are preventable, nor are all post-discharge ED visits associated with the initial IPF admission. Therefore, we do not expect rates for the IPF ED Visit measure to be zero. However, because engaging patients to improve post-discharge outcomes is an important element of providing quality care, we seek to develop and implement measures that assess this post-discharge outcome.

While there are many circumstances that may cause a patient to seek emergency care that are unrelated to the IPF, approximately 40 percent of Medicare beneficiaries discharged from IPFs seek acute care treatment in hospitals within 30 days of their discharge from the IPF, with approximately half of those patients being admitted to an inpatient hospital and half of those patients receiving treatment in the emergency department without a subsequent admission.[68] In 2021, approximately 4 percent of Medicare beneficiaries visited an ED each month with or without a subsequent admission,[69] which is significantly lower than the percentage of discharged IPF patients vising an ED. While we recognize that many patients discharged from IPFs are more clinically complex than the general Medicare population, we also believe that there is opportunity to close the gap in ED utilization between IPF patients and the Medicare beneficiary population at-large.

Furthermore, we developed an all-cause measure for the three reasons previously discussed: (1) to align with the IPF Unplanned Readmissions measure; (2) to emphasize whole-person care; and (3) to ensure that patients who visit the ED for symptoms related to their behavioral health condition or that could have been appropriately addressed by the IPF during the patient's stay or at discharge are included in the measure. These reasons continue to be important elements of assessing and reporting on post-discharge use of acute care.

We recognize that other CMS quality reporting and value-based purchasing programs have developed measures that assess the use of acute care services for more narrowly defined groups of patients or that focus on ''potentially preventable'' use of acute care services. However, we note that other programs have developed measures that more broadly assess outcomes after discharge. For example, the Hospital Inpatient Quality Reporting Program (IQR) Program has two measures that broadly assess outcomes after discharge: (1) the Hybrid Hospital-Wide Unplanned Readmission (HWR) measure[70] and (2) the Hybrid Hospital-Wide Mortality (HWM) measure.[71] The Hospital Outpatient Quality Reporting Program has one measure, the Surgery Measure (OP–36).[72]

We note that unmanaged behavioral health conditions can present in many ways including physical and mental symptoms. During an ED visit it is possible that the relationship between the presenting condition and the patient's behavioral health condition may not be assessed and documented. Therefore, we chose to develop a more broadly specified measure than some of the measures in use in other programs. This does not imply that IPFs have more control over or accountability for use of acute care than other care providers. It is a consequence of the complexity of the patients that seek care in IPFs. We reiterate we do not expect IPFs to achieve zero post-discharge acute care visits.

We believe that commenters may have been concerned regarding financial accountability for patients seeking emergency care after discharge from an IPF. We note that the IPFQR Program is a pay-for-reporting program. CMS only has the authority under section 1886(s)(4)(A) to apply a financial penalty if an IPF fails to submit data on a quality measure in the form and manner, and at a time, specified by CMS. CMS does not otherwise adjust payments based on the IPF's performance on the measures adopted in the IPFQR Program.

Comment: A commenter stated that IPFs do not have the appropriate health information technology (HIT) to electronically connect with local partners. These commenters stated that

[66] For more information regarding this equity testing, we refer readers to the ''Equity'' tab of the information submitted to the CBE for review and available during the pre-rulemaking review. This is available at: *https://p4qm.org/measures/4190.*

[67] For more information regarding this equity testing, we refer readers to the ''Equity'' tab of the information submitted to the CBE for review and available during the pre-rulemaking review. This is available at: *https://p4qm.org/measures/4190.*

[68] We refer readers to the FY 2025 IPF PPS proposed rule for more information regarding these calculations (89 FR 23207).

[69] CDC, Emergency Department Visit Rates by Selected Characteristics: United States, 2021. Accessed at *https://www.cdc.gov/nchs/data/databriefs/db478.pdf.*

[70] This measure evaluates whether a patient has an unplanned readmission within 30 days of discharge. For more addition on this measure, we refer readers to the hybrid measures section of the QualityNet website: *https://qualitynet.cms.gov/inpatient/measures/hybrid.*

[71] This measure estimates a hospital-level 30-day risk-standardized mortality rate, which is defined as death from any cause within 30 days after the index admission date. For more information on this measure, we refer readers to the hybrid measures section of the QualityNet website: *https://qualitynet.cms.gov/inpatient/measures/hybrid.*

[72] This measure estimates facility-specific risk-standardized hospital visits within seven days of hospital outpatient surgery. For more information on this measure, we refer readers to the surgery measure section of the QualityNet website: *https://qualitynet.cms.gov/outpatient/measures/surgery.*

this makes it more difficult for IPFs to engage in meaningful cross-setting discharge and follow-up care coordination.

Response: We understand that many IPFs have limited access to certified electronic health record technology (CEHRT) [73] and that this impacts their access to interoperable communications with other healthcare providers. However, there are many strategies for comprehensive discharge planning that do not rely on interoperable electronic systems. For example, the Agency for Healthcare Research and Quality (AHRQ) has the Include-Discuss-Educate-Assess-Listen (IDEAL) discharge planning guide which does not require any use of HIT.[74] We therefore believe that performance on this measure is not directly dependent on an IPF's technological capabilities.

Comment: Several commenters expressed concern that patients may not have access to post-discharge care other than through the ED. Commenters noted the following reasons for lack of access to lower acuity care: (1) underserved communities may not have lower acuity care available; (2) communal living settings may have policies that restrict access to lower acuity care settings; and (3) long wait times for outpatient appointments. A few commenters stated that utilization of the ED without subsequent admissions may demonstrate that patients are seeking medical care before their condition becomes so severe that inpatient care is required, and is therefore positive. A commenter stated that this measure may restrict patient access to EDs.

Response: While we agree that patients seeking medical care before their condition becomes so severe that inpatient care is required is preferable to patients needing to be readmitted, we disagree that seeking that care in the ED is a positive indication. Receiving care in the ED without an admission indicates that either the patient's condition has become urgent, or the patient is receiving lower-acuity care in the ED. A preferable outcome would be for the patient to be able to receive care in the community setting without having to use emergency services for low acuity care and improved care management.

Receiving lower acuity care in the ED can be time-consuming for the patient and can lead to increased spending and unnecessary testing and treatment,[75] and patients receiving care in EDs are at particularly high risk for adverse events.[76] Furthermore, patients receiving lower acuity care in the ED can lead to ED crowding, which can affect the ED's ability to provide care to higher acuity patients, and reduce the overall quality of care provided by the ED.[77] To avoid the potential risks associated with lower acuity care provided in the ED, guiding patients to other available resources, to the extent possible, is part of high quality discharge planning and post-discharge care coordination.

However, we recognize that EDs are valuable resources, which provide necessary care for urgent needs, and that there are areas in which EDs may be the only source of care available to patients. We also recognize that there are many situations in which care in an ED is clinically appropriate and not related to the care provided by the discharging IPF. We reiterate that the IPF ED Visit measure is designed to provide information regarding how IPFs perform relative to similar IPFs, including IPFs in the same geographic areas and shared community resources. The goal of this measure is to reduce rates of 30-day post-discharge ED visits in comparison to other similarly situated IPFs, but there is no expectation that IPFs would reach zero 30-day post-discharge ED visits.

Regarding the concern that this measure may restrict access to EDs following discharge from an IPF, we note that the intention of this measure is not for IPFs to discourage patients from seeking care in EDs when appropriate. Rather, we believe that IPFs play an important role in helping patients understand purposes of, and how to access, all levels of care within their communities, and that it is also their responsibility to help patients understand when to seek treatment in an ED setting. We also reiterate that, while lower scores on this measure are better, we would not expect IPFs to reach zero ED visits following discharge because there are circumstances that require the use of the ED.

Comment: A few commenters recommended that CMS develop a risk adjustment strategy for this measure. Another commenter stated that IPFs may refuse to admit patients who have complex medical needs because of the increased possibility that these patients would later seek emergency care and reflect poorly on the discharging IPF.

Response: As described in the FY 2025 IPF PPS proposed rule, this measure is risk-adjusted (89 FR 23208). The steps to calculate this measure are: (1) identify all IPF admissions in the one-year performance period; (2) apply inclusion and exclusion criteria to identify index admissions; (3) identify ED visits and observation stays within 30 days of discharge from each index admission; (4) identify risk factors in the 12 months prior to index admission and during the index admission; and (5) run hierarchical logistic regression to compute the risk-standardized ED visit rate for each IPF. We developed the hierarchical logistic regression model to understand which clinical patient characteristics had effects on the patients' risk of needing care in the ED within 30 days of discharge from the IPF. This analysis allows us to ensure that the measure results are comparable across IPFs regardless of the clinical complexity of each IPF's patient population. The hierarchical logistic regression model was provided for CBE review and was available to the public at the time of publication of the FY 2025 IPF PPS proposed rule. For more information on this model we refer readers to *https://p4qm.org/sites/default/files/2023-10/Copy%20of%20Risk-model specifications.xlsx.* Because this measure is risk adjusted for patient complexity, IPFs that admit patients with complex medical needs do not increase their risk of appearing to perform poorly on this measure.

Comment: Some commenters were concerned that IPFs may be penalized for factors outside of their control.

Response: We note that the IPFQR Program is a pay-for-reporting program. We only have the authority under section 1886(s)(4)(A) of the Act to apply a financial penalty if an IPF fails to submit data on a quality measure in the

[73] We note that CEHRT refers to EHR technology that qualifies for use in the Medicare Promoting Interoperability Program, though it is used by a variety of health care providers that do not participate in that Program. For more information about CEHRT, we refer readers to: *https://www.cms.gov/medicare/regulations-guidance/promoting-interoperability-programs/certified-ehr-technology.*

[74] Agency for Healthcare Research and Quality (AHRQ) Accessed at *https://www.ahrq.gov/sites/default/files/wysiwyg/professionals/systems/hospital/engagingfamilies/strategy4/Strat4_Tool_1_IDEAL_chklst_508.pdf.*

[75] Uscher-Pines L, Pines J, Kellermann A, Gillen E, Mehrotra A. Emergency department visits for nonurgent conditions: systematic literature review. Am J Manag Care. 2013 Jan;19(1):47–59. PMID: 23379744; PMCID: PMC4156292.

[76] Pini R, Ralli ML, Shanmugam S. Emergency Department Clinical Risk. 2020 Dec 15. In: Donaldson L, Ricciardi W, Sheridan S, et al., editors. Textbook of Patient Safety and Clinical Risk Management [internet]. Cham (CH): Springer; 2021. Chapter 15. Available from: *https://www.ncbi.nlm.nih.gov/books/NBK585618/* doi: 10.1007/978-3-030-59403-9_15.

[77] Sartini M, Carbone A, Demartini A, Giribone L, Oliva M, Spagnolo AM, Cremonesi P, Canale F, Cristina ML. Overcrowding in Emergency Department: Causes, Consequences, and Solutions-A Narrative Review. Healthcare (Basel). 2022 Aug 25;10(9):1625. doi: 10.3390/healthcare10091625. PMID: 36141237; PMCID: PMC9498666.

form and manner, and at a time, CMS specifies. We do not otherwise adjust or penalize payments based on the IPF's performance on the measures adopted in the IPFQR Program.

We understand commenters may be concerned about the impact of public reporting of IPFs performance on this measure as required by section 1886(s)(4)(F) of the Act, such as patients seeking care at higher performing IPFs. We reiterate that the goal of this measure is to reduce rates of 30-day post-discharge ED visits in comparison to other similarly situated IPFs and that we seek to achieve this by publicly reporting IPF performance on this measure. In addition, because the IPF ED Visit measure is risk standardized, it provides a tool for comparing IPFs that treat clinically different patient populations. Furthermore, by comparing IPFs which treat patients with similar levels of unmet social needs (by comparing IPFs which report similar rates on the Screen Positive for SDOH measure), patients would be able to use the IPF ED Visit measure as an element of their care decisions. We note that IPFs that experience extraordinary events, such as natural disasters, which affect their ability to submit required measure data under the IPFQR Program could request an extraordinary circumstances exception in accordance with our regulation at § 412.433(f).

Comment: A few commenters recommended that, for the IPFQR Program, CMS should only develop and adopt quality measures specific to the provision of inpatient psychiatric care. A few commenters recommended that CMS develop quality measures that focus on factors within the IPF's control, such as a discharge planning measure or a follow-up after discharge measure to better assess discharge planning and care coordination. Some commenters recommended development of condition-specific measures to assess post-discharge use of acute care. A commenter recommended assessing care coordination through use of a patient experience survey.

Response: Regarding the recommendation that CMS should only develop and adopt quality measures specific to the provision of inpatient psychiatric care, we note that helping patients successfully reintegrate into their communities upon discharge is an important element of the provision of high-quality inpatient psychiatric care. However, we believe the commenter is recommending that we more narrowly focus measures on actions performed by the IPF while the patient is receiving care at the facility.

Consistent with the CMS National Quality Strategy's Focus on a health care system that promotes quality outcomes,[78] we focus on measures that assess outcomes where possible. We recognize that one limitation of measures that assess outcomes is that outcomes are the result of numerous factors, many beyond providers' control.[79] We considered other ways of assessing discharge planning and care coordination. However, we chose to develop this measure instead of a discharge planning measure because it more directly assesses the outcome we wish to achieve (improved reintegration into communities after discharge) and can be calculated using data that IPFs already provide. We note that we already have the Follow-Up After Psychiatric Hospitalization (FAPH) measure[80] in the IPFQR Program. For more information about the FAPH measure and how the IPF ED Visit measure complements we refer readers to our discussion in section VI.B.2.a. of this final rule.

Regarding the recommendation that we include care transition questions in a patient experience measure, we agree that the patient's experience of being prepared to successfully reintegrate into the community is an important element of discharge planning and care coordination. We note that the Psychiatric Inpatient Experience (PIX) survey measure, which we finalized in the FY 2024 IPF PPS final rule (88 FR 51121 through 51128), includes a treatment effectiveness domain, including questions related to the patient's perspective of whether their care experience has prepared them to transition back into the community. However, the patient's perspective at time of discharge is only one element of a complex set of elements that lead to a successful reintegration into the community, including, for example, the appropriateness and completeness of documentation and whether recommendations for outpatient care appropriately account for the patient's ability to access this care.

Comment: Some commenters were concerned about the lack of CBE endorsement, specifically expressing the belief that the CBE's lack of consensus on whether to endorse the measure indicated that the measure was not reliable or valid. A commenter recommended the inclusion of experts in the measure development process, including individuals involved in providing care in IPFs. A commenter stated the belief that the measure developer misinterpreted the statistical significance of the measure in reliability and validity testing. Other commenters stated that the measure specifications do not provide a clear connection between evidence-based interventions and measure outcomes. A commenter stated the belief that adopting this measure, despite lack of CBE endorsement, with the sole justification that there is no endorsed measure that addresses this topic is an insufficient justification for adopting a measure that is not endorsed by the CBE.

Response: We agree that it is important to adopt measures that are reliable and valid and have been reviewed by clinical experts. Through the development and testing of this measure, which we described in the FY 2025 IPF PPS proposed rule (89 FR 23208) and in more detail in the measure information submitted for CBE review[81] as discussed in the FY 2025 IPF PPS proposed rule (89 FR 23209 through 23210), it meets these criteria.

Specifically, the measure developer tested the measure for reliability using a bootstrapped test-retest approach (which is a statistical method for testing using a single data set)[82] and calculated the intra-class correlation coefficient (ICC) which reflects correlation and agreement between measurements. The mean ICC obtained by through this method was 0.690 with a range of 0.683 through 0.756.[83] Generally, ICC values between 0.5 and 0.75 are considered moderate and between 0.75 and 0.9 are considered good.[84] Therefore this measure is in the high-moderate to low-good range of reliability, which is

[78] CMS, CMS Quality in Motion: Acting on the CMS National Quality Strategy. April 2024. Available at: *https://www.cms.gov/files/document/quality-motion-cms-national-quality-strategy.pdf.*

[79] Agency for Healthcare Research and Quality, Types of Health Care Quality Measures. Access May 30, 2024. Available at: *https://www.ahrq.gov/talkingquality/measures/types.html#:~:text=Outcome measures%20may%20seemto, %20many%20beyond%20providers'%20control.*

[80] For more information about this measure, we refer readers to the codebook, available at: *https://qualitynet.cms.gov/files/6675efeba629e067996f932d?filename=FY25_IPFQR_FAPH_Codebook.xlsx.*

[81] Available at Partnership for Quality Measurement. *https://p4qm.org/measures/4190.*

[82] PennState, Eberly College of Science, Applied Statistics. Available at *https://online.stat.psu.edu/stat500/lesson/11/11.2/11.2.1.*

[83] Information available on the Partnership for Quality Measurement measure page, available at *https://p4qm.org/measures/4190.*

[84] Koo TK, Li MY. A Guideline of Selecting and Reporting Intraclass Correlation Coefficients for Reliability Research. J Chiropr Med. 2016 Jun;15(2):155–63. doi: 10.1016/j.jcm.2016.02.012. Epub. 2016 Mar. 31. Erratum in: J. Chiropr. Med. 2017 Dec;16(4):346. PMID: 27330520; PMCID: PMC4913118.

sufficiently reliable for adoption into the IPFQR Program.

To test the validity, the measure developer assessed the relationship between the IPF ED Visit measure rate and the IPF Unplanned Readmission measure rate. The measure developer also performed hypothesis-driven validity testing to determine if performance rates among subgroups of patients (including based on sex, race/ethnicity, dual eligibility status, and patients with a longer length of stay) were consistent with empirical literature regarding ED usage among these patients. There was a positive relationship between facility rates on the IPF ED Visit measure and the IPF Unplanned Readmissions measure and there were small differences in the ED measure rate across the patient subgroups they evaluated in the direction consistent with expectations based on literature.[85] These results demonstrate the validity of the measure. Furthermore, as part of the standard measure development process [86] the measure developer convened a Technical Expert Panel (TEP) representing a diverse set of viewpoints (89 FR 23208) to ensure that the measure would addresses a gap that is important to interested parties. We further note that, while the measure did not meet the 75 percent threshold required for endorsement, the majority (60.6 percent) of the CBE committee did support endorsement, or endorsement with conditions.

Regarding the concern that the measure developer misinterpreted the statistical data, we have assessed the results achieved in testing to be consistent with appropriate statistical methods.

While there is limited research focused entirely on reducing ED visits without subsequent admission following discharge from an IPF, the literature that exists, as well as literature on reducing readmissions following IPF discharge, show clear links between steps IPFs can take and reduced use of acute care after discharge from the IPF. Additionally, IPFs can play a role in care coordination by arranging follow-up appointments for patients, ensuring medications are available at discharge, assisting patients with accessing medications from external providers, and engaging the patients' social support system. Patients who missed their first post-IPF discharge follow-up appointment had a 140 percent increased risk of readmission,[87] which indicates the importance of providing sufficient patient education and post-discharge support to ensure the patient is able to keep their first post-IPF discharge follow-up appointment.

When we propose a measure that is not endorsed by the CBE, we must evaluate whether the exception in 1886(s)(4)(D)(ii) of the Act applies. This exception 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 stated in the proposed rule that there are no measures that address this topic that have been adopted by the CBE to explain why the second part of this exception applies to this measure (89 FR 23210). We are adopting the IPF ED Visit measure because it is a measure that has been tested for feasibility, validity, and reliability, which was developed with input from a diverse set of experts, that will provide data that patients and their families can use to inform care decisions and IPFs can use to drive quality improvement activities. We gave due consideration to measures endorsed by the CBE and there were no measures that address this important outcome.

Final Decision: After consideration of the comments we received, we are finalizing our proposal to adopt the IPF ED Visit measure beginning with the CY 2025 performance period/FY 2027 payment determination as proposed.

C. Summary of IPFQR Program Measures for the FY 2027 Payment Determination for the IPFQR Program

We are adopting one new measure for the FY 2027 payment determination for the IPFQR Program. With the adoption of this measure, the FY 2027 IPFQR Program measure set includes 16 mandatory and one voluntary measure. Table 19 sets forth the measures in the FY 2027 IPFQR Program.

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[85] Information available on the Partnership for Quality Measurement measure page, available at *https://p4qm.org/measures/4190*.

[86] CMS. Blueprint Measure Lifecycle. Available at *https://mmshub.cms.gov/blueprint-measure-lifecycle-overview*.

[87] Hamilton, J.E., Rhoades, H., Galvez, J. et al. (2015). Factors differentially associated with early readmission at a university teaching psychiatric hospital. Journal of Evaluation in Clinical Practice, 21(4), 572–578.

TABLE 19: IPFQR PROGRAM MEASURE SET FOR THE FY 2027 PAYMENT DETERMINATION FOR THE IPFQR PROGRAM

CBE #	Measure ID	Measure
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
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
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
N/A	N/A	30-Day Risk-Standardized All-Cause Emergency Department Visit Following an Inpatient Psychiatric Facility Discharge measure[1]
3205*	Med Cont.	Medication Continuation Following Inpatient Psychiatric Discharge
N/A	N/A	Modified COVID-19 Healthcare Personnel (HCP) Vaccination Measure
N/A	Facility Commitment	Facility Commitment to Health Equity
N/A	Screening for SDOH	Screening for Social Drivers of Health
N/A	Screen Positive	Screen Positive Rate for Social Drivers of Health
Voluntary Measure		
N/A	PIX Survey	Psychiatric Inpatient Experience Survey[2]

* 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 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] Measure finalized for adoption in Section VI.B.2. of this final rule.

[2] We note that the PIX measure will become mandatory for the FY 2028 payment determination, as finalized in the FY 2024 IPF PPS Final Rule (88 FR 51128).

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D. Retention of Data Submission Requirements for the FY 2027 Payment Determination and Subsequent Years

Section 1886(s)(4)(C) of the Act requires the submission of quality data in a form and manner, and at a time, specified by the Secretary. In the Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2013 Rates; Hospitals' Resident Caps for Graduate Medical Education Payment Purposes; Quality Reporting Requirements for Specific Providers and for Ambulatory Surgical Centers (FY 2013 IPPS/LTCH PPS) final rule (77 FR 53655), we specified that data must be submitted between July 1 and August 15 of the calendar year preceding a given payment determination year (for example, data were required to be submitted between July 1, 2015 and August 15, 2015 for the FY 2016 payment determination). In the Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2014 Rates; Quality Reporting Requirements for Specific Providers; Hospital Conditions of Participation; Payment Policies Related to Patient Status (FY 2014 IPPS/LTCH PPS) final rule (78 FR 50899), we clarified that this policy applied to all future years of data submission for the IPFQR Program unless we changed the policy through future rulemaking.

In the FY 2018 IPF PPS final rule (82 FR 38472 through 38473) we updated this policy by stating that the data submission period will be a 45-day period beginning at least 30 days following the end of the data collection period and that we will provide notification of the exact dates through subregulatory means.

In the FY 2022 IPF PPS Final Rule (86 FR 42658 through 42661), we finalized voluntary patient-level data reporting for the FY 2023 payment determination and mandatory patient-level data reporting for chart-abstracted measures within the IPFQR Program beginning with FY 2024 payment determination and subsequent years. The measures currently in the IPFQR Program affected by this requirement are set forth in Table 20.

TABLE 20: IPFQR PROGRAM MEASURES REQURING PATIENT-LEVEL DATA SUBMISSION

CBE #	Measure ID	Measure
Required Measures		
0640	HBIPS-2	Hours of Physical Restraint Use (numerator only)
0641	HBIPS-3	Hours of Seclusion Use (numerator only)
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
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

* 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 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.

As we have gained experience with patient-level data submission for the IPFQR program, during the voluntary data submission period for FY 2023 (which occurred in CY 2022) and the first mandatory data submission period for FY 2024 (which occurred in CY 2023), we have observed that annual data submission periods require IPFs to store large volumes of patient data to prepare for transmission to CMS. Furthermore, the volume of data associated with all IPFs reporting a full year of patient-level data during one data submission period creates the risk that systems will be unable to handle the volume of data.

We have reviewed how other quality reporting programs that require patient-level data submission address these concerns and determined that the Hospital Inpatient Quality Reporting (IQR) Program (78 FR 50811) and the Hospital Outpatient Quality Reporting (OQR) Program (72 FR 66872) both require quarterly submission of patient-level data. As we considered requiring quarterly reporting for the IPFQR Program, we also determined that increasing the frequency of data submission would allow additional analysis of measure trends over time. In the FY 2025 IPF PPS proposed rule, we stated that having additional data points (from additional quarters of data) could allow for more nuanced analyses of the IPFQR Program's measures (89 FR 23212). We stated that specifically, we would be able to better identify quarterly highs or lows that may be less apparent when data are combined over a full year. We recognized that, if we updated data reporting requirements to require reporting four times per year instead of once per year, then IPFs would need to meet four incremental deadlines instead of one deadline, and that this increased the risk that an individual IPF may fail to submit data specified for the measures and not receive its full market basket update. However, we believe that this risk is low because IPFs already have experience submitting some data required by the IPFQR Program on a more frequent basis. Specifically, the COVID–19 Healthcare Personnel (HCP) Vaccination Measure is currently reported into the CDC's National Healthcare Safety Network (NHSN) for one week per month resulting in a quarterly measure result (as originally adopted in the FY 2022 IPF PPS final rule (86 FR 42636) and restated in the FY 2024 IPF PPS final rule (88 FR 51131 through 51132). In addition, if this proposal for quarterly data submission were finalized, data submission for each calendar quarter would have been required during a

period of at least 45 days beginning three months after the end of the calendar quarter. Table 21 summarizes the deadlines we proposed for the CY 2025 and CY 2026 performance periods:

TABLE 21: QUARTERLY SUBMISSION DEADLINES FOR CY 2025 AND CY 2026 PERFORMANCE PERIODS, AS PROPOSED

Performance Period	Submission Deadline
January 1, 2025- March 31, 2025 (Q1 2025)	November 15, 2025
April 1, 2025 – June 30, 2025 (Q2 2025)	November 15, 2025
July 1, 2025 – September 30, 2025 (Q3 2025)	February 15, 2026
October 1, 2025 – December 31, 2025 (Q4 2025)	May 15, 2026
January 1, 2026- March 31, 2026 (Q1 2026)	August 15, 2026
April 1, 2026 – June 30, 2026 (Q2 2026)	November 15, 2026
July 1, 2026 – September 30, 2026 (Q3 2026)	February 15, 2027
October 1, 2026 – December 31, 2026 (Q4 2026)	May 15, 2027

Furthermore, we proposed that all data which continue to be reported on an annual basis (that is, non-measure data, aggregate measures, and attestations) would have been required to be reported concurrently with the data from the fourth quarter of the applicable year. For example, data reflecting the entirety of CY 2025 (that is, non-measure data, aggregate measures, and attestations) would have been required by the Q4 2025 submission deadline (that is, May 15, 2026).

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported our proposal to transition to quarterly submission of patient-level data. A commenter agreed that this may reduce the risk that systems are unable to handle the data volume and increase the data available for trend analysis.

Response: We thank these commenters for their support.

Comment: Several commenters expressed concerns regarding the proposed timeline of requiring quarterly submission of patient level data beginning with the CY 2025 performance period. Some of these commenters expressed concern that IPFs would not be able to update processes and systems to meet the November 15, 2025 submission deadline for the first quarter of the CY 2025 performance period (January 1, 2025–March 31, 2025). Other commenters stated that the CMS Specifications Manual releases are often delayed from discharge dates, which affects when IPFs can abstract data to prepare for submission. A commenter stated that transitioning to quarterly reporting may affect the ability of newly certified IPFs to successfully participate in the IPFQR Program due to the time it takes to receive notice of accreditation.

Response: After reviewing the concerns raised by commenters regarding the challenges of transitioning to quarterly reporting, we agree with commenters that these challenges would affect some IPFs' ability to report data for the CY 2025 performance period (that is, the FY 2027 payment determination). Therefore, we are not finalizing this proposal at this time.

If we propose to adopt quarterly reporting in the future, we will consider the transition time required for IPFs to update their submissions, evaluate the timing of the CMS Specifications Manual with respect to reporting deadlines, and ensure that newly certified facilities are able to participate in the IPFQR Program.

Comment: Several commenters recommended that CMS delay adoption of this policy. Some of these commenters recommended a stepped approach in which CMS gradually transitions to quarterly reporting. A commenter recommended only requiring data submission twice annually. A few commenters recommended delaying adoption of this policy until CMS and IPFs have more experience with patient-level data submission and to decrease financial risk to IPFs.

Response: We thank these commenters for their recommendations. We are not finalizing this proposal at this time. If we propose more frequent reporting in the future, we will consider these approaches to more frequent reporting in any future rulemaking.

Comment: A few commenters expressed concern that this proposal would quadruple IPF's information collection burden.

Response: We understand commenters' concerns that there would be an increase in reporting burden associated with increasing the required frequency of reporting patient-level data. We note that we are not finalizing this proposal at this time. However, we disagree that increasing from annual reporting to quarterly reporting would quadruple the information collection burden. We note that reviewing patient medical records to determine which patients are included in numerators and denominators for each measure is the portion of measure submission which entails the highest information collection burden, and that changing the

frequency with which data are to be reported would have no impact on the number of patients for whom IPFs are required medical records to calculate measure results.

Comment: Several commenters expressed concern that the increase in staff time spent reporting would reduce staff availability for patient care duties. A commenter expressed that this data reporting frequency would be more burdensome for IPFs than quarterly reporting is for other healthcare providers because IPFs experience more challenges related to outdated HIT. Some commenters recommended that CMS provide financial support, potentially by increasing payment rates for IPFs, for the increased reporting frequency due to the increased burden it would require. Several commenters expressed concern that this increased reporting frequency would disproportionately increase IPF costs relative to benefits that more frequent reporting would provide.

Response: We understand commenters' concerns that there would be an increase in reporting burden associated with increasing the required frequency of reporting patient-level data. We recognize that IPFs have faced more barriers in adopting and updating HIT than acute care hospitals, and that this may affect their ability to abstract, store, and submit quality measure data on a more frequent basis. We note that we are not finalizing this proposal at this time. However, we disagree with commenters regarding the impact this proposed increase in reporting frequency would have. As previously discussed, reporting the information to CMS is a small portion of the total information collection burden associated with participating in the IPFQR Program. Therefore, we believe that the increase in reporting frequency would have a relatively small impact on IPFs' reporting burden and that this impact would not meaningfully affect IPFs' ability to provide patient care. We also do not believe that the increase in reporting frequency would significantly increase the cost of reporting and therefore we do not believe that an increase in payment to account for this increase would be necessary or appropriate. However, we will consider the potential impact on reporting burden to ensure that the benefits of more frequent collection outweigh the increase in costs of participation if we propose quarterly reporting in future rulemaking.

Comment: A commenter requested clarification regarding whether data submission for the PIX survey measure would be included in the transition to quarterly data submission.

Response: We are not finalizing our proposal to transition to quarterly reporting. If we propose a transition to quarterly reporting in future rulemaking, we will state what data is included in that proposal at that time.

Comment: A few commenters provided recommendations for actions to take prior to transitioning to quarterly data submission. These actions were: (1) ensure alignment of IPFQR submission deadlines with deadlines for other CMS quality reporting programs; (2) reduce the number of program measures; (3) reduce the number of measures which require manual abstraction or submission; and (4) align measures across programs, as feasible and appropriate.

Response: We thank commenters for these recommendations. We will consider these recommendations as we evaluate the IPFQR Program for future transition to quarterly data submission.

Comment: Some commenters expressed concern that the accuracy of the data submitted may be compromised unless non-measure data and aggregate measures were also submitted quarterly. These commenters stated that updates to billing and medical records could occur after the submission of quarterly patient-level data that could create inconsistencies between the data submitted on a quarterly basis and that submitted on an annual basis. These commenters provided an example of their concern, specifically that denominator for the Hours of Physical Restraint Use (Hospital-Based Inpatient Psychiatric Services—HBIPS–2) and Hours of Seclusion Use (HBIPS–3) measures [88] is included in the non-measure data set and therefore these measures would be particularly susceptible to data inaccuracies. A few commenters stated that because of the relatively small number of patients served by IPFs (compared to patients served by acute care hospitals) quarterly sample sizes would likely be too small to perform improved trend analysis with the increased frequency of data submission.

Response: We agree with commenters that ensuring that the data we publicly report are accurate and complete is an important part of the IPFQR Program. We recognize commenters' concerns that, without additional guidance regarding timing of data abstraction and reporting with respect to billing and medical record updates, there is a potential to create discrepancies between data submitted on a quarterly basis and data submitted on an annual basis. We further agree with commenters that this could be particularly concerning regarding the HBIPS–2 and HBIPS–3 measures because the denominators for these measures would be included in the annually reported data set and the numerators would be included in the quarterly reported dated set. We understand commenters' concern that the relatively small sample sizes may be too small to perform improved trend analysis. We note that we are not finalizing this proposal at this time. We will consider these recommendations as we evaluate the IPFQR Program for future transition to quarterly data submission.

Final Decision: After consideration of the comments we received, we are not finalizing our proposal to modify data submission requirements, beginning with the FY 2027 payment determination, to transition to quarterly data submission for patient-level data.

VII. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

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

This final rule refers to associated information collections that are not discussed in the regulation text contained in this document.

The following changes will be submitted to OMB for review under control number 0938–1171 (CMS–10432). We did not propose changes that would change any of the data collection instruments that are currently approved under that control number.

[88] For more information on the HBIPS–2 and HBIPS–3 measures we refer readers to the IPF Specifications Manual available at: *https://qualitynet.cms.gov/files/6675e252a629e067996f9205?filename=IPF_SpecMan_v1.3.pdf.*

A. Wage Estimates

In the FY 2024 IPF PPS final rule, we utilized the median hourly wage rate for Medical Records Specialists, in accordance with the Bureau of Labor Statistics (BLS), to calculate our burden estimates for the IPFQR Program (88 FR 51145). While the most recent data from the BLS reflects a mean hourly wage of $24.65 per hour for all medical records specialists, $26.06 is the mean hourly wage for ''general medical and surgical hospitals,'' which is an industry within medical records specialists.[89] We believe the industry of ''general medical and surgical hospitals'' is more specific to the IPF setting for use in our calculations than other industries that fall under medical records specialists, such as ''office of physicians'' or ''nursing care facilities (skilled nursing facilities).'' We calculated the cost of indirect costs, including fringe benefits, at 100 percent of the median hourly wage, consistent with previous years. This is necessarily a rough adjustment, both because fringe benefits and other indirect costs vary significantly by employer and methods of estimating these costs vary widely in the literature. Nonetheless, we believe that doubling the hourly wage rate ($26.06 × 2 = $52.12) to estimate total cost is a reasonably accurate estimation method. Accordingly, unless otherwise specified, we will calculate cost burden to IPFs using a wage plus benefits estimate of $52.12 per hour throughout the discussion in this section of this rule for the IPFQR Program.

Some of the activities previously finalized for the IPFQR Program require beneficiaries to undertake tasks such as responding to survey questions on their own time. In the FY 2024 IPF PPS final rule, we estimated the hourly wage rate for these activities to be $20.71/hr (88 FR 51145). We updated the estimate to a post-tax wage of $24.04/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.[90] To derive the costs for beneficiaries, we used a measurement of the usual weekly earnings of wage and salary workers of $1,118, divided by 40 hours to calculate an hourly pre-tax wage rate of $27.95/hr.[91] The rate is adjusted downwards by an estimate of the effective tax rate for median income households of about 14 percent calculated by comparing pre- and post-tax income,[92] resulting in the post-tax hourly wage rate of $24.04/hr. Unlike our State and private sector wage adjustments, we did not adjust beneficiary wages for fringe benefits and other indirect costs since the individuals' activities, if any, would occur outside the scope of their employment.

B. Previously Finalized IPFQR Estimates

We finalized provisions that impact policies beginning with the FY 2027 payment determination. For the purposes of calculating burden, we attribute the costs to the year in which the costs begin. Under our previously finalized policies, data submission for the measures that affect the FY 2027 payment determination occurs during CY 2026 and generally reflects care provided during CY 2025. Our currently approved burden for CY 2025 is set forth in Table 22.

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[89] Medical Records Specialists (*bls.gov*).

[90] *https://aspe.hhs.gov/reports/valuing-time-us-department-health-human-services-regulatory-impact-analyses-conceptual-framework.*

[91] *https://www.bls.gov/news.release/pdf/wkyeng.pdf.* Accessed January 1, 2024.

[92] *https://www.census.gov/library/stories/2023/09/median-household-income.html.* Accessed January 2, 2024.

TABLE 22: PREVIOUSLY IPFQR PROGRAM FOR CY 2025

Measure/Response Description	Number Respondents	Number of Responses/ Respondent	Total Annual Responses	Time per Response (hrs)	Time per Facility (hrs)	Total Annual Time (hrs)	Applicable Wage Rate ($/hr)	Cost per Facility ($)	Total Annual Cost ($)
Hours of Physical Restraint Use	1,596	1,261	2,012,556	0.25	315	503,139	44.86	14,142	22,570,816
Hours of Seclusion Use	1,596	1,261	2,012,556	0.25	315	503,139	44.86	14,142	22,570,816
Follow-Up After Psychiatric Hospitalization	1,596	0	0	0	0	0	44.86	0	0
Alcohol Use Brief Intervention Provided or Offered and SUB-2a Alcohol Use Brief Intervention	1,596	609	971,964	0.25	152	242,991	44.86	6,830	10,900,576
Alcohol and Other Drug Use Disorder Treatment Provided or Offered at Discharge and SUB-3a Alcohol and Other Drug Use Disorder Treatment at Discharge	1,596	609	971,964	0.25	152	242,991	44.86	6,830	10,900,576
Tobacco Use Treatment Provided or Offered at Discharge and TOB-3a Tobacco Use Treatment at Discharge	1,596	609	971,964	0.25	152	242,991	44.86	6,830	10,900,576
Influenza Immunization	1,596	609	971,964	0.25	152	242,991	44.86	6,830	10,900,576
Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care)	1,596	609	971,964	0.25	152	242,991	44.86	6,830	10,900,576

Measure/Response Description	Number Respondents	Number of Responses/ Respondent	Total Annual Responses	Time per Response (hrs)	Time per Facility (hrs)	Total Annual Time (hrs)	Applicable Wage Rate ($/hr)	Cost per Facility ($)	Total Annual Cost ($)
Screening for Metabolic Disorders	1,596	609	971,964	0.25	152	242,991	44.86	6,830	10,900,576
Thirty-Day All-Cause Unplanned Readmission Following Psychiatric Hospitalization in an Inpaticnt Psychiatric Facility	1,596	0	0	0	0	0	44.86	0	0
30-Day Risk-Standardized All-Cause Emergency Department Visit Following an Inpatient Psychiatric Facility Discharge measure	1,596	0	0	0	0	0	44.86	0	0
Medication Continuation Following Inpatient Psychiatric Discharge	1,596	0	0	0	0	0	44.86	0	0
Modified COVID-19 Healthcare Personnel (HCP) Vaccination Measure	1,596	0	0	0	0	0	44.86	0	0
Facility Commitment to Health Equity	1,596	1	1,596	0.167	0	267	44.86	7	11,957
Screening for Social Drivers of Health (Data Submission)	798	1	798	0.167	0	133	44.86	7	5,978
Screen Positive Rate for Social Drivers of Health	798	1	798	0.167	0	133	44.86	7	5,978
Non Measure Data Collection	1,596	4	6,384	0.5	2	3,192	44.86	90	143,193
Subtotal for Medical Records Specialists	*1,596*	*6,183*	*9,866,472*	*Varies*	*1,547*	*2,467,949*	*44.86*	*69,376*	*110,712,195*
Screening for Social Drivers of Health (Patient Screening)	1,596	1,261	2,012,556	0.033	42	66,414	20.71	862	1,375,441
Psychiatric Inpatient Experience Survey	798	300	239,400	0.121	36	28,967	20.71	752	599,915
Subtotal for Individuals	*1,596*	*1,561*	*2,251,956*	*Varies*	*78*	*95,382*	*20.71*	*1,614*	*1,975,356*
Totals	**1,596**	**7,744**	**12,118,428**	**3.155**	**1,624**	**2,563,331**	**804.04**	**70,990**	**112,687,551**

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C. Updates Due to More Recent Information

In section VI.A of this final rule, we described our updated wage rates which increase from $44.86/hr to $52.12/hr (an increase of $7.26/hr) for activities performed by Medical Records Specialists and from $20.71/hr to $24.04/hr (an increase of $3.33/hr) for activities performed by individuals. The effects of these updates are set forth in Table 23.

TABLE 23: EFFECTS OF WAGE RATE UPDATES

Measure/Response Description	Total Annual Responses	Time Per Response (hrs)	Time per Facility (hrs)	Total Annual Time (hrs)	Change in Applicable Wage Rate ($/hr)	Change in Cost per Facility ($)	Change in Total Annual Cost ($)
Subtotal for Medical Records Specialists	9,866,472	Varies	1,547	2,467,949	7.26	11,228	17,919,245
Subtotal for Individuals	2,251,956	Varies	78	95,382	3.33	259	414,083
Totals	12,118,428	Varies	1,624	2,563,331	Varies	11,487	18,333,328

D. Updates Due to Policies in This Final Rule

In section VI.B.2 of this final rule, we are adopting the 30-Day Risk-Standardized All-Cause ED Visit Following an IPF Discharge (IPF ED Visit) measure beginning with the CY 2025 performance period/FY 2027 payment determination. As described in section VI.B.2.c. of this final rule, we will calculate the IPF ED Visit measure using Medicare claims that IPFs and other providers submit for payment. Since this is a claims-based measure, there is no additional burden outside of submitting a claim. The claim submission is approved by OMB under control number 0938–0050 (CMS–2552–10). This rule does not warrant any changes under that control number.

In Section VI.D. of this final rule, we are not finalizing our proposal to require IPFs to submit data on chart-abstracted measures quarterly. Because we are not finalizing this proposal it will have no effect on information collection burden.

E. Consideration of Burden Related to Clarification of Eligibility Criteria for the Option To Elect To File an All-Inclusive Cost Report

As discussed in section IV.E.4 of this final rule, we clarified the eligibility criteria to be approved to file all-inclusive cost reports. Only government-owned, IHS, and tribally owned facilities are able to satisfy these criteria, and thus only these facilities will be permitted to file an all-inclusive cost report for cost reporting periods beginning on or after October 1, 2024.

We do not estimate any change in the burden associated with the hospital cost report (CMS–2552–10) OMB control number 0938–0050. We anticipate that IPFs which are currently filing all-inclusive cost reports, but are not government-owned or tribally owned, will not incur additional burden related to the submission of the cost report. The approved burden estimate associated with the submission of the hospital cost report includes the same amount of burden for the submission of an all-inclusive cost report as for the submission of a cost report with a charge structure.

We recognize that these IPFs will be required to track ancillary costs and charges using a charge structure; however, we expect that any burden associated with this tracking will be part of the normal course of a hospital's activities.

F. Submission of PRA-Related Comments

We have submitted a copy of the final rule's information collection requirements to OMB for their review. The requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections discussed above, please visit the CMS website at *https://www.cms.gov/regulationsand-guidance/legislation/paperworkreductionactof1995/pra-listing,* or call the Reports Clearance Office at 410–786–1326.

We invited public comments on these potential information collection requirements.

Comment: We summarized comments on the proposed information collection burden associated with the proposed transition to quarterly reporting in Section VI.D. of this final rule.

Response: As noted in Section VI.D. of this final rule, we are not finalizing our proposal to require IPFs to submit data on chart-abstracted measures quarterly. Because we are not finalizing this proposal it will have no effect on information collection burden.

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 2025 (October 1, 2024 through September 30, 2025). We are finalizing our proposal to apply the 2021-based IPF market basket increase for FY 2025 of 3.3 percent, reduced by the productivity adjustment of 0.5 percentage point as required by section 1886(s)(2)(A)(i) of the Act for a final total FY 2025 payment rate update of 2.8 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, adopt new CBSA delineations based on OMB Bulletin 23–01, and update the IPF wage index to reflect the FY 2025 hospital inpatient wage index. Section 1886(s)(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 on 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). Section 3(f) of Executive Order 12866, as amended by Executive Order 14094, defines a ''significant regulatory action'' as an action that is likely to result in a rule that may: (1) have an annual effect on the economy of $200 million or more (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) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impacts of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in Executive Order 12866. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

A regulatory impact analysis (RIA) must be prepared for regulatory actions that are significant under section 3(f)(1) of Executive Order 12866. We estimate that the total impact of these changes for FY 2025 payments compared to FY 2024 payments will be a net increase of approximately $65 million. This reflects a $75 million increase from the update to the payment rates (+$90 million from the 2nd quarter 2024 IGI forecast of the 2021-based IPF market basket of 3.3 percent, and −$15 million for the productivity adjustment of 0.5 percentage point), as well as a $10 million decrease as a result of the update to the outlier threshold amount. Outlier payments are estimated to change from 2.3 percent in FY 2024 to 2.0 percent of total estimated IPF payments in FY 2025.

Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is not significant per section 3(f)(1) as measured by the $200 million or more in any 1 year, but does meet the criteria under 5 U.S.C. 804(2) (Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996, also known as the Congressional Review Act). Nevertheless, because of the potentially substantial impact to IPF providers, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking. Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined that this rulemaking is ''significant.'' Therefore, OMB has reviewed the final regulations, and the Departments have provided the following assessment of their impact.

C. Detailed Economic Analysis

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

1. Budgetary Impact

As discussed in the RY 2005 and RY 2007 IPF PPS final rules, we applied a budget neutrality factor to the Federal per diem base rate and ECT payment per treatment to ensure that total estimated payments under the IPF PPS in the implementation period would equal the amount that would have been paid if the IPF PPS had not been implemented. 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 IV.D.1.d of this final rule, we are updating the wage index and labor-related share, as well as update the CBSA delineations based on OMB Bulletin 23–01, 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. In addition, as discussed in section IV.F of this final rule, we are applying a refinement standardization factor to the Federal per diem base rate and ECT payment per treatment to account for the proposed revisions to the ECT per treatment amount, ED adjustment, and patient-level adjustment factors (as previously discussed in sections IV.B, IV.C, and IV.D of this final rule, and summarized in Addendum A), which must be made budget-neutrally. Therefore, the budgetary impact to the Medicare program of the final rule will be due to the final market basket update for FY 2025 of 3.3 percent (see section IV.A.2 of this final rule) reduced by the productivity adjustment of 0.5 percentage point required by section 1886(s)(2)(A)(i) of the Act and the update to the outlier fixed dollar loss threshold amount.

We estimate that the FY 2025 impact will be a net increase of $65 million in payments to IPF providers. This reflects an estimated $75 million increase from the update to the payment rates and a $10 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 2025. This estimate does not include the implementation of the required 2.0 percentage point reduction of the productivity-adjusted 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 compared estimated payments under the IPF PPS rates and factors for FY 2025 versus those under FY 2024. We determined the percent change in the estimated FY 2025 IPF PPS payments compared to the estimated FY 2024 IPF PPS payments for each category of IPFs. In addition, for each category of IPFs, we have included the estimated percent change in payments resulting from the update to the outlier fixed dollar loss threshold amount; the revisions to the patient-level adjustment factors, ED adjustment, and ECT per treatment amount; the updated wage index data including the labor-related share and the changes to the CBSA delineations; and the market basket increase for FY 2025, as reduced by the productivity adjustment according to section 1886(s)(2)(A)(i) of the Act.

To illustrate the impacts of the final FY 2025 changes in this rule, our analysis begins with FY 2023 IPF PPS claims (based on the 2023 MedPAR claims, March 2024 update). We estimated FY 2024 IPF PPS payments using these 2023 claims, the finalized FY 2024 IPF PPS Federal per diem base rate and ECT per treatment amount, and the finalized FY 2024 IPF PPS patient and facility level adjustment factors (as published in the FY 2024 IPF PPS final

rule (88 FR 51054)). We then estimated the FY 2024 outlier payments based on these simulated FY 2024 IPF PPS payments using the same methodology as finalized in the FY 2024 IPF PPS final rule (88 FR 51090 through 51092) where total outlier payments are maintained at 2 percent of total estimated FY 2024 IPF PPS payments.

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

- The update to the outlier fixed dollar loss threshold amount.
- The revisions to patient-level adjustment factors, ED adjustment, and the ECT per treatment amount.
- The FY 2025 IPF wage index, the changes to the CBSA delineations, and the FY 2025 labor-related share (LRS).
- The market basket increase for FY 2025 of 3.3 percent reduced by the productivity adjustment of 0.5 percentage point in accordance with section 1886(s)(2)(A)(i) of the Act for a payment rate update of 2.8 percent.

Our column comparison in Table 24 illustrates the percent change in payments from FY 2024 (that is, October 1, 2023, to September 30, 2024) to FY 2025 (that is, October 1, 2024, to September 30, 2025) including all the final payment policy changes.

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TABLE 24: FY 2025 IPF PPS PAYMENT IMPACTS

[Percent Change in columns 3 through 6]

Facility by Type	Number of Facilities	Outlier	Refinement of Patient-Level Adjustments and ECT	Wage Index FY25, LRS, and 5% Cap	Total Percent Change[1]
(1)	(2)	(3)	(4)	(5)	(6)
All Facilities	1,419	-0.3	0.0	0.0	2.5
Total Urban	1,162	-0.3	0.0	-0.2	2.3
Urban unit	645	-0.4	0.5	-0.6	2.3
Urban hospital	517	-0.1	-0.5	0.2	2.5
Total Rural	257	-0.1	-0.3	1.4	3.8
Rural unit	197	-0.1	0.1	1.1	4.0
Rural hospital	60	-0.2	-1.1	2.1	3.6
By Type of Ownership:					
Freestanding IPFs					
Urban Psychiatric Hospitals					
Government	119	-0.5	1.1	-0.6	2.7
Non-Profit	97	-0.1	-0.1	-0.3	2.3
For-Profit	301	0.0	-0.9	0.6	2.5
Rural Psychiatric Hospitals					
Government	30	-0.3	1.6	-0.3	3.9
Non-Profit	12	-0.5	-1.5	0.3	1.0
For-Profit	18	0.0	-2.3	3.7	4.2
IPF Units					
Urban					
Government	93	-0.8	0.8	-0.1	2.7
Non-Profit	430	-0.4	0.7	-0.9	2.1
For-Profit	122	-0.2	-0.5	0.1	2.3
Rural					
Government	44	-0.1	-0.1	0.7	3.4
Non-Profit	113	-0.2	0.4	1.2	4.2
For-Profit	40	-0.1	-0.1	1.3	3.9
By Teaching Status:					
Non-teaching	1,217	-0.2	-0.2	0.3	2.7
Less than 10% interns and residents to beds	100	-0.5	0.6	-1.1	1.9
10% to 30% interns and residents to beds	76	-0.6	1.2	-1.2	2.2

More than 30% interns and residents to beds	26	-0.7	1.2	-0.1	3.2
By Region:					
New England	99	-0.4	0.9	-1.5	1.8
Mid-Atlantic	191	-0.4	0.3	-1.7	0.9
South Atlantic	228	-0.2	0.4	1.3	4.4
East North Central	225	-0.2	0.0	0.5	3.2
East South Central	140	-0.1	-0.2	2.6	5.0
West North Central	95	-0.5	1.1	0.0	3.4
West South Central	213	-0.1	-1.2	1.6	3.2
Mountain	102	-0.2	-0.3	0.8	3.1
Pacific	126	-0.3	-0.5	-1.8	0.1
By Bed Size:					
Psychiatric Hospitals					
Beds: 0-24	87	-0.1	-0.9	0.8	2.5
Beds: 25-49	86	0.0	-1.3	1.3	2.7
Beds: 50-75	91	-0.1	-0.4	0.9	3.2
Beds: 76 +	313	-0.1	-0.3	0.0	2.3
Psychiatric Units					
Beds: 0-24	440	-0.2	0.0	0.3	2.9
Beds: 25-49	229	-0.3	0.5	-0.7	2.3
Beds: 50-75	103	-0.4	0.7	0.1	3.2
Beds: 76 +	70	-0.7	0.6	-1.2	1.5

[1] This column includes the impact of the updates in columns (3) through (6) above, and of the IPF market basket percentage for FY 2025 of 3.3 percent, reduced by 0.5 percentage point for the productivity adjustment as required by section 1886(s)(2)(A)(i) of the Act.

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3. Impact Results

Table 24 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 1,419 IPFs included in the analysis. In column 2, we present the number of facilities of each type that had information available in the PSF, had claims in the MedPAR dataset for FY 2023. We note that providers are assigned urban or rural status in Table 24 based on the current CBSA delineations for FY 2024.

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 2.3 percent in FY 2024. Therefore, we adjusted the outlier threshold amount to set total estimated outlier payments equal to 2.0 percent of total payments in FY 2025. The estimated change in total IPF payments for FY 2025, therefore, includes an approximate 0.3 percent decrease in payments because we would expect the outlier portion of total payments to decrease from approximately 2.3 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 24), across all hospital groups, is a 0.3 percent decrease. The largest decrease in payments due to this change is estimated to be 0.8 percent for urban government-owned IPF units.

In column 4, we present the effects of the revisions to the patient-level adjustment factors, ED adjustment, and ECT per treatment amount and the application of the refinement standardization factor that is discussed in section IV.F of this final rule. These revisions are budget neutral; therefore, there is no projected change in aggregate payments to IPFs, as indicated in the first row of column 4. We estimate the largest payment increases would be 1.6 percent for rural government-owned IPF hospitals. Conversely, we estimate that rural for-profit IPF hospitals would experience the largest payment decrease of −2.3 percent. Payments to IPF units in urban areas would increase by 0.5 percent, and payments to IPF units in rural areas would increase by 0.1 percent.

In column 5, we presented the effects of the budget-neutral update to the IPF wage index, the LRS, and the changes to the CBSA delineations for FY 2025. In addition, this column includes the application of the 5-percent cap on any decrease to a provider's wage index from its wage index in the prior year as finalized in the FY 2023 IPF PPS final rule (87 FR 46856 through 46859). The change in this column 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 2024 IPF wage index to the FY 2025 IPF wage index, which includes basing the FY 2025 IPF wage index on the FY 2025

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 78.7 percent in FY 2024 to 78.8 percent in FY 2025. We note that there is no projected change in aggregate payments to IPFs, as indicated in the first row of column 5; however, there will be distributional effects among different categories of IPFs. For example, we estimate the largest increase in payments to be 3.7 percent for rural for-profit IPF hospitals, and the largest decrease in payments to be −1.8 percent for IPFs located in the Pacific region.

Overall, IPFs are estimated to experience a net increase in payments of 2.5 percent as a result of the updates in this final rule. IPF payments are estimated to increase by 2.3 percent in urban areas and 3.8 percent in rural areas. The largest payment increase is estimated at 5.0 percent for IPFs located in the East South Central region.

4. Effect on Beneficiaries

Under the FY 2025 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 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 2025 IPF PPS will enhance the efficiency of the Medicare program.

As discussed in sections V.B.2 of this final rule, we expect that the additional IPFQR Program measure will support improving discharge planning and care coordination to decrease the likelihood that a patient will need to seek emergency care within 30 days of discharge from an IPF.

5. Effects of the Updates to the IPFQR Program

In section V.B.2. of the rule, we are adopting the 30-Day Risk-Standardized All-Cause ED Visit Following an Inpatient Psychiatric Facility Discharge measure beginning with data from the CY 2025 performance period for the FY 2027 payment determination.

We do not believe this update will impact providers' workflows or information systems to collect or report the data because this measure is calculated by CMS using information that IPFs already submit as part of the claims process. There may be some effects of this measure on IPF workflows and clinical processes to improve care coordination and discharge planning to improve performance on the measure.

We are not finalizing our proposal to adopt a quarterly data submission requirement for measures for which we require patient-level data. We do not believe there will be any effect of maintaining our previously finalized policy.

In accordance with section 1886(s)(4)(A) of the Act, we will apply a 2-percentage point reduction to the FY 2025 market basket update for IPFs that have failed to comply with the IPFQR Program requirements for FY 2025, including reporting on the mandatory measures. For the FY 2024 payment determination, of the 1,568 IPFs eligible for the IPFQR Program, 194 IPFs did not receive the full market basket update because of the IPFQR Program; 42 of these IPFs chose not to participate and 152 did not meet the requirements of the program.

We intended to closely monitor the effects of the IPFQR Program on IPFs and help facilitate successful reporting outcomes through ongoing 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 the proposed rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will be directly impacted and will review this final rule, we assume that the total number of unique commenters on the most recent IPF proposed rule will be the number of reviewers of the final rule. For this FY 2025 IPF PPS final rule, the most recent IPF proposed rule was the FY 2025 IPF PPS proposed rule, and we received 67 unique comments on the proposed rule. We acknowledged that this assumption may understate or overstate the costs of reviewing the final rule. It is possible that not all commenters reviewed the FY 2025 IPF proposed rule in detail, and it is also possible that some reviewers chose not to comment on that proposed rule. For these reasons, we thought that the number of commenters would be a fair estimate of the number of reviewers who are directly impacted by this final rule. We solicited comments on this assumption.

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

Using the May, 2023 mean (average) wage information from the BLS for medical and health service managers (Code 11–9111), we estimated that the cost of reviewing this final rule is $129.28 per hour, including other indirect costs *https://www.bls.gov/oes/current/oes119111.htm.* Assuming an average reading speed of 250 words per minute, we estimate that it would take approximately 154 minutes (2.57 hours) for the staff to review half of this final rule, which contains a total of approximately 77,000 words. For each IPF that reviews the final rule, the estimated cost is ($2.57 \times \$129.28$) or $332.25. Therefore, we estimate that the total cost of reviewing this final rule is $22,260.75 ($\$332.25 \times 67$ reviewers).

D. Alternatives Considered

The statute gives the Secretary discretion in establishing an update methodology to the IPF PPS. We continued 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 proposed and are finalizing updates to: the IPF PPS using the methodology published in the RY 2005 IPF PPS final rule (our ''standard methodology'') pre-floor, pre-reclassified IPPS hospital wage index as its basis, along with the proposed changes to the CBSA delineations. Additionally, we apply a 5-percent cap on any decrease to a provider's wage index from its wage index in the prior year. Lastly, we are finalizing our proposal to revise the patient-level adjustment factors, ED adjustment, and to increase the ECT per treatment amount for FY 2025 (reflecting the pre-scaled and pre-adjusted CY 2024 OPPS geometric mean cost).

E. Accounting Statement

As required by OMB Circular A–4 (available at *www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf*), in Table 25, 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 25 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 1,419 IPFs that had

data available in the PSF and claims in our FY 2023 MedPAR claims dataset. Lastly, Table 25 also includes our best estimate of the costs of reviewing and understanding this final rule.

TABLE 25: Accounting Statement: Classification of Estimated Costs, Savings, and Transfers

Category	Primary estimate ($million/year)			
			Year dollars	Period covered
Regulatory Review Costs	0.22		2024	FY 2025
Annualized Monetized Transfers from Federal Government to IPF Medicare Providers	65	2024		FY 2025

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. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the Small Business Administration (SBA) definition of a small business (having revenues of less than $47 million in any 1 year).

According to the SBA's website at *http://www.sba.gov/content/small-business-size-standards,* IPFs falls into the North American Industrial Classification System (NAICS) code 622210, Psychiatric and Substance Abuse hospitals. The SBA defines small Psychiatric and Substance Abuse hospitals as businesses having less than $47 million.

As discussed earlier in this final rule, the only costs imposed by this final rule are the regulatory review costs, which we estimate at $22,260.75 per IPF.

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TABLE 26: NAICS 622210 Psychiatric and Substance Abuse Hospitals Size Standards

NAICS (6-digit)	Industry Subsector Description	SBA Size Standard/Small Entity Threshold	Total Small Businesses
622210	Psychiatric and Substance Abuse Hospitals	$47 Million	213

Source: US Census 2017 SUSB

TABLE 27: Concentration Ratios (NAICS 622210) Psychiatric and Substance Abuse Hospitals

Firm Size (by Receipts)	Firm Count	% of Small Firms	Average Revenue
SMALL HOSPITALS	**213**	**100.0%**	**$ 20,634,779.34**
<100,000	0	0	
100,000-499,999	4	1.9%	$ 250,750
500,000-999,999	5	2.3%	$ 713,000
1,000,000-2,499,999	3	1.4%	$ 1,249,000
2,500,000-4,999,999	13	6.1%	$ 3,870,077
5,000,000-7,499,999	10	4.7%	$ 5,523,800
7,500,000-9,999,999	12	5.6%	$ 7,507,917
10,000,000-14,999,999	23	10.8%	$ 12,227,391
15,000,000-19,999,999	27	12.7%	$ 14,432,111
20,000,000-24,999,999	21	9.9%	$ 19,257,762
25,000,000-29,999,999	21	9.9%	$ 26,277,000
30,000,000-34,999,999	23	10.8%	$ 28,937,261
35,000,000-39,999,999	21	9.9%	$ 35,550,095
40,000,000-49,999,999	30	14.1%	$ 38,400,433
LARGE HOSPITALS			
Receipts > 49 million	181	NA	$ 104,798,552.49

Source: US Census 2017 SUSB

Table 28: (NAICS 622210) Psychiatric and Substance Abuse Hospitals Impacts on Small Entities

Firm Size (by Receipts)	Avg. Annual Revenue	Annualized Cost per Firm	% of Small Firms	Revenue Test
All Hospitals	$ 125,433,331.83	$22,260.75	**N/A**	0.02%
Small Hospitals	**$ 20,634,779.34**	$22,260.75	**100%**	0.1%
<100,000	0	0	0	
100,000-499,999	$ 250,750	$22,260.75	1.9%	8.8%
500,000-999,999	$ 713,000	$22,260.75	2.3%	3.1%
1,000,000-2,499,999	$ 1,249,000	$22,260.75	1.4%	1.8%
2,500,000-4,999,999	$ 3,870,077	$22,260.75	6.1%	0.6%
5,000,000-7,499,999	$ 5,523,800	$22,260.75	4.7%	0.4%
7,500,000-9,999,999	$ 7,507,917	$22,260.75	5.6%	0.3%
10,000,000-14,999,999	$ 12,227,391	$22,260.75	10.8%	0.2%
15,000,000-19,999,999	$ 14,432,111	$22,260.75	12.7%	0.2%
20,000,000-24,999,999	$ 19,257,762	$22,260.75	9.9%	0.1%
25,000,000-29,999,999	$ 26,277,000	$22,260.75	9.9%	0.1%
30,000,000-34,999,999	$ 28,937,261	$22,260.75	10.8%	0.1%
35,000,000-39,999,999	$ 35,550,095	$22,260.75	9.9%	0.1%
40,000,000-49,999,999	$ 38,400,433	$22,260.75	14.1%	0.1%

Source: US Census 2017 SUSB

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According to Table 26, 213 psychiatric and substance abuse hospitals can be considered small according to the SBA. As we stated earlier, the SBA defines small Psychiatric and Substance Abuse hospitals as businesses having less than $47 million. Note, Tables 26 and 27 show revenue more than $49.9 million since the data does not provide the exact estimate for $47 million. Table 27 shows that there are 181 Psychiatric and Substance Abuse hospitals that earn revenue in excess of $49 million.

The Department of Health and Human Services generally uses a revenue impact of 3 to 5 percent as a significance threshold under the RFA. For the purposes of the RFA, we estimate that only 0.1 percent of small Psychiatric and Substance Abuse hospitals are small entities as that term is used in the RFA.

As its measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 to 5 percent. According to Table 27, we believe that this threshold will not be reached, 0.1 percent, by the requirements in this final rule. Therefore, the Secretary has certified that this final rule will have a *de minimis* economic impact on the small entities.

Since there is not a significant impact on a substantial number of small entities, the Secretary has certified that this final rule will not have a significant economic 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 197 rural excluded psychiatric units and 60 rural psychiatric hospitals in our database of 1,419 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 2024, that threshold is approximately $183 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 $183 million in any 1 year.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on July 24, 2024.

Xavier Becerra,

Secretary, Department of Health and Human Services.

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