DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 412

[CMS–1690–F]

RIN 0938–AT32

Medicare Program; FY 2019 Inpatient Psychiatric Facilities Prospective Payment System and Quality Reporting Updates for Fiscal Year Beginning October 1, 2018 (FY 2019)

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

ACTION: Final rule.

SUMMARY: This final rule updates the prospective payment rates for Medicare inpatient hospital services provided by inpatient psychiatric facilities (IPFs), which include psychiatric hospitals and excluded psychiatric units of an acute care hospital or critical access hospital. These changes are effective for IPF discharges occurring during the fiscal year (FY) beginning October 1, 2018 through September 30, 2019 (FY 2019). This final rule also updates the IPF labor-related share, the IPF wage index for FY 2019, and the International Classification of Diseases 10th Revision, Clinical Modification (ICD–10–CM) codes for FY 2019. It also makes technical corrections to the IPF regulations, and updates quality measures and reporting requirements under the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program. In addition, it updates providers on the status of IPF PPS refinements.

DATES: These regulations are effective on October 1, 2018.

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

Mollie Knight (410) 786–7948 or Hudson Osgood (410) 786–7897, for information regarding the market basket update or the labor related share.

Theresa Bean (410) 786–2287 or James Hardesty (410) 786–2629, for information regarding the regulatory impact analysis.

James Poyer (410) 786–2261 or Jeffrey Buck (410) 786–0407, for information regarding the inpatient psychiatric facility quality reporting program.

SUPPLEMENTARY INFORMATION:

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

Tables setting forth the final fiscal year (FY) 2019 Wage Index for Urban Areas Based on Core-Based Statistical Area (CBSA) Labor Market Areas and the FY 2019 Wage Index Based on CBSA Labor Market Areas for Rural Areas are available exclusively through the internet, on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/IPFPPS/WageIndex.html.*

In addition, tables showing the complete listing of final ICD–10 Clinical Modification (CM) and Procedure Coding System (PCS) codes underlying the FY 2019 Inpatient Psychiatric Facilities (IPF) Prospective Payment System (PPS) for the IPF comorbidity adjustment, code first, and electroconvulsive therapy (ECT) are available online at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html.* Addenda B–1 to B–4 to this final rule show the tables of the ICD–10–CM/PCS codes, which affect FY 2019 IPF PPS comorbidity categories, code first, and non-specific codes with regards to laterality.

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 the Fiscal Year (FY) beginning October 1, 2018 through September 30, 2019. Additionally, this final rule makes technical corrections to the IPF regulations and updates the Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program.

B. Summary of the Major Provisions

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

In this final rule, we update the IPF PPS, as specified in 42 CFR 412.428. The updates include the following:

- Effective for the FY 2019, we adjusted the final 2012-based IPF market basket update of 2.9 percent by a reduction for economy-wide productivity of 0.8 percentage point as required by section 1886(s)(2)(A)(i) of the Social Security Act (the Act). We reduced the 2012-based IPF market basket update by 0.75 percentage point as required by section 1886(s)(2)(A)(ii) of the Act, resulting in a final IPF payment rate update of 1.35 percent for FY 2019.
- The 2012-based IPF market basket results in a labor-related share of 74.8 percent for FY 2019.
- We updated the IPF PPS federal per diem base rate from $771.35 to $782.78.
- Providers who failed to report quality data for FY 2019 payment will receive a FY 2019 federal per diem base rate of $767.33.
- We updated the electroconvulsive therapy (ECT) payment per treatment from $332.08 to $337.00.
- Providers who failed to report quality data for FY 2019 payment will receive a FY 2019 ECT payment per treatment of $330.35.
- We updated the labor-related share of 74.8 percent (based on the 2012-based IPF market basket) and core base statistical area (CBSA) rural and urban wage indices for FY 2019, and provided a wage index budget-neutrality adjustment of 1.0013.
- We updated the fixed dollar loss threshold amount from $11,425 to $12,865 to maintain estimated outlier payments at 2 percent of total estimated aggregate IPF PPS payments.
- We implemented minor technical corrections to IPF regulations.

2. Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program

We are adopting several proposals related to measures and one proposal related to data submission for the IPFQR Program. Specifically, we proposed the removal of eight (8) measures beginning with the FY 2020 payment determination.

1. Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431);
2. Alcohol Use Screening, SUB–1 (NQF #1661);
3. Assessment of Patient Experience of Care;
4. Use of an Electronic Health Record;
5. Tobacco Use Screening, TOB–1 (NQF #1651);
6. Hours of Physical Restraint Use (NQF #0640);
7. Hours of Seclusion Use (NQF #0641); and
8. Tobacco Use Treatment Provided or Offered at Discharge and Tobacco Use Treatment at Discharge, TOB–3 and TOB–3a (NQF #1656).

We are finalizing the removal of five of these eight measures:

1. Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431);
2. Alcohol Use Screening, SUB–1 (NQF #1661);
3. Assessment of Patient Experience of Care;
4. Use of an Electronic Health Record; and

5. Tobacco Use Screening, TOB–1 (NQF #1651).

In addition, we proposed to no longer require facilities to submit the sample size count for measures for which sampling is performed beginning with the FY 2020 Payment Determination (that is, data reported during summer of CY 2019) and are finalizing this policy as proposed.

3. Summary of Impacts

Provision description	Total transfers and cost reductions
FY 2019 IPF PPS payment update	The overall economic impact of this final rule is an estimated $50 million in increased payments to IPFs during FY 2019.
Updated IPFQR Program requirements	The total reduction in costs beginning in FY 2018 calculated in 2018 dollars for IPFs as a result of the updates to quality reporting requirements is estimated to be $20 million.

II. Background

A. Overview of the Legislative Requirements

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 PPS for inpatient hospital services furnished in psychiatric hospitals and excluded psychiatric units including an adequate patient classification system that reflects the differences in patient resource use and costs among psychiatric hospitals and excluded psychiatric units. ''Excluded'' psychiatric unit means a psychiatric unit in an acute care hospital that is excluded from the Inpatient Prospective Payment System (IPPS), or a psychiatric unit in a Critical Access Hospital (CAH) that is excluded from the CAH payment system. These excluded psychiatric units would be paid under the IPF PPS.

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

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

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

Section 1886(s)(2)(A)(i) of the Act requires the application of the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act to the IPF PPS for the rate year (RY) beginning in 2012 (that is, a RY that coincides with a fiscal year (FY)) and each subsequent RY. As noted in our FY 2018 IPF PPS notice, published in the **Federal Register** on August 7, 2017 (82 FR 36771 through 36789), for the RY beginning in 2017, the productivity adjustment currently in place is equal to 0.6 percentage point.

Section 1886(s)(2)(A)(ii) of the Act requires the application of an ''other adjustment'' that reduces any update to an IPF PPS base rate by percentages 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 2018 IPF PPS notice, for the RY beginning in 2017, section 1886(s)(3)(D) of the Act requires that the reduction currently in place be equal to 0.75 percentage point.

Sections 1886(s)(4)(A) and 1886(s)(4)(B) 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 shall 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 shall apply only to the RY involved, and the Secretary shall not take into account such reduction in computing the payment amount for a subsequent RY. We refer readers to section II.B of this final rule for an explanation of the IPF RY. More information about the specifics of the current IPFQR Program is available in the FY 2018 IPPS/Long-Term Care Hospital (LTCH) PPS final rule (82 FR 38461 through 38474).

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

B. Overview of the IPF PPS

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

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

The federal per diem payment under the IPF PPS is comprised of the federal per diem base rate described previously and certain patient- and facility-level payment adjustments that were found in the regression analysis to be associated with statistically significant per diem cost differences.

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

for the presence of a qualifying emergency department (ED).

The IPF PPS provides additional payment policies for outlier cases, interrupted stays, and a per treatment payment for patients who undergo electroconvulsive therapy (ECT). During the IPF PPS mandatory 3-year transition period, stop-loss payments were also provided; however, since the transition ended as of January 1, 2008, these payments are no longer available.

A complete discussion of the regression analysis that established the IPF PPS adjustment factors can be found in the November 2004 IPF PPS final rule (69 FR 66933 through 66936).

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

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

In RY 2012, we proposed and finalized switching the IPF PPS payment rate update from a RY that begins on July 1 and ends on June 30, to one that coincides with the federal FY that begins October 1 and ends on September 30. In order to transition from one timeframe to another, the RY 2012 IPF PPS covered a 15-month period from July 1, 2011 through September 30, 2012. Therefore, the IPF RY has been equivalent to the October 1 through September 30 federal FY since RY 2013. For further discussion of the 15-month market basket update for RY 2012 and changing the payment rate update period to coincide with a FY period, we refer readers to the RY 2012 IPF PPS proposed rule (76 FR 4998) and the RY 2012 IPF PPS final rule (76 FR 26432).

C. Annual Requirements for Updating the IPF PPS

In November 2004, we implemented the IPF PPS in a final rule that published on November 15, 2004 in the **Federal Register** (69 FR 66922). In developing the IPF PPS, and to ensure that the IPF PPS is able to account adequately for each IPF's case-mix, we performed an extensive regression analysis of the relationship between the per diem costs and certain patient and facility characteristics to determine those characteristics associated with statistically significant cost differences on a per diem basis. 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 that final rule, we explained the reasons for delaying an update to the adjustment factors, derived from the regression analysis, including waiting until we have IPF PPS data that yields as much information as possible regarding the patient-level characteristics of the population that each IPF serves. We indicated that we did not intend to update the regression analysis and the patient-level and facility-level adjustments until we complete that analysis. Until that analysis is complete, we stated our intention to publish a notice in the **Federal Register** each spring to update the IPF PPS (69 FR 66966).

On May 6, 2011, we published a final rule in the **Federal Register** titled, ''Inpatient Psychiatric Facilities Prospective Payment System—Update for Rate Year Beginning July 1, 2011 (RY 2012)'' (76 FR 26432), which changed the payment rate update period to a RY that coincides with a FY update. Therefore, final rules are now published in the **Federal Register** in the summer to be effective on October 1. When proposing changes in IPF payment policy, a proposed rule would be issued in the spring and the final rule in the summer to be effective on October 1. For further discussion on changing the IPF PPS payment rate update period to a RY that coincides with a FY, we refer readers to our RY 2012 IPF PPS final rule (76 FR 26434 through 26435). For a detailed list of updates to the IPF PPS, we refer readers to our regulations at 42 CFR 412.428.

Our most recent IPF PPS annual update was published in a notice with comment period on August 7, 2017 in the **Federal Register** titled, ''Medicare Program; FY 2018 Inpatient Psychiatric Facilities Prospective Payment System—Rate Update'' (82 FR 36771), which updated the IPF PPS payment rates for FY 2018. That notice with comment period updated the IPF PPS federal per diem base rates that were published in the FY 2017 IPF PPS notice (81 FR 50502) in accordance with our established policies.

III. Provisions of the FY 2019 IPF PPS Final Rule and Responses to Comments

On May 8, 2018, we published a proposed rule in the **Federal Register** (83 FR 21104) entitled Medicare Program: FY 2019 Inpatient Psychiatric Facilities Prospective Payment System and Quality Reporting Updates for Fiscal Year Beginning October 1, 2018 (FY 2019). The May 8, 2018 proposed rule (herein referred to as the FY 2019 IPF PPS proposed rule) proposed updates to the prospective payment rates for Medicare inpatient hospital services provided by inpatient psychiatric facilities. In addition to the updates, we proposed to make minor technical corrections to several IPF regulations, and proposed updates to the IPF Quality Reporting program.

We received a total of 88 comments on these proposals from 44 providers, 21 industry groups or associations, 6 advocacy groups, 10 individuals, and 4 anonymous sources. Of the 88 comments, 9 focused on payment policies, 85 focused on the quality reporting proposals, and 12 focused on the RFI. A summary of the proposals, the comments and our responses follows.

A. Update to the FY 2019 Market Basket for the IPF PPS

1. Background

The input price index that was used to develop the IPF PPS was the ''Excluded Hospital with Capital'' market basket. This market basket was based on 1997 Medicare cost reports for Medicare participating inpatient rehabilitation facilities (IRFs), IPFs, 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 2016 IPF PPS rule, where we adopted a 2012-based IPF market basket, using Medicare cost report data for both Medicare participating psychiatric hospitals and excluded psychiatric units. We refer readers to the FY 2016 IPF PPS final rule for a detailed discussion of the 2012-based IPF PPS Market Basket and its development (80 FR 46656 through 46679). The FY 2016 IPS PPS final rule also includes references to the historical market baskets used to update IPF PPS payments since PPS implementation.

2. FY 2019 IPF Market Basket Update

For FY 2019 (beginning October 1, 2018 and ending September 30, 2019), we used an estimate of the 2012-based IPF market basket increase factor to update the IPF PPS base payment rate. Consistent with historical practice, we estimated the market basket update for the IPF PPS based on IHS Global, Inc.'s (IGI) forecast. IGI is a nationally recognized economic and financial forecasting firm that contracts with the CMS to forecast the components of the market baskets and multifactor productivity (MFP). For the proposed rule, based on IGI's first quarter 2018 forecast with historical data through the fourth quarter of 2017, the 2012-based IPF market basket increase factor for FY 2019 was 2.8 percent. As stated in the proposed rule (89 FR 21107), if more recent data subsequently became available, we would use such data, if appropriate, to determine the FY 2019 IPF market basket update and MFP adjustment for the final rule. Based on IGI's most recent second quarter 2018 forecast with historical data through the first quarter of 2018, the final 2012-based IPF market basket increase factor for FY 2019 is 2.9 percent.

Section 1886(s)(2)(A)(i) of the Act requires the application of the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act to the IPF PPS for the RY beginning in 2012 (a RY that coincides with a FY) and each subsequent RY. For this FY 2019 IPF PPS rule, based on IGI's second quarter 2018 forecast, the MFP adjustment for FY 2019 (the 10-year moving average of MFP for the period ending FY 2019) is projected to be 0.8 percent. We reduced the 2.9 percent IPF market basket update by this 0.8 percentage point productivity adjustment, as mandated by the Act. We note that the MFP adjustment did not change from the 0.8 percentage point that was proposed (89 FR 21107). For more information on the productivity adjustment, we refer reader to the discussion in the FY 2016 IPF PPS final rule (80 FR 46675).

In addition, for FY 2019 the 2012-based IPF PPS market basket update is further reduced by 0.75 percentage point as required by sections 1886(s)(2)(A)(ii) and 1886(s)(3)(E) of the Act. This results in an estimated FY 2019 IPF PPS payment rate update of 1.35 percent (2.9 − 0.8 − 0.75 = 1.35).

3. IPF Labor-Related Share

Due to variations in geographic wage levels and other labor-related costs, we continue to adjust the payment rates under the IPF PPS by a geographic wage index, which applies to the labor-related portion of the federal per diem base rate (hereafter referred to as the labor-related share).

The labor-related share is determined by identifying the national average proportion of total costs that are related to, influenced by, or vary with the local labor market. We 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 2012-based IPF market basket, we continue to include in the labor-related share the sum of the relative importance of Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair; All Other: Labor-related Services; and a portion (46 percent) of the Capital-Related cost weight from the 2012-based IPF market basket. The relative importance reflects the different rates of price change for these cost categories between the base year (FY 2012) and FY 2019. Using IGI's second quarter 2018 forecast for the 2012-based IPF market basket, the IPF labor-related share for FY 2019 is the sum of the FY 2019 relative importance of each labor-related cost category. For more information on the labor-related share and its calculation, we refer readers to the FY 2016 IPF PPS final rule (80 FR 46676 through 46679). For FY 2019, the update to the labor-related share based on IGI's second quarter 2018 forecast of the 2012-based IPF PPS market basket is 74.8 percent.

Comment: A few commenters appreciated the increase to the rates from the market basket update, but were concerned about the required reductions to the market basket update. One noted that these small increases don't keep up with the cost of care and that the updates need to account properly for inflation. Another commenter noted that the Department of Health and Human Service (HHS) is obligated to negatively adjust the market base rate as stipulated by the Act. The commenter also stated that the mandated adjustment fails to recognize the negative impacts that decreased payments can have on the ability of psychiatrists and IPFs to provide services, and recommend CMS to look at avenues to increase reimbursement for psychiatrists and mental and behavioral health (MBH) services in order to incentivize an expansion of access and treatment.

Response: The IPF market basket was developed to be specific to IPFs and their cost structures. Therefore, we believe it properly accounts for the inflation associated with providing IPF services. For more details on how that IPF-specific market basket was developed, we refer readers to the FY 2016 IPF Final rule (80 FR 46656 through 46679).

We appreciate the commenters' support for our increases to the payments, and their recognition that HHS (specifically, CMS) is obligated to reduce the market basket update in accordance with the Social Security Act. We note that section 1886(s)(3)(E) of the Act was amended by the Affordable Care Act at 3401(f)(3) and required an ''other adjustment'' for each RY beginning in 2010 through 2019. This section of the Act currently requires the ''other adjustment'' of 0.75 percentage point to be in place for only one more FY (the FY beginning in October 2019, which is FY 2020).

The IPF PPS is designed to account for provider resource use, including patient-level and facility-level differences in costs. We believe the IPF payment system supports and encourages access to IPFs.

Payments for professional services of psychiatrists are outside the scope of this IPF PPS rule.

B. Updates to the IPF PPS Rates for FY Beginning October 1, 2018

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

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

Section 124(a)(1) of the BBRA required that we implement the IPF PPS in a budget-neutral manner. In other words, the amount of total payments under the IPF PPS, including any payment adjustments, must be projected to be equal to the amount of total payments that would have been made if the IPF PPS were not implemented. Therefore, we calculated the budget-neutrality factor by setting the total estimated IPF PPS payments to be equal to the total estimated payments that would have been made under the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) (Pub. L. 97–248) methodology had the IPF PPS not been

implemented. A step-by-step description of the methodology used to estimate payments under the TEFRA payment system appears in the November 2004 IPF PPS Final rule (69 FR 66926).

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

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

The federal per diem base rate has been updated in accordance with applicable statutory requirements and § 412.428 through publication of annual notices or proposed and final rules. A detailed discussion on the standardized budget-neutral federal per diem base rate and the electroconvulsive therapy (ECT) payment per treatment appears in the FY 2014 IPF PPS update notice (78 FR 46738 through 46739). These documents are available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/index.html.*

IPFs must include a valid procedure code for ECT services provided to IPF beneficiaries in order to bill for ECT services, as described in our Medicare Claims Processing Manual, Chapter 3, Section 190.7.3 (available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf.*) There were no changes to the ECT procedure codes used on IPF claims as a result of the final update to the ICD–10–PCS code set for FY 2019.

Comment: A commenter appreciated our maintaining the ICD–10 codes for ECT.

Response: We appreciate the commenter's support.

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

The current (FY 2018) federal per diem base rate is $771.35 and the ECT payment per treatment is $332.08. For the FY 2019 federal per diem base rate, we applied the payment rate update of 1.35 percent (that is, the 2012-based IPF market basket increase for FY 2019 of 2.9 percent less the productivity adjustment of 0.8 percentage point, and further reduced by the 0.75 percentage point required under section 1886(s)(3)(E) of the Act), and the wage index budget-neutrality factor of 1.0013 (as discussed in section III.D.1.e of this rule) to the FY 2018 federal per diem base rate of $771.35, yielding a federal per diem base rate of $782.78 for FY 2019. Similarly, we applied the 1.35 percent payment rate update and the 1.0013 wage index budget-neutrality factor to the FY 2018 ECT payment per treatment, yielding an ECT payment per treatment of $337.00 for FY 2019.

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 rate year, the Secretary shall reduce any annual update to a standard federal rate for discharges during the RY by 2.0 percentage points. Therefore, we are applying a 2.0 percentage point reduction to the federal per diem base rate and the ECT payment per treatment as follows:

- For IPFs that fail requirements under the Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program, we applied a −0.65 percent payment rate update (that is, the IPF market basket increase for FY 2019 of 2.9 percent less the productivity adjustment of 0.8 percentage point, further reduced by the 0.75 percentage point for an update of 1.35 percent, and further reduced by 2 percentage points in accordance with section 1886(s)(4)(A)(ii) of the Act, which results in a negative update percentage) and the wage index budget-neutrality factor of 1.0013 to the FY 2018 federal per diem base rate of $771.35, yielding a federal per diem base rate of $767.33 for FY 2019.
- For IPFs that fail to meet requirements under the IPFQR Program, we applied the −0.65 percent annual payment rate update and the 1.0013 wage index budget-neutrality factor to the FY 2018 ECT payment per treatment of $332.08, yielding a ECT payment per treatment of $330.35 for FY 2019.

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

1. Overview of the IPF PPS Adjustment Factors

The IPF PPS payment adjustments were derived from a regression analysis of 100 percent of the FY 2002 Medicare Provider and Analysis Review (MedPAR) data file, which contained 483,038 cases. For a more detailed description of the data file used for the regression analysis, see the November 2004 IPF PPS final rule (69 FR 66935 through 66936). We continue to use the existing regression-derived adjustment factors established in 2005 for FY 2019. However, we have used more recent claims data to simulate payments to finalize the outlier fixed dollar loss threshold amount and to assess the impact of the IPF PPS updates.

2. IPF PPS Patient-Level Adjustments

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

a. Update to MS–DRG Assignment

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

adjustment categories to the current MS–DRG adjustment categories, we refer readers to the RY 2009 IPF PPS notice (73 FR 25714).

The IPF PPS includes payment adjustments for designated psychiatric DRGs assigned to the claim based on the patient's principal diagnosis. The DRG adjustment factors were expressed relative to the most frequently reported psychiatric DRG in FY 2002, that is, DRG 430 (psychoses). The coefficient values and adjustment factors were derived from the regression analysis. Mapping the DRGs to the MS–DRGs resulted in the current 17 IPF MS–DRGs, instead of the original 15 DRGs, for which the IPF PPS provides an adjustment. For FY 2019, we did not propose any changes to the IPF MS–DRG adjustment factors but proposed to maintain the existing IPF MS–DRG adjustment factors.

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

For FY 2019, we continue to make the existing payment adjustment for psychiatric diagnoses that group to one of the existing 17 IPF MS–DRGs listed in Addendum A. Addendum A is available on our website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html.* Psychiatric principal diagnoses that do not group to one of the 17 designated MS–DRGs will still receive the federal per diem base rate and all other applicable adjustments, but the payment will not include an MS–DRG adjustment.

The diagnoses for each IPF MS–DRG will be updated as of October 1, 2018, using the final IPPS FY 2019 ICD–10–CM/PCS code sets. The FY 2019 IPPS rule includes tables of the changes to the ICD–10–CM/PCS code sets which underlie the FY 2019 IPF MS–DRGs. Both the FY 2019 IPPS rule and the tables of changes to the ICD–10–CM/PCS code sets which underlie the FY 2019 MS–DRGs are available on the IPPS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*

Code First

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

For more information on the code first policy, see our November 2004 IPF PPS final rule (69 FR 66945) and see sections I.A.13 and I.B.7 of the FY 2019 ICD–10–CM Coding Guidelines, available at *https://www.cdc.gov/nchs/icd/icd10cm.htm#FY%202019%20release%20of%20ICD-10-CM.* In the FY 2015 IPF PPS final rule, we provided a code first table for reference that highlights the same or similar manifestation codes where the code first instructions apply in ICD–10–CM that were present in ICD–9–CM (79 FR 46009). From FY 2018 to FY 2019, there were no changes to the final ICD–10–CM/PCS codes in the IPF Code First table. The final FY 2019 Code First table is shown in Addendum B–2 on our website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html.*

Comment: A commenter appreciated our consistency in maintaining the IPF MS–DRGs.

Response: We appreciate the commenter's support.

b. Payment for Comorbid Conditions

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

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

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

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

As noted previously, it is our policy to maintain the same diagnostic coding set for IPFs that is used under the IPPS for providing the same psychiatric care. The 17 comorbidity categories formerly defined using ICD–9–CM codes were converted to ICD–10–CM/PCS in our FY 2015 IPF PPS final rule (79 FR 45947 through 45955). The goal for converting the comorbidity categories is referred to as replication, meaning that the payment adjustment for a given patient

encounter is the same after ICD–10–CM implementation as it would be if the same record had been coded in ICD–9–CM and submitted prior to ICD–10–CM/PCS implementation on October 1, 2015. All conversion efforts were made with the intent of achieving this goal. For FY 2019, we are finalizing our proposal to use the same comorbidity adjustment factors in effect in FY 2018, which are found in Addendum A, available on our website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html.*

We have updated the ICD–10–CM/PCS codes which are associated with the existing IPF PPS comorbidity categories, based upon the final FY 2019 update to the ICD–10–CM/PCS code set. The FY 2019 ICD–10–CM/PCS updates included ICD–10–CM/PCS codes added to the Drug and/or Alcohol Abuse, Gangrene, Oncology Treatment, and Poisoning comorbidity categories, and codes deleted from the Oncology Treatment comorbidity category. These updates are detailed in Addenda B–1 and B–3 of this final rule, which is available on our website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html.*

In accordance with the policy established in the FY 2015 IPF PPS final rule (79 FR 45949 through 45952), we reviewed all FY 2019 ICD–10–CM codes to remove site unspecified codes from the FY 2019 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 condition exist should be used when coding patients' diagnoses whenever these codes are available. We finalized that we would remove site unspecified codes from the IPF PPS ICD–10–CM/PCS codes in instances in which more specific codes are available, as the clinician should be able to identify a more specific diagnosis based on clinical assessment at the medical encounter. Therefore, we are removing 3 site unspecified codes from the list of Oncology Treatment Diagnosis codes. See Addendum B–4 to this rule for a listing of the 3 ICD–10–CM/PCS site unspecified codes to be removed. Addendum B–4 is available on our website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html.*

c. Patient Age Adjustments

As explained in the November 2004 IPF PPS final rule (69 FR 66922), we analyzed the impact of age on per diem cost by examining the age variable (range of ages) for payment adjustments. In general, we found that the cost per day increases with age. The older age groups are more costly than the under 45 age group, the differences in per diem cost increase for each successive age group, and the differences are statistically significant. For FY 2019, we are finalizing our proposal to continue to use the patient age adjustments currently in effect in FY 2018, as shown in Addendum A of this rule (see *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html*).

d. Variable per Diem Adjustments

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

Final Decision: For FY 2019, we are finalizing our proposal to continue to use the variable per diem adjustment factors currently in effect as shown in Addendum A of this rule (available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html*). A complete discussion of the variable per diem adjustments appears in the November 2004 IPF PPS final rule (69 FR 66946).

D. Updates to the IPF PPS Facility-Level Adjustments

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

1. Wage Index Adjustment

a. Background

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

b. Updated Wage Index for FY 2019

Since the inception of the IPF PPS, we have used the pre-floor, pre-reclassified acute care hospital wage index in developing a wage index to be applied to IPFs, because there is not an IPF-specific wage index available. We believe that IPFs compete in the same labor markets as acute care hospitals, so the pre-floor, pre-reclassified hospital wage index should reflect IPF labor costs. As discussed in the RY 2007 IPF PPS final rule (71 FR 27061 through 27067) for RY 2007, under the IPF PPS, the wage index is calculated using the IPPS wage index for the labor market area in which the IPF is located, without taking into account geographic reclassifications, floors, and other adjustments made to the wage index under the IPPS. For a complete description of these IPPS wage index adjustments, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53365 through 53374). For FY 2019, we will continue to apply the most recent hospital wage index (the FY 2018 pre-floor, pre-reclassified hospital wage index, which is the most appropriate index as it best reflects the variation in local labor costs of IPFs in the various geographic areas) using the most recent hospital wage data (data from hospital cost reports for the cost reporting period beginning during FY 2014) without any geographic reclassifications, floors, or other adjustments. We will apply the FY 2019 IPF wage index to payments beginning October 1, 2018.

We will apply the wage index adjustment to the labor-related portion of the federal rate, which will change from 75.0 percent in FY 2018 to 74.8 percent in FY 2019. This percentage reflects the labor-related share of the final 2012-based IPF market basket for FY 2019 (see section III.A.3 of this rule).

c. Office of Management and Budget Bulletins

Office of Management and Budget (OMB) publishes bulletins regarding Core-Based Statistical Area (CBSA)

changes, including changes to CBSA numbers and titles. 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 applies to the hospital wage index used to determine the current IPF wage index and stated that we expect 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). The OMB bulletins may be accessed online at *https://www.whitehouse.gov/omb/bulletins/.*

In accordance with our established methodology, we have historically adopted any CBSA changes that are published in the OMB bulletin that corresponds with the hospital wage index used to determine the IPF wage index. For the FY 2015 IPF wage index, we used the FY 2014 pre-floor, pre-reclassified hospital wage index to adjust the IPF PPS payments. On February 28, 2013, OMB issued OMB Bulletin No. 13–01, which established revised delineations for MSAs, Micropolitan Statistical Areas, and Combined Statistical Areas, and provided guidance on the use of the delineations of these statistical areas. A copy of this bulletin may be obtained at *https://www.whitehouse.gov/omb/bulletins/.*

Because the FY 2014 pre-floor, pre-reclassified hospital wage index was finalized before the issuance of this Bulletin, the FY 2015 IPF wage index, which was based on the FY 2014 pre-floor, pre-reclassified hospital wage index, did not reflect OMB's new area delineations based on the 2010 Census. According to OMB, ''[t]his bulletin provides the delineations of all Metropolitan Statistical Areas, Metropolitan Divisions, Micropolitan Statistical Areas, Combined Statistical Areas, and New England City and Town Areas in the United States and Puerto Rico based on the standards published on June 28, 2010, in the **Federal Register** (75 FR 37246 through 37252) and Census Bureau data.'' These OMB Bulletin changes are reflected in the FY 2015 pre-floor, pre-reclassified hospital wage index, upon which the FY 2016 IPF wage index was based. We adopted these new OMB CBSA delineations in the FY 2016 IPF wage index and subsequent IPF wage indexes.

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

OMB Bulletin No. 15–01 establishes revised delineations for the Nation's Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas. The bulletin also provides delineations of Metropolitan Divisions as well as delineations of New England City and Town Areas.

In accordance with our longstanding policy, the IPF PPS continues to use the latest labor market area delineations available as soon as is reasonably possible to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions. As discussed in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56913), the updated labor market area definitions from OMB Bulletin 15–01 were implemented under the IPPS beginning on October 1, 2016 (FY 2017). Therefore, we implemented these revisions for the IPF PPS beginning October 1, 2017 (FY 2018), consistent with our historical practice of modeling IPF PPS adoption of the labor market area delineations after IPPS adoption of these delineations.

In summary, the FY 2018 pre-floor, pre-reclassified hospital wage index, which is used to determine the FY 2019 IPF wage index, has no changes to its OMB designations and already includes changes adopted in previous FYs.

The final FY 2019 IPF wage index is located on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/WageIndex.html.*

We received the following comments related to the IPF wage index.

Comment: Three commenters suggested changes to the IPF wage index. One commenter indicated that IPFs are subject to wage index protocols that differ from those applied to other post-acute care providers, which result in providers in the same labor market being subject to inconsistent wage index adjustments. Specifically, the commenter stated that the IPF PPS uses the prior year pre-classified acute care inpatient PPS wage index values, even though this 1-year lag is not applied for long term acute care hospitals or skilled nursing facilities. This commenter also stated that given all of the post-acute care settings are on a track that may result in payment under a single, combined system, there was a lack of justification for this unique treatment of IPFs. The commenter requested that CMS explore harmonizing the different wage methodologies across all post-acute care settings to ensure consistency for all providers.

Two commenters agreed with CMS' statement in the proposed rule that IPFs compete in the same labor markets as acute care hospitals. However, these commenters noted that under the IPF PPS, the wage index is calculated using the IPPS wage index for the labor market area in which the IPF is located, without taking into account geographic reclassifications, floors, and other adjustments made to the wage index under the IPPS. Because the IPF PPS wage index uses the pre-floor, pre-reclassified IPPS wage index as its basis, these commenters indicated that IPFs are at a severe disadvantage when competing with general acute care hospitals, since their payments under the IPF PPS simply do not reflect the economic conditions of these labor markets. The commenters stated that this issue is particularly acute in the ''frontier states,'' so named by the Affordable Care Act provision that established a floor on the area wage indexes in particularly rural states. The commenters noted that under the Affordable Care Act provision, states with a high share of low population-density counties have a ''floor'' on their area wage index. The commenters added that in accordance section 10324(a) of the Affordable Care Act, the frontier state adjustment is not subject to budget neutrality. They indicated that

because CMS does not take this floor into account when applying the IPPS wage index to IPFs, the wage index for an acute hospital can be up to 30 percent higher than an IPF in the same labor market. Consequently, IPFs in a frontier state are underpaid relative to general acute care hospitals in the same geographic areas, even though they compete directly for the same employees. These commenters recommended CMS not to disregard the frontier state ''floor'' of 1.0 when it applies the acute care hospital wage index to IPFs, including the non-application of budget neutrality, which is consistent with the IPPS payment methodology.

Response: We thank the commenters for their input on these wage index issues. Regarding the comment to harmonize the IPF wage index with those of other post-acute care (PAC) providers, we are not sure if the commenter is referring to the FY 2019 President's Budget proposal to reform PAC payment and consolidate into one payment system (consistent with a recommendation made by the Medicare Payment Advisory Commission [1]), or if the commenter is referring to a demonstration project of PAC payment reform (*https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Research-Reports-Items/PAC_Payment_Reform_Demo_Final.html*). Regardless, IPFs are not included in either the President's FY 2019 Budget proposal or the PAC payment reform demonstration project.

We also note that other Medicare providers (for example, Inpatient Rehabilitation Facilities and hospices) also have a 1-year lag in their wage index. This lag was established at a time when computerized data systems were not as agile as at present, and the preparation of the hospital wage index (which is the basis of the IPF wage index) was more time-consuming. By using the prior FY's hospital wage index for developing the IPF wage index, IPFs are able to use the most reliable wage index data. Any errors in the prior year's hospital wage index would have been identified and corrected prior to using it for developing the IPF wage index.

Regarding the comments requesting us to consider the ''frontier'' floor, we will take the commenters' suggestions into consideration.

[1] Medicare Payment Advisory Commission. Report to the Congress. Medicare and the Health Care Delivery System, Chapter 3, ''Mandated Report: Developing a unified payment system for post-acute care,'' pages 57–105. June 2016.

d. Adjustment for Rural Location

In the November 2004 IPF PPS final rule, 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. For FY 2019, we are finalizing our proposal to continue to apply a 17 percent payment adjustment for IPFs located in a rural area as defined at § 412.64(b)(1)(ii)(C). A complete discussion of the adjustment for rural locations appears in the November 2004 IPF PPS final rule (69 FR 66954).

Comment: One commenter supported CMS' maintaining the 17 percent IPF rural adjustment.

Response: We appreciate the commenter's support for our IPF rural adjustment.

e. 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 2019, we are finalizing our proposal to continue to apply a budget-neutrality adjustment in accordance with our existing budget-neutrality policy. This policy requires us to update the wage index in such a way that total estimated payments to IPFs for FY 2019 are the same with or without the changes (that is, in a budget-neutral manner) by applying a budget neutrality factor to the IPF PPS rates. We use the following steps to ensure that the rates reflect the update to the wage indexes (based on the FY 2014 hospital cost report data) and the labor-related share in a budget-neutral manner:

Step 1. Simulate estimated IPF PPS payments, using the FY 2018 IPF wage index values (available on the CMS website) and labor-related share (as published in the FY 2018 IPF PPS notice with comment period (82 FR 35771)).

Step 2. Simulate estimated IPF PPS payments using the FY 2019 IPF wage index values (available on the CMS website) and FY 2019 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 2019 budget-neutral wage adjustment factor of 1.0013.

Step 4. Apply the FY 2019 budget-neutral wage adjustment factor from step 3 to the FY 2018 IPF PPS federal per diem base rate after the application of the market basket update described in section III.A.2 of this rule, to determine the FY 2019 IPF PPS federal per diem base rate.

2. Teaching Adjustment

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

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

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

We established the teaching adjustment in a manner that limited the incentives for IPFs to add FTE residents for the purpose of increasing their teaching adjustment. We imposed a cap on the number of FTE residents that may be counted for purposes of calculating the teaching adjustment. The cap limits the number of FTE residents that teaching IPFs may count for the purpose of calculating the IPF PPS teaching adjustment, not the number of residents teaching institutions can hire or train. We calculated the number of FTE residents that trained in the IPF during a ''base year'' and used that FTE

resident number as the cap. An IPF's FTE resident cap is ultimately determined based on the final settlement of the IPF's most recent cost report filed before November 15, 2004 (publication date of the IPF PPS final rule). A complete discussion of the temporary adjustment to the FTE cap to reflect residents added due to hospital closure and by residency program appears in the RY 2012 IPF PPS proposed rule (76 FR 5018 through 5020) and the RY 2012 IPF PPS final rule (76 FR 26453 through 26456).

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

Therefore, in this FY 2019 rule, we are finalizing our proposal to continue to retain the coefficient value of 0.5150 for the teaching adjustment to the federal per diem base rate.

Comment: One commenter took no position on the IPF teaching adjustment, but encouraged CMS to lift the graduate medical education (GME) cap on psychiatric residents.

Response: The IPF PPS teaching adjustment is associated with indirect medical education (IME) rather than with GME. GME policies are outside the scope of this rule.

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

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

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

The COLA factors through 2009 are published on the Office of Personnel Management (OPM) website (*https://www.opm.gov/oca/cola/rates.asp*).

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

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

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

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

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

Final Decision: For FY 2019, we are finalizing our proposal to continue to use the COLA factors established for the IPF PPS in FY 2018 to adjust the nonlabor-related portion of the per diem amount for IPFs located in Alaska and Hawaii. These factors are shown in Table 1. For comparison purposes, we also are showing the FY 2015 through FY 2017 COLA factors.

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

Area	FY 2015 through 2017	FY 2018 and FY 2019
Alaska:		
City of Anchorage and 80-kilometer (50-mile) radius by road	1.23	1.25
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.23	1.25
City of Juneau and 80-kilometer (50-mile) radius by road	1.23	1.25

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

Area	FY 2015 through 2017	FY 2018 and FY 2019
Rest of Alaska	1.25	1.25
Hawaii:		
City and County of Honolulu	1.25	1.25
County of Hawaii	1.19	1.21
County of Kauai	1.25	1.25
County of Maui and County of Kalawao	1.25	1.25

The IPF PPS COLA factors for FY 2019 are also shown in Addendum A of this rule, available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html.*

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

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

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

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

Therefore, when patients are discharged from an acute care hospital or CAH and admitted to the same hospital's or CAH's excluded psychiatric unit, the IPF receives the 1.19 adjustment factor as the variable per diem adjustment for the first day of the patient's stay in the IPF. For FY 2019, we will continue to retain the 1.31 adjustment factor for IPFs with qualifying EDs. A complete discussion of the steps involved in the calculation of the ED adjustment factor in our November 2004 IPF PPS final rule (69 FR 66959 through 66960) and the RY 2007 IPF PPS final rule (71 FR 27070 through 27072).

Final Decision: We did not receive any comments on the ED adjustment. Therefore, we are finalizing this section as proposed.

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

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

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

Based on an analysis of the latest available data (the March 2018 update of FY 2017 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. We will update the IPF outlier threshold amount for FY 2019 using FY 2017 claims data and the same methodology that we used to set the initial outlier threshold amount in the RY 2007 IPF PPS final rule (71 FR 27072 and 27073), which is also the same methodology that we used to update the outlier threshold amounts for years 2008 through 2018. Based on an analysis of these updated data, we estimate that IPF outlier payments as a percentage of total estimated payments are approximately 2.24 percent in FY 2018 (compared to approximately 2.27 percent in the proposed rule). Therefore, we are updating the outlier threshold amount to $12,865 to maintain estimated outlier payments at 2 percent of total estimated aggregate IPF payments for FY 2019. This final rule update is a decrease from the proposed threshold of $12,935.

Comment: A commenter was appreciative of our updating the outlier threshold, and noted that it is critical to receive reimbursement that allows IPFs to accept high cost patients.

Response: We thank the commenter for their support of our outlier policy.

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

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

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

- Calculated two national ceilings, one for IPFs located in rural areas and one for IPFs located in urban areas.
- Computed the ceilings by first calculating the national average and the standard deviation of the CCR for both urban and rural IPFs using the most recent CCRs entered in the CY 2018 Provider Specific File.

For FY 2019, we will continue to follow this methodology.

To determine the rural and urban ceilings, we multiplied each of the standard deviations by 3 and added the result to the appropriate national CCR average (either rural or urban). The upper threshold CCR for IPFs in FY 2019 is 2.0068 for rural IPFs, and 1.6862 for urban IPFs, based on CBSA-based geographic designations. If an IPF's CCR is above the applicable ceiling, the ratio is considered statistically inaccurate, and we assign the appropriate national (either rural or urban) median CCR to the IPF.

We apply the national CCRs to the following situations:

- New IPFs that have not yet submitted their first Medicare cost report. We continue to use these national CCRs until the facility's actual CCR can be computed using the first tentatively or final settled cost report.
- IPFs whose overall CCR is in excess of three standard deviations above the corresponding national geometric mean (that is, above the ceiling).
- Other IPFs for which the Medicare Administrative Contractor (MAC) obtains inaccurate or incomplete data with which to calculate a CCR.

We will continue to update the FY 2019 national median and ceiling CCRs for urban and rural IPFs based on the CCRs entered in the latest available IPF PPS Provider Specific File. Specifically, for FY 2019, to be used in each of the three situations listed previously, using the most recent CCRs entered in the CY 2018 Provider Specific File, we provide an estimated national median CCR of 0.5890 for rural IPFs and a national median CCR of 0.4365 for urban IPFs. These calculations are based on the IPF's location (either urban or rural) using the CBSA-based geographic designations.

A complete discussion regarding the national median CCRs appears in the November 2004 IPF PPS final rule (69 FR 66961 through 66964).

IV. Technical Corrections to the IPF Regulations

We proposed to make minor technical corrections to the IPF payment regulations at § 412.27(a), § 412.402 and § 412.428 to update, correct, or clarify existing regulations text. We note that these are technical corrections and they do not affect or change any existing policies.

Excluded Psychiatric Units: Additional Requirements (§ 412.27)

At § 412.27, we set forth additional requirements for excluded psychiatric units. In paragraph (a) we detail admission requirements and state that eligible patients must have a psychiatric principal diagnosis that is listed in the Fourth Edition of the American Psychiatric Association's Diagnostic and Statistical Manual (DSM) or Chapter Five (''Mental Disorders'') of the International Classification of Diseases, Ninth Revision, Clinical Modification. This language has been in place since 2006, but there have since been updates to the versions of these code sets.

In a final rule published on September 5, 2012 (77 FR 54664), the Secretary adopted ICD–10–CM and ICD–10–PCS, in place of ICD–9–CM, as standard medical data code sets under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). This change is reflected in the HIPAA regulations at 45 CFR 162.1002(c). In the August 4, 2014 final rule (79 FR 45128), the Secretary set October 1, 2015 as the compliance date for HIPAA covered entities to use the ICD–10 code sets. Because we are required to use the HIPAA standards, in the FY 2015 IPF PPS final rule published August 6, 2014 in the **Federal Register** titled, ''Inpatient Psychiatric Facilities Prospective Payment System—Update for FY Beginning October 1, 2014 (FY 2015)'' (79 FR 45945 through 45947), we finalized conversions of the ICD–9–CM-based MS–DRGs to ICD–10–CM/PCS-based MS–DRGs. However, we neglected to make a conforming change to § 412.27(a). Therefore, we proposed to correct § 412.27(a) to state that eligible patients must have a psychiatric principal diagnosis that is listed in ICD–10–CM.

The revision to § 412.27(a) will simply continue our longstanding policy of recognizing psychiatric diagnoses that are DSM diagnosis codes. We note that the DSM diagnosis codes map to ICD–10–CM codes, but the mapping is not exclusive to chapter 5 of the ICD–10–CM, as it was with ICD–9–CM; rather, they map to other chapters in ICD–10–CM as well. Therefore, the correction to § 412.27(a) will no longer reference the DSM and would not specifically mention chapter 5 of ICD–10–CM.

Comment: A commenter supported the continued technical updates that represent psychiatric principal diagnoses based on current editions of

the American Psychiatric Association's Diagnostic and Statistical Manual (DSM) and the International Classification of Diseases. Another commenter made an out-of-scope suggestion that we change the regulation at § 412.27 so that the 190-day lifetime maximum on inpatient days at psychiatric hospitals would also apply to psychiatric units. In addition, this commenter also commented on a proposal in the FY 2019 IPPS proposed rule.

Response: We appreciate the support for the technical correction we proposed, and note that the DSM codes are encompassed in the ICD–10–CM code set. We are not responding to the comments related to applying the 190-day lifetime maximum on inpatient psychiatric hospital days to IPF units or to the IPPS proposed rule because they are out of scope of this rulemaking.

Final Decision: We are finalizing the proposed update to § 412.27(a) with no change.

Definitions § 412.402

At § 412.402, there is a typographical error in the definition of ''Principal Diagnosis.'' We inadvertently repeat the language that a principal diagnosis is also referred to as a primary diagnosis.

Final Decision: We received no comments on this proposal. Therefore, we are finalizing our proposal to correct this error by removing the duplicate language.

Publication of Changes to the Inpatient Psychiatric Facility Prospective Payment System (§ 412.428)

In the FY 2016 IPF PPS regulations, we proposed and finalized an IPF-specific market basket for updating the annual IPF payment rates (80 FR 46656 through 46679). This new IPF-specific market basket replaced the Rehabilitation, Psychiatric, and Long-Term Care (RPL) market basket, which had been in place for discharges occurring from July 1, 2006 through September 30, 2015. However, in our FY 2016 IPF PPS final rule, we did not update the regulations text at § 412.428 to reflect the adoption of the IPF-specific market basket. Therefore, we are updating § 412.428 to indicate that the use of the RPL market basket ended as of September 30, 2015, and that the IPF market basket was implemented for use in updating IPF PPS payment rates for discharges occurring on or after October 1, 2015. In addition, we are making other technical changes to this section for clarification and consistency.

Final Decision: We received no comments on this proposal. Therefore, we are finalizing these changes as proposed.

V. Update on IPF PPS Refinements and Comment Solicitation

For RY 2012, we identified several areas of concern for future refinement, and we invited comments on these issues in the RY 2012 IPF PPS proposed and final rules. For further discussion of these issues and to review the public comments, we refer readers to the RY 2012 IPF PPS proposed rule (76 FR 4998) and final rule (76 FR 26432).

We have delayed making refinements to the IPF PPS until we have completed a thorough analysis of IPF PPS data on which to base those refinements. Specifically, we will delay updating the adjustment factors derived from the regression analysis until we have IPF PPS data that include as much information as possible regarding the patient-level characteristics of the population that each IPF serves. We have begun and will continue the necessary analysis to better understand IPF industry practices so that we may refine the IPF PPS in the future, as appropriate. Our preliminary analysis has also revealed variation in cost and claim data, particularly related to labor costs, drugs costs, and laboratory services. Some providers have very low labor costs, or very low or missing drug or laboratory costs or charges, relative to other providers. In the proposed rule, we solicited comments about differences in the IPF labor mix, differences in IPF patient mix, and differences in provision of drugs and laboratory services. We anticipated that these comments would better inform our refinement process.

As we noted in the FY 2016 IPF PPS final rule (80 FR 46693 through 46694), our preliminary analysis of 2012 to 2013 IPF data found that over 20 percent of IPF stays reported no ancillary costs, such as laboratory and drug costs, in their cost reports, or laboratory or drug charges on their claims. Because we expect that most patients requiring hospitalization for active psychiatric treatment will need drugs and laboratory services, we again remind providers that the IPF PPS federal per diem base rate includes the cost of all ancillary services, including drugs and laboratory services. OnNovember 17, 2017, we issued Transmittal 12, which made changes to the hospital cost report form CMS–2552–10 (OMB No. 0938–0050), and included cost report Level I edit 10710S, effective for cost reporting periods ending on or after August 31, 2017. Edit 10710S now requires 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. For details, we refer readers to see these Transmittals, which are available on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/index.html*. CMS suspended edit 10710S effective April 27, 2018, pending evaluation of the application of the edit to all-inclusive-rate providers.

We pay only the IPF for services furnished to a Medicare beneficiary who is an inpatient of that IPF (except for certain professional services), and payments are considered to be payments in full for all inpatient hospital services provided directly or under arrangement (see 42 CFR 412.404(d)), as specified in 42 CFR 409.10.

We will continue to analyze data from claims and cost reports that do not include ancillary charges or costs, and will be sharing our findings with CMS Office of the Center for Program Integrity and CMS Office of Financial Management for further investigation, as the results warrant. Our refinement analysis is dependent on recent precise data for costs, including ancillary costs. We will continue to collect these data and analyze them for both timeliness and accuracy with the expectation that these data will be used in a future refinement. It is currently our intent to explore refinements to the adjustments in future rulemaking. Since we are not making refinements in this rule, for FY 2019 we will continue to use the existing adjustment factors.

We did not receive any comments on our solicitation; however, we did receive three comments related to missing ancillary costs or charges.

Comment: We received a few comments related to missing ancillary charges, and costs on the Medicare cost report. Two commenters stated that because these ancillary costs often represent a relatively low portion of their member hospitals' costs, they typically do not make a separate charge for ancillary services. The commenters stated that costs associated with ancillary services are typically reported in the routine cost center in the Medicare cost report. In addition, they stated that laboratory and drug costs represent approximately 1 percent and 4 percent respectively, of the costs of IPF services and these commenters did not consider these costs sufficiently significant to justify a separate calculation of costs.

A third commenter stated that a number of State psychiatric hospitals complete the Medicare Cost Report utilizing an all-inclusive rate

methodology and as a result may not separately report these ancillary costs. This commenter suggested that CMS review the data analysis to identify correlation between the reporting of ancillary costs and all-inclusive rate providers. The commenter also suggested that the cost report edit related to ancillary costs should probably not be applied to all-inclusive rate providers.

Response: We agree that CMS Pub. 15–1, chapter 22, section 2208.1.A, states that all-inclusive-rate providers' ancillary services may not be considered sufficiently significant to justify a separate calculation of costs for Medicare and non-Medicare patients. Therefore, we agree that the edit related to ancillary costs should not apply to the all-inclusive-rate providers. CMS will exclude all-inclusive rate providers from the application of the edit. We are aware that some providers are not identifying as an all-inclusive-rate provider on Worksheet S–2, Part I, line 115, and are reporting ancillary services costs that represent a low portion of the hospital's cost in the routine cost center on the Medicare cost report. The providers are using section 2208 to justify not reporting the ancillary costs. Providers that are approved as all-inclusive rate but that do not identify as all-inclusive rate on the Medicare cost report will not benefit from the exclusion from the edit and will be required to report ancillary services accordingly.

VI. Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program

A. Background and Statutory Authority

Section 1886(s)(4) of the Act, as added and amended by sections 3401(f) and 10322(a) of the Patient Protection and Affordable Care Act, requires the Secretary to implement a quality reporting program for inpatient psychiatric hospitals and psychiatric units. Section 1886(s)(4)(A)(i) of the Act requires that, for FY 2014 [2] and each subsequent FY, the Secretary must reduce any annual update to a standard federal rate for discharges occurring during the FY by 2.0 percentage points in the case of a psychiatric hospital or psychiatric unit that does not comply with quality data submission requirements with respect to an applicable FY.

As provided in section 1886(s)(4)(A)(ii) of the Act, the application of the reduction for failure to report under section 1886(s)(4)(A)(i) of the Act may result in an annual update of less than 0.0 percent for a FY, and may result in payment rates under section 1886(s)(1) of the Act being less than the payment rates for the preceding year. In addition, section 1886(s)(4)(B) of the Act requires that the application of the reduction to a standard federal rate update be noncumulative across FYs. Thus, any reduction applied under section 1886(s)(4)(A) of the Act will apply only with respect to the FY rate involved and the Secretary may not take into account the reduction in computing the payment amount under the system described in section 1886(s)(1) of the Act for subsequent years.

Section 1886(s)(4)(C) of the Act requires that, for FY 2014 and each subsequent FY, each psychiatric hospital and psychiatric unit must submit to the Secretary data on quality measures as specified by the Secretary. The data must be submitted in a form and manner and at a time specified by the Secretary. Under section 1886(s)(4)(D)(i) of the Act, unless the exception of subclause (ii) applies, measures selected for the quality reporting program must have been endorsed by the entity with a contract under section 1890(a) of the Act. The National Quality Forum (NQF) currently holds this contract.

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

Section 1886(s)(4)(E) of the Act requires the Secretary to establish procedures for making public the quality measure data submitted by inpatient psychiatric hospitals and psychiatric units under the IPFQR Program. These procedures must ensure that an inpatient psychiatric facility or unit has the opportunity to review its data before the data are made public. The Secretary must report quality measures that relate to services furnished in inpatient settings and psychiatric hospitals and units on the CMS website.

B. Covered Entities

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

C. Previously Finalized Measures and Administrative Procedures

The current IPFQR Program includes 18 measures. For more information on these measures, we refer readers to the following final rules:

- The FY 2013 IPPS/LTCH PPS final rule (77 FR 53646 through 53652);
- The FY 2014 IPPS/LTCH PPS final rule (78 FR 50889 through 50897);
- The FY 2015 IPF PPS final rule (79 FR 45963 through 45975);
- The FY 2016 IPF PPS final rule (80 FR 46695 through 46714); and
- The FY 2017 IPPS/LTCH PPS final rule (81 FR 57238 through 57247).

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

- The FY 2013 IPPS/LTCH PPS final rule (77 FR 53653 through 53660);
- The FY 2014 IPPS/LTCH PPS final rule (78 FR 50897 through 50903;
- The FY 2015 IPF PPS final rule (79 FR 45975 through 45978);
- The FY 2016 IPF PPS final rule (80 FR 46715 through 46719);
- The FY 2017 IPPS/LTCH PPS final rule (81 FR 57248 through 57249); and
- The FY 2018 IPPS/LTCH PPS final rule (82 FR 38471 through 38474)

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

D. Accounting for Social Risk Factors

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38462 through 38463), we discussed the importance of improving beneficiary outcomes including reducing health disparities. We also discussed our commitment to ensuring that medically complex patients, as well as those with social risk factors, receive excellent care. We discussed how studies show that social risk factors, such as being near or below the poverty level as determined by HHS, belonging to a racial or ethnic minority group, or living with a disability, can be associated with poor health outcomes and how some of this disparity is related to the quality of health care.[3] Among our core objectives, we aim to improve health outcomes, attain health equity for all beneficiaries, and ensure that complex patients as well as those with social risk factors receive excellent care. Within this context, reports by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) and the National Academy of Medicine have examined the influence of social risk factors in CMS value-based purchasing programs.[4] As we noted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38404), ASPE's report to the Congress found that, in the context of value-based purchasing programs, dual eligibility (that is, eligibility for both Medicare and Medicaid) was the most powerful predictor of poor health care outcomes among those social risk factors that they examined and tested. In addition, as we noted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38241), the National Quality Forum (NQF) undertook a 2-year trial period in which certain new measures and measures undergoing maintenance review have been assessed to determine if risk adjustment for social risk factors is appropriate for these measures.[5] The trial period ended in April 2017 and a final report is available at: *http://www.qualityforum.org/SES_Trial_Period.aspx.* The trial concluded that ''measures with a conceptual basis for adjustment generally did not demonstrate an empirical relationship'' between social risk factors and the outcomes measured. This discrepancy may be explained in part by the methods used for adjustment and the limited availability of robust data on social risk factors. NQF has extended the socioeconomic status (SES) trial,[6] allowing further examination of social risk factors in outcome measures.

In the FY 2018 and CY 2018 proposed rules for our quality reporting and value-based purchasing programs, we solicited feedback on which social risk factors provide the most valuable information to stakeholders and the methodology for illuminating differences in outcomes rates among patient groups within a hospital or provider that would also allow for a comparison of those differences, or disparities, across providers. Feedback we received across our quality reporting programs included encouraging CMS to explore whether factors that could be used to stratify or risk adjust the measures (beyond dual eligibility); considering the full range of differences in patient backgrounds that might affect outcomes; exploring risk adjustment approaches; and to offer careful consideration of what type of information display would be most useful to the public. We also sought public comment on confidential reporting and future public reporting of some of our measures stratified by patient dual eligibility. In general, commenters stated that stratified measures could serve as tools for hospitals to identify gaps in outcomes for different groups of patients, improve the quality of health care for all patients, and empower consumers to make informed decisions about health care. Commenters encouraged us to stratify measures by other social risk factors such as age, income, and educational attainment. With regard to value-based purchasing programs, commenters also cautioned to balance fair and equitable payment while avoiding payment penalties that mask health disparities or discourage the provision of care to more medically complex patients. Commenters also noted that value-based payment program measure selection, domain weighting, performance scoring, and payment methodology must account for social risk.

As a next step, we are considering options to improve health disparities among patient groups within and across hospitals by increasing the transparency of disparities as shown by quality measures. We also are considering how this work applies to other CMS quality programs in the future. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38403 through 38409) and the FY 2019 IPPS/LTCH PPS Proposed Rule (83 FR 20495 through 20496) published in the May 7, 2018 **Federal Register** for more details, where we discuss the potential stratification of certain Hospital IQR Program outcome measures. Furthermore, we continue to consider options to address equity and disparities in our value-based purchasing programs.

We plan to continue working with ASPE, the public, and other key stakeholders on this important issue to identify policy solutions that achieve the goals of attaining health equity for all beneficiaries and minimizing unintended consequences.

Comment: Several commenters supported CMS's ongoing evaluation of social risk factors. One commenter recommended evaluating social risk factors specific to the IPF setting and analyzing factors such as facilities with high numbers of specialty populations (such as geriatric or diagnosis-specific) as well as stratifying outcomes for locked versus unlocked facilities. Another commenter expressed support for stratification by race, ethnicity, geographic area, sex, and disability, and recommended evaluation of stratification by primary language.

Response: We thank these commenters for their support and will consider these topics in our future analyses of social risk factors.

E. Improving Patient Outcomes and Reducing Burden Through Meaningful Measures

Regulatory reform and reducing regulatory burden are high priorities for CMS. To reduce the regulatory burden on the healthcare industry, lower health care costs, and enhance patient care, in October 2017, we launched the Meaningful Measures Initiative.[7] This initiative is one component of our agency-wide Patients Over Paperwork Initiative,[8] which is aimed at evaluating and streamlining regulations with a goal to reduce unnecessary cost and burden,

[3] See, for example United States Department of Health and Human Services. ''Healthy People 2020: Disparities. 2014.'' Available at: *http://www.healthypeople.gov/2020/about/foundation-health-measures/Disparities;* or National Academies of Sciences, Engineering, and Medicine. Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors. Washington, DC: National Academies of Sciences, Engineering, and Medicine 2016.

[4] Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (ASPE), ''Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs.'' December 2016. Available at: *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[5] Available at: *http://www.qualityforum.org/SES_Trial_Period.aspx.*

[6] Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86357.*

[7] Meaningful Measures web page: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.html.*

[8] Remarks by Administrator Seema Verma at the Health Care Payment Learning and Action Network (LAN) Fall Summit, as prepared for delivery on October 30, 2017. Available at: *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-10-30.html.*

increase efficiencies, and improve beneficiary experience. The Meaningful Measures Initiative is aimed at identifying the highest priority areas for quality measurement and quality improvement in order to assess the core quality of care issues that are most vital to advancing our work to improve patient outcomes. The Meaningful Measures Initiative represents a new approach to quality measures that fosters operational efficiencies, and will reduce costs including collection and reporting burden while producing quality measurement that is more focused on meaningful outcomes.

The Meaningful Measures Framework has the following objectives:

- Address high-impact measure areas that safeguard public health;
- Patient-centered and meaningful to patients;
- Outcome-based where possible;
- Fulfill each program's statutory requirements;
- Minimize the level of burden for health care providers (for example, through a preference for EHR-based measures where possible, such as electronic clinical quality measures);
- Significant opportunity for improvement;
- Address measure needs for population based payment through alternative payment models and,
- Align across programs and/or with other payers.

In order to achieve these objectives, we have identified 19 Meaningful Measures areas and mapped them to six overarching quality priorities as shown in Table 2:

TABLE 2—MAPPING OF MEANINGFUL MEASURES AREAS TO QUALITY PRIORITIES

Quality priority	Meaningful measure area
Making Care Safer by Reducing Harm Caused in the Delivery of Care	Healthcare-Associated Infections. Preventable Healthcare Harm.
Strengthen Person and Family Engagement as Partners in Their Care	Care is Personalized and Aligned with Patient's Goals. End of Life Care according to Preferences. Patient's Experience of Care. Patient Reported Functional Outcomes.
Promote Effective Communication and Coordination of Care	Medication Management. Admissions and Readmissions to Hospitals. Transfer of Health Information and Interoperability.
Promote Effective Prevention and Treatment of Chronic Disease	Preventive Care. Management of Chronic Conditions. Prevention, Treatment, and Management of Mental Health. Prevention and Treatment of Opioid and Substance Use Disorders.
Work with Communities to Promote Best Practices of Healthy Living	Risk Adjusted Mortality. Equity of Care. Community Engagement.
Make Care Affordable	Appropriate Use of Healthcare. Patient-focused Episode of Care. Risk Adjusted Total Cost of Care.

By including Meaningful Measures in our programs, we believe that we can also address the following cross-cutting measure considerations:

- Eliminating disparities;
- Tracking measurable outcomes and impact;
- Safeguarding public health;
- Achieving cost savings;
- Improving access for rural communities; and,
- Reducing burden.

We believe that the Meaningful Measures Initiative will improve outcomes for patients, families, and health care providers while reducing burden and costs for clinicians and providers, as well as promoting operational efficiencies.

Comment: Several commenters expressed support for the Meaningful Measures Initiative and the associated effort to assess measures, align programs and reduce burden. One commenter further recommended that CMS collaborate with other entities (such as accreditation agencies and states) to further reduce burden.

Response: We thank these commenters for their support and will consider additional ways to put patients first through our measures and reduce burden.

F. Removal or Retention of IPFQR Program Measures

1. Considerations for Removing or Retaining Measures

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38463 through 38465), we finalized our proposals to adopt considerations for removing or retaining measures within the IPFQR Program. In that final rule, we finalized: (1) Measure removal factors; (2) criteria for determining when a measure is ''topped-out;'' and (3) measure retention factors.

Specifically, the measure removal factors we adopted are:

- Factor 1. Measure performance among IPFs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped-out'' measures);
- Factor 2. Measure does not align with current clinical guidelines or practice;
- Factor 3. Measure can be replaced by a more broadly applicable measure (across settings or populations) or a measure that is more proximal in time to desired patient outcomes for the particular topic;
- Factor 4. Measure performance or improvement does not result in better patient outcomes;
- Factor 5. Measure can be replaced by a measure that is more strongly associated with desired patient outcomes for the particular topic;
- Factor 6. Measure collection or public reporting leads to negative unintended consequences other than patient harm; and
- Factor 7. Measure is not feasible to implement as specified.

The ''topped out'' criteria that we adopted are: (1) Statistically indistinguishable performance at the 75th and 90th percentiles; and (2) the truncated coefficient of variation is less than or equal to 0.10.

The measure retention factors that we adopted are:

- Measure aligns with other CMS and HHS policy goals, such as those delineated in the National Quality Strategy or CMS Quality Strategy;

- Measure aligns with other CMS programs, including other quality reporting programs; and
- Measure supports efforts to move IPFs towards reporting electronic measures.

We are not making any changes to these previously finalized measure removal or retention factors, or our criteria for determining when a measure is topped-out. However, we are adding an additional measure removal factor. This is discussed in more detail below.

a. New Removal Factor

We are adopting the following additional factor to consider when evaluating measures for removal from the IPFQR Program measure set: Factor 8. The costs associated with a measure outweigh the benefit of its continued use in the program.

As we discussed in section VI.E. of this final rule on our new Meaningful Measures Initiative, we are engaging in efforts to ensure that the IPFQR Program measure set continues to promote improved health outcomes for beneficiaries while minimizing the overall costs associated with the program. We believe these costs are multi-faceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining the program. We have identified several different types of costs, including, but not limited to: (1) Provider and clinician information collection burden and related cost and burden associated with the submitting/reporting of quality measures to CMS; (2) the provider and clinician cost associated with complying with other IPFQR programmatic requirements; (3) the provider and clinician cost associated with participating in multiple quality programs, and tracking multiple similar or duplicative measures within or across those programs; (4) the CMS cost associated with the program oversight of the measure, including maintenance and public display; and/or (5) the provider and clinician cost associated with compliance to other federal and/or State regulations (if applicable).

For example, it may be needlessly costly and/or of limited benefit to retain or maintain a measure which our analyses show no longer meaningfully supports program objectives (for example, informing beneficiary choice or payment scoring). It may also be costly for health care providers to track confidential feedback preview reports, and publicly reported information on a measure where we use the measure in more than one program. CMS may also have to expend unnecessary resources to maintain the specifications for the measure, as well as the tools needed to collect, validate, analyze, and publicly report the measure data. Furthermore, beneficiaries may find it confusing to see public reporting on the same measure in different programs.

When these costs outweigh the evidence supporting the continued use of a measure in the IPFQR Program, we believe it may be appropriate to remove the measure from the program. Although we recognize that one of the main goals of the IPFQR Program is to improve beneficiary outcomes by incentivizing health care providers to focus on specific care issues and making public data related to those issues, we also recognize that those goals can have limited utility where, for example, the publicly reported data are of limited use because they cannot be easily interpreted by beneficiaries to influence their choice of providers. In these cases, removing the measure from the IPFQR Program may better accommodate the costs of program administration and compliance without sacrificing improved health outcomes and beneficiary choice.

We are removing measures based on this factor on a case-by-case basis. We might, for example, decide to retain a measure that is burdensome for health care providers to report if we conclude that the benefit to beneficiaries justifies the reporting burden. Our goal is to move the program forward in the least burdensome manner possible, while maintaining a parsimonious set of meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients.

We solicited public comments on our proposal to adopt an additional measure removal factor, ''the costs associated with a measure outweigh the benefit of its continued use in the program,'' effective upon publication of the FY 2019 IPF PPS final rule. We refer readers to section VI.F.2.a of this final rule for discussion on removing four IPFQR Program measures based on this removal factor.

Comment: Several commenters expressed support for adoption of the new measure removal factor ''the costs associated with a measure outweigh the benefit of its continued use in the program.''

Response: We thank these commenters for their support.

Comment: Several commenters expressed concern about adoption of the measure removal Factor 8. The costs associated with a measure outweigh the benefit of its continued use in the program. One commenter expressed concern that this factor is not supported by scientific criteria, and that therefore, adoption of this factor could cause significant harm to patients. Another commenter stated their belief that it is inappropriate to apply a cost-benefit analysis to measures which can save lives and ensure patient safety.

Response: We agree with commenters that it is important to adequately weigh the potential benefits of a measure in determining whether the costs outweigh those benefits. However, we disagree that this can only be achieved by applying scientific criteria. We believe that an appropriate measure set for a specific program is achieved by applying a balanced set of factors to ensure that each measure serves a purpose in the program, and this cost-benefit analysis is one element of that set of factors. Under this analysis, qualitative benefits (that is, benefits that cannot be assigned a specific numerical value) would be weighed against potential costs to ensure that measures that save lives and ensure patient safety are retained when appropriate.

Comment: One commenter urged CMS to retain measures that are high-cost, but continue to serve beneficiaries in cases when the benefits would justify the cost.

Response: We agree with this commenter's suggestion that costs may be outweighed by benefits (especially benefits to beneficiaries), and intend to evaluate measures on a case-by-case basis to achieve this balance.

Comment: Several commenters requested that CMS clarify how it intends to evaluate the costs and benefits of each measure. One commenter observed that costs should include investing resources for quality improvement and tracking performance. Another commenter observed that benefits should prioritize benefits specific to the psychiatric needs that drive admission.

Response: In the FY 2019 IPF PPS proposed rule (83 FR 21118), we expressed that we will evaluate costs and benefits on a case-by-case basis and identified several types of costs to provide examples of costs which we would evaluate in this analysis. We refer readers to section VI.F.1.a. of this final rule and the FY 2019 IPF PPS proposed rule for non-exhaustive examples of the different types of costs we will consider (83 FR 21118). These costs include, but are not limited to: (1) Provider and clinician information collection burden and related cost and burden associated with the submitting/reporting of quality measures to CMS; (2) the provider and clinician cost associated with complying with other

IPFQR programmatic requirements; (3) the provider and clinician cost associated with participating in multiple quality programs, and tracking multiple similar or duplicative measures within or across those programs; (4) the CMS cost associated with the program oversight of the measure, including maintenance and public display; and/or (5) the provider and clinician cost associated with compliance to other federal and/or state regulations (if applicable). We intend to evaluate each measure on a case-by-case basis, while considering input from a variety of stakeholders, including, but not limited to: patients, caregivers, patient and family advocates, providers, provider associations, healthcare researchers, healthcare payers, data vendors, and other stakeholders with insight into the direct and indirect benefits and costs, financial and otherwise, of maintaining the specific measure in the IPFQR Program. We note that we intend to assess the costs and benefits to all program stakeholders, including but not limited to, those listed above. We further note that our assessment of costs is not limited to a strictly quantitative analysis.

The commenter's example of resources for quality improvement is an example of a cost that would be evaluated on a case-by-case basis because we believe that investing resources in quality improvement is an inherent part of delivering high-quality, patient-centered care, and is therefore, generally not considered a part of the quality reporting program requirements. However, there may be cases in which a measure would require such a specific quality improvement initiative that it would be appropriate to consider this cost to be associated with the measure. We also believe that in assessing the benefits of a measure, it is appropriate to consider the patient's whole experience of care, not only the primary reason for admission. Therefore, we believe that the benefits to be evaluated for each measure are specific to the measure and the original reasons for including the measure in the program.

Comment: One commenter recommended that CMS ensure screening measures, including those for vaccinations and substance use, are truly duplicative, topped-out, or part of best practices prior to removing such measures.

Response: Factors regarding a measure's continued ability to achieve program objectives, such as whether the measure is duplicative, topped-out, or part of best practices, are among the factors we will consider when evaluating a measure's continued benefit within the program. We evaluate each measure on a case-by-case basis using the previously established criteria for topped-out status (that is, that a measure is topped-out if there is statistically indistinguishable performance at the 75th and 90th percentiles and the truncated coefficient of variation is less than or equal to 0.10 (82 FR 38463)). To determine whether a measure is duplicative, we evaluate the IPFQR program measure set and measure sets of other programs, if applicable, to ensure that other measures are not capturing the same data. We determine whether a measure is part of best practices in a variety of ways, including but not limited to a review of nationally recognized clinical guidelines and having technical expert panels review the measure. Generally, if we determine that a measure is duplicative, topped-out, or part of best practices we would consider that its benefits have been reduced and therefore this would be a factor to consider in evaluating whether the costs outweigh the benefits. However, there may be times when a screening measure is not duplicative, topped-out, or part of best practices, but that the costs are sufficiently high (or the continued benefit has become reduced by some other means, such as a reduction in the prevalence of the condition being screened for) that the measure would be appropriate to remove. We will continue to evaluate the benefits and costs of each measure on a case-by-case basis. We will also continue to propose measures for removal, including screening measures, through the notice and comment rulemaking process in which we will provide descriptions of the analyses which led us to conclude that measures are appropriate to remove.

Final Decision: After careful consideration of the comments received, we are finalizing our proposal to adopt the new measure removal Factor 8. The costs associated with a measure outweigh the benefit of its continued use in the program as proposed.

2. Measures for Removal

In the FY 2019 IPF PPS proposed rule (83 FR 21118 through 21123), we proposed to remove eight measures from the IPFQR Program. We developed these proposals after conducting an overall review of the program under the Framework associated with our new Meaningful Measures Initiative, which is discussed in more detail in section VI.E. of this final rule. We believe that the Framework will allow IPFs and patients to continue to obtain meaningful information about IPF performance and incentivize quality improvement, while streamlining the measure sets to reduce program complexity so that the costs do not outweigh the benefits of improving beneficiary care. In addition, we note that in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38464), several commenters requested that we evaluate the current measures in the IPFQR Program using the removal and retention factors that we finalized in that rule.

In evaluating the IPFQR Program measure set under our Meaningful Measures Framework and according to our measure removal and retention factors, we identified eight measures which we believed were appropriate to remove from the IPFQR Program for the FY 2020 payment determination and subsequent years. First, we identified five measures for which the costs associated with each measure outweigh the benefit of its continued use in the program, under new measure removal Factor 8 adopted in section VI.F.1.a of this final rule. Second, we identified three measures that meet our topped-out criteria under measure removal Factor 1. These measures are discussed in more detail below.

a. Measures in Which Costs Outweigh Benefits

i. Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) Measure

In the FY 2019 IPF PPS proposed rule (83 FR 21119 through 21120) we proposed to remove the Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) measure, a National Healthcare Safety Network (NHSN) measure, from the IPFQR Program beginning with FY 2020 payment determination under our measure removal Factor 8. The costs associated with a measure outweigh the benefit of its continued use in the program. We initially adopted the Influenza Vaccination Coverage Among Healthcare Personnel measure because we recognize that influenza immunization is an important public health issue, especially for vulnerable patients who may have limited access to the healthcare system, such as patients in IPFs.

We adopted the Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) measure in in the FY 2015 IPF PPS final rule (79 FR 45968 through 45970) due to public health concerns regarding influenza virus infection among the IPF population. We believe that the Influenza Vaccination Coverage Among Healthcare Personnel (NQF

#0431) measure addresses this public health concern by assessing influenza vaccination in the IPF among healthcare personnel (HCP), who can serve as vectors for influenza transmission. We also adopted the Influenza Immunization (IMM–2, NQF #1659) measure in the FY 2015 IPF PPS final rule (79 FR 45967 through 45968) to address the same public health concern of influenza virus infection in the IPF patient population by assessing patient screening for and provision of influenza vaccinations.

The information collection burden for the Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) measure is less than the information collection burden for measures that require chart abstraction of patient data because influenza vaccination among healthcare personnel can be calculated through review of records maintained in administrative systems and because facilities have fewer healthcare personnel than patients; therefore, the measure does not require review of as many records; however, this measure does still pose some information collection burden on facilities due to the requirement to identify personnel who have been vaccinated against influenza, and the reason that unvaccinated personnel have not been vaccinated.

Furthermore, as we stated in section VI.F.1.a of this final rule, costs are multi-faceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining the program. For example, it may be costly for health care providers to maintain general administrative knowledge to report these measures. Additionally, CMS must expend resources in maintaining information collection systems, analyzing reported data, and providing public reporting of the collected information. In our analysis of the IPFQR Program measure set, we recognized that some facilities face challenges with the administrative requirements of the NHSN for reporting the Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) measure. These administrative requirements (which are unique to the NHSN) include annually completing NHSN system user authentication. Enrolling in NHSN is a five-step process that the CDC estimates takes an average of 263 minutes per facility.[9]

Furthermore, submission via NHSN requires the system security administrator of participating facilities to re-consent electronically, ensure that contact information is kept current, ensure that the IPF has an active facility administrator account, keep Secure Access Management Service (SAMS) credentials active by logging in approximately every 2 months and changing their password, create a monthly reporting plan, and ensure that the facility's CCN information is up-to date. Unlike acute care hospitals which participate in other quality reporting programs which may require NHSN reporting, such as the Hospital IQR Program and HAC Reduction Program, IPFs are only required to participate in NHSN to submit data for this one measure. This may unduly disadvantage smaller IPFs, specifically those that are not part of larger hospital systems, because these IPFs do not have NHSN access for other quality reporting or value-based payment programs. It is our goal to ensure that the IPFQR Program is equitable to all providers and this measure may disproportionately affect small, independent IPFs. Especially for these small, independent IPFs, the incremental costs of this measure over the rest of the IPFQR Program measure set are significant because of the requirements of NHSN participation. As a result, we believe that the costs and burdens associated with this chart-abstracted measure outweigh the benefit of its continued use in the program.

We continue to believe that the Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) measure provides the benefit of protecting IPF patients against influenza; however, we believe that these benefits are offset by other efforts to reduce influenza infection among IPF patients, such as numerous healthcare employer requirements for healthcare personnel to be vaccinated against influenza.[10]

We also believe that by continuing to include the Influenza Immunization (IMM–2, NQF #1659) measure in the IPFQR program, the measure set remains responsive to the public health concern of influenza infection within the IPF population by collecting data on rates of influenza immunization among IPF patients. Further, we believe that while the Influenza Immunization (IMM–2, NQF #1659) measure has information collection burden associated with chart abstracting data, this measure is less costly than the NHSN Participation required for the Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) measure in the IPF context.

We wish to minimize the level of cost of our programs for providers, as discussed under the Meaningful Measures Initiative in section VI.E. of this final rule. In our assessment of the IPFQR measure set, we prioritized measures that align with this Framework, as the most important to the IPF population. Our assessment concluded that while the Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) measure continues to provide benefits, these benefits are diminished by other efforts and are outweighed by the significant costs of reporting this measure.

For these reasons, we proposed to remove the Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) measure from the IPFQR Program for the FY 2020 payment determination and subsequent years.

Comment: Several commenters expressed support for removal of the Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) measure and agreed with CMS's rationale that this measure is unduly burdensome for IPFs whose only requirement for NHSN participation is reporting this measure with already high performance.

Response: We thank these commenters for their support.

Comment: Several commenters recommended that CMS not remove the Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) measure. Some commenters observed that IPFs are high-risk settings for the spread of flu from personnel to patients because of group activities and communal atmospheres expose patients and that this measure is targeted at preventing inpatient outbreaks, which is a different target than the Influenza Immunization (IMM–2, NQF #1659) measure. Several commenters observed that the rationale for removing this measure from the IPFQR Program is contradictory to the rationale for retaining it in the Hospital IQR Program.

Response: We thank these commenters for their input. We agree that influenza vaccination for both patients and healthcare personnel is important in the IPF setting, as well as other healthcare settings, and we believe that these two activities are both intended to address the public health concern of reducing influenza infection. We also believe that patients in the inpatient psychiatric setting may have additional risk of contracting influenza

[9] *https://www.cdc.gov/nhsn/ipfs/enroll.html* (the estimates for time to complete are 2 hours 45 minutes for step 1, 10 minutes for step 2, 16 minutes for step 3a, 35 minutes for step 3b, 32 minutes for step 4, and 5 minutes for step 5; totaling 263 minutes).

[10] CDC, Influenza Vaccination Information for Health Care Workers, Accessed at *https://www.cdc.gov/flu/healthcareworkers.htm.*

due to group activities and a communal setting. However, we do not believe that group activities and a communal setting increase the risk of contracting influenza from healthcare personnel, rather we believe that these increase the risk of contracting influenza from other patients. Therefore, we do not believe that ensuring influenza vaccination coverage among healthcare personnel addresses the increased risk specific to group activities and a communal setting.

We believe that the burden of reporting this measure is greater for IPFs compared to the relative burden for acute care hospitals participating in the Hospital IQR and Hospital-Acquired Condition Reduction Programs. The entire burden of registering for and maintaining access to the CDC's NHSN system for IPFs, especially independent or freestanding IPFs, is due to this one measure; whereas acute care hospitals paid under IPPS, participating in the Hospital IQR Program, the Hospital-Acquired Condition Reduction Program and the Hospital Value-Based Purchasing Program, for example, must register and maintain NHSN access for several healthcare safety measures, not just one. Furthermore, because the topic is addressed in other initiatives, such as state laws [11] and employer programs, we believe that the burden of this measure on IPFs, especially independent or freestanding IPFs, outweighs the benefit of addressing this topic again under the IPFQR Program.

Final Decision: After careful consideration of the comments received, we are finalizing our proposal as proposed to remove the Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) measure from the IPFQR Program for the FY 2020 payment determination and subsequent years.

ii. Alcohol Use Screening (NQF #1661) Measure

In the FY 2019 IPF PPS proposed rule (83 FR 21120), we proposed to remove the Alcohol Use Screening, (SUB–1, NQF #1661) measure from the IPFQR Program beginning with the FY 2020 payment determination under our measure removal Factor 8. The costs associated with a measure outweigh the benefit of its continued use in the program. We adopted the Alcohol Use Screening (SUB–1, NQF #1661) measure in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50890 through 50892) because we believe it is important to address the common comorbidity of alcohol use among IPF patients. This measure requires facilities to chart-abstract measure data on a sample of IPF patient records, in accordance with established sampling policies (FY 2016 IPF PPS final rule, 80 FR 46717 through 46719). We have previously stated our intent to move away from chart-abstracted measures in order to reduce information collection burden in other CMS quality programs (78 FR 50808; 79 FR 50242; 80 FR 49693).

When we introduced the Alcohol Use Screening (NQF #1661) measure to the IPFQR Program, the benefits of this measure were high, because facility performance was not consistent and therefore the measure provided a means of distinguishing facility performance and incentivized facilities to improve rates of screening for this common comorbidity.

Now, data collected for the FY 2016 through FY 2018 payment determinations show high levels of measure performance, as indicated in Table 3.

TABLE 3—PERFORMANCE ANALYSIS FOR ALCOHOL USE SCREENING

Year	Mean	Median	75th percentile	90th percentile	Truncated coefficient of variation (TCV)
2014 (FY 2016 Payment Determination)	74.8	86.8	97.0	100	.32
2015 (FY 2017 Payment Determination)	88.5	97.5	99.6	100	.13
2016 (FY 2018 Payment Determination)	92.4	98.4	99.7	100	.07

These data further show that there is little room for improvement in the Alcohol Use Screening (NQF #1661) measure, and that the quality improvement benefits from the measure have greatly diminished. Based on these data, we believe that most IPFs routinely provide alcohol use screening, and that IPFs will continue to provide alcohol use screening to patients because it has become an embedded part of their clinical workflows. Therefore, we believe that this measure no longer meaningfully supports the program objectives of informing beneficiary choice and driving improvement in IPF screening for alcohol use.

Furthermore, as we stated in section VI.F.1.a of this final rule, costs are multi-faceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining the program. For example, it may be costly for health care providers to maintain general administrative knowledge to report these measures. Additionally, CMS must expend resources in maintaining information collection systems, analyzing reported data, and providing public reporting of the collected information. Here, IPF information collection burden and related costs associated with reporting this measure to CMS is high because the measure is a chart-abstracted measure. Furthermore, CMS incurs costs associated with the program oversight of the measure for public display. As a result, we believe that the costs and burdens associated with this chart-abstracted measure outweigh the benefit of its continued use in the program.

Therefore, we proposed to remove the Alcohol Use Screening (SUB–1, NQF #1661) measure from the IPFQR Program beginning with the FY 2020 payment determination.

Comment: Many commenters supported our proposal to remove the Alcohol Use Screening (SUB–1, NQF #1661) measure. Several commenters agreed that performance on this measure is sufficiently high to indicate that the benefit of including the measure in the IPFQR Program has diminished, and that now the costs of this measure outweigh the benefits of retaining it. Some commenters recommended that CMS remove the Alcohol Use Brief Intervention Provided or Offered and Alcohol Use Brief Intervention (SUB–2/SUB–2a, NQF #1663) measure and the Alcohol and Other Drug Use Disorder Treatment Provided or Offered at

[11] CDC, Menu of State Hospital Influenza Vaccination Laws, Accessed at *https://www.cdc.gov/phlp/docs/menu-shfluvacclaws.pdf.*

Discharge and Alcohol and Other Drug Use Disorder Treatment at Discharge (SUB–3/SUB–3a, NQF #1654) measure as well because the removal of SUB–1 measure, while retaining the rest of the SUB measure set, does not reduce provider burden because the denominators of the SUB–2/SUB–2a and SUB–3/SUB–3a measures require collecting the data for the SUB–1 measure.

Response: We thank these commenters for their support, but disagree that removal of SUB–1 alone does not reduce provider burden. We believe that removal of SUB–1 will reduce provider information collection, abstraction, and reporting burden even while SUB–2/SUB–2a and SUB–3/SUB–3a measures are part of the IPFQR Program measure set. We will evaluate the continued use of SUB–2/SUB–2a and SUB–3/SUB–3a as we continue to analyze the IPFQR Program measure set.

Comment: Many commenters recommended that CMS retain the Alcohol Use Screening (SUB–1, NQF #1661) measure. Some commenters observed that substance use is a common comorbid condition with serious mental illness, and that the societal costs of untreated alcoholism outweigh the costs associated with collecting and reporting this measure. Another commenter expressed that CMS has not provided sufficient evidence that alcohol use screening has become an embedded part of clinical practice. One commenter also observed that there has been an increase in alcoholism among the elderly.

Response: We believe that processes such as screening are supported by the infrastructure and workflows within an IPF. Therefore, we believe the consistently high performance on the Alcohol Use Screening (SUB–1, NQF #1661) measure serves as substantial evidence that most IPFs have built and utilize the appropriate infrastructure to facilitate this screening as part of their workflows. We believe that this evidence is sufficient evidence that alcohol use screening has become an embedded part of clinical practice. We agree with commenters that alcoholism is a common and costly comorbidity with serious mental illness, and that these costs include societal costs, such as lost productivity, treatment for alcohol associated illness, and mortality. We also agree with commenters that there is an increase in alcoholism among the elderly. However, we believe that the high performance on the Alcohol Use Screening (SUB–1, NQF #1661) measure indicates that its continued benefit has diminished which was supported by many commenters who expressed support for our proposal and agreed with our rationale. We note that we are retaining the Alcohol Use Brief Intervention Provided or Offered and Alcohol Use Brief Intervention Provided (SUB–2 and SUB–2a, NQF #1663) measure and the Alcohol and Other Drug Use Disorder Treatment Provided or Offered at Discharge and Alcohol and Other Drug Use Disorder Treatment at Discharge (SUB–3 and SUB–3a, NQF #1654) measure because we believe these measures provide significant benefit by encouraging IPFs to provide alcohol use interventions.

Comment: Several commenters expressed concerns regarding the proposal to remove the Alcohol Use Screening (SUB–1, NQF #1661) measure. One commenter requested that CMS provide data showing that screening measures, including alcohol screening, are truly duplicative, topped-out, or part of best practices prior to removing these measures. Another commenter expressed that it is unclear how to identify the need for addiction counseling and referrals without the alcohol use screening measure.

Response: We thank these commenters for this input. We note that we proposed to remove the Alcohol Use Screening (SUB–1, NQF #1661) measure because our data, which were included in the FY 2019 IPF PPS proposed rule (83 FR 21120) and is repeated in Table 3 show that there is little room for improvement on this measure (as of the FY 2018 payment determination, it meets our statistical criteria for ''topped-out'' because the performance at the 75th and 90th percentiles is statistically indistinguishable at 99.7 percent and 100 percent respectively, and the TCV is 0.07 which is less than 0.1). For these reasons, these data indicate that the benefits of maintaining it have been reduced such that they no longer outweigh the costs of including the measure in the program. We recognize that IPFs will still need to continue to screen for alcohol use, through a standardized assessment instrument consistent with their internal procedures, to identify patients who need addiction counseling or referrals to be able to report on the Alcohol Use Brief Intervention Provided or Offered and Alcohol Use Brief Intervention (SUB–2/SUB–2a, NQF #1663) measure and to report on the Alcohol and Other Drug Use Disorder Treatment Provided or Offered at Discharge and Alcohol and Other Drug Use Disorder Treatment at Discharge (SUB–3/SUB–3a, NQF #1664) measure. However, due to this measure removal, facilities will no longer be required to abstract and report on the process of performing this screening for purposes of the IPFQR Program.

Final Decision: After careful consideration of the comments we received, we are finalizing our proposal as proposed to remove the Alcohol Use Screening (SUB–1, NQF #1663) measure from the IPFQR program for FY 2020 payment determination and subsequent years.

iii. Assessment of Patient Experience of Care Measure and Use of an Electronic Health Record (EHR) Measure

In the FY 2019 IPF PPS proposed rule (83 FR 21120 through 21121), we proposed to remove two measures: (1) Assessment of Patient Experience of Care measure; and (2) Use of an EHR measure from the IPFQR Program beginning with the FY 2020 payment determination under measure removal Factor 8. The costs associated with a measure outweigh the benefit of its continued use in the program.

We adopted the Assessment of Patient Experience of Care measure as a voluntary information collection in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50896 through 50897) and adopted it as a measure for the IPFQR Program in the FY 2015 IPF PPS final rule (79 FR 45964 through 45965). The Assessment of Patient Experience of Care measure collects data on whether each facility administers a patient experience of care survey. However, it does not provide data on the results of this survey, or the percentage of patients to whom the survey was administered. The measure was adopted in part to inform potential future development of patient experience of care measures. We believe that we have now collected sufficient information to inform development of such a measure and, therefore, the benefit of collecting this measure has been significantly reduced.

Similarly, we adopted the Use of an EHR measure in the FY 2015 IPF PPS final rule (79 FR 45965 through 45967) because of evidence demonstrating the positive effects of EHRs on multiple aspects of medical care. The Use of an EHR measure requires facilities to select between the following three statements:

- The facility most commonly used paper documents or other forms of information exchange (for example, email) not involving the transfer of health information using EHR technology at times of transitions in care;
- The facility most commonly exchanged health information using non-certified EHR technology (that is, not certified under the ONC HIT Certification Program) at times of transitions in care; and

• The facility most commonly exchanged health information using certified EHR technology (certified under the ONC HIT Certification Program) at times of transitions in care.

The measure then requires the facility to provide a ''yes'' or ''no'' answer to the following question: ''Did the transfers of health information at times of transitions in care include the exchange of interoperable health information with a health information service provider (HISP)?''

As discussed in section VI.E of this final rule, one of the goals of the Meaningful Measures Initiative is to reduce costs associated with payment policy, quality measures, documentation requirements, conditions of participation, and health information technology. Another goal of the Meaningful Measures Initiative is to utilize measures that are ''outcome-based where possible.'' As shown above, the Use of an EHR measure is a structural measure that tracks facility-level use of EHR technology, but does not directly measure patient outcomes. Furthermore, performance on this measure has remained relatively static for the past two program years. We believe that we have now collected sufficient data to inform potential future development of measures that more directly target the aspects of medical care addressed using EHRs (for example, care coordination, care transitions, and care provided to individual patients).

While some of the intended objectives of both the Assessment of Patient Experience of Care measure and Use of an EHR measure have been met, keeping both measures in the IPFQR Program's measure set creates administrative cost to hospitals associated with reporting these measures. We believe that removing these measures would alleviate some administrative cost. While the information collection burden associated with these measures is relatively low, as we stated in section VI.F.1.a of this final rule, costs are multi-faceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining the program. For example, it may be costly for health care providers to maintain general administrative knowledge to report these measures. Additionally, CMS must expend resources in maintaining information collection systems, analyzing reported data, and providing public reporting of the collected information. In light of the fact that the benefits for both the Assessment of Patient Experience of Care measure and Use of an EHR measure have been significantly reduced, the costs of these measures now outweigh their benefits.

Therefore, in the FY 2019 IPF PPS proposed rule, we proposed to remove: (1) The Assessment of Patient Experience of Care measure; and (2) the Use of an EHR measure from the IPFQR Program beginning with the FY 2020 payment determination and subsequent years.

Comment: Several commenters expressed support for removing the Assessment of Patient Experience of Care measure and the Use of an Electronic Health Record (EHR) measure because the costs of retaining these measures in the IPFQR Program outweigh the benefits.

Response: We thank these commenters for their support.

Comment: Several commenters recommended that CMS retain the Assessment of Patient Experience of Care measure. Some of these commenters expressed that this measure encourages facilities to ensure that patients have an opportunity to express their perspectives and recommended that this measure be retained until we can introduce a better patient experience measure. One commenter expressed concern about removing the Patient Experience of Care measure because understanding consumer experience is important in ensuring a person-centered healthcare system.

Response: We agree with commenters that encouraging facilities to ensure that patients have an opportunity to express their perspectives is an important aspect of patient-centered care, and therefore a measure that encourages this practice has value. However, we note that the Patient Experience of Care measure only collects data on whether each facility administers a patient experience of care survey, not the results of such a survey or the percentage of patients to whom the survey was administered. As a result, this measure does not assess or publicly report data on patients' experience of care within a given IPF.

Comment: One commenter recommended that CMS update the Use of an EHR measure to exclude the option for non-certified EHR use because use of this technology is ineffective.

Response: We believe that the Use of an EHR measure's inclusion of an attestation option for IPFs using non-certified EHRs is appropriate because doing so allows assessment of the degree to which IPFs nationwide employ EHR systems in their service program. Without such an option, IPFs which are either in the process of transitioning to a certified EHR or have encountered other implementation difficulties, such as a lack of resources to adopt a certified EHR, would be inappropriately categorized as not using an EHR at all. We note this measure is not intended to collect data on the effectiveness of an IPF's EHR, only the use of this technology. We further note that, as discussed below, we are finalizing our proposal to remove this measure.

Comment: One commenter opposed removal of the Use of an EHR measure because the data are valuable in understanding the use of EHRs in IPFs and in encouraging IPFs to use this technology.

Response: Because the data on this measure has remained relatively static for the past two years, we believe that the measure is no longer providing value in understanding the use of EHRs in IPFs. Furthermore, we believe that resources invested in continuing to maintain, report, and display data for this measure could be better allocated to measure or improve other aspects of quality.

Comment: Several commenters expressed that these measures have negligible burden and therefore disagreed with the removal factor under which CMS proposed to remove these measures.

Response: We agree with commenters that the reporting burden associated with these measures is small; however, we believe that costs are multi-faceted and include administrative costs to hospitals and costs to CMS in maintaining information collection systems, analyzing reported data, and providing public reporting of the collected information to the point that the benefits of these measures have been greatly reduced, and the costs of these measures now outweigh their benefits.

Final Decision: After carefully considering the comments received, we are finalizing our proposal as proposed to remove the Assessment of Patient Experience of Care measure and the Use of an EHR measure for the FY 2020 payment determination and subsequent years.

iv. Tobacco Use Treatment Provided or Offered at Discharge (TOB–3 and TOB–3a, NQF #1656) Measure

In the FY 2019 IPF PPS proposed rule (83 FR 21121 through 21122), we proposed to remove the Tobacco Use Treatment Provided or Offered at Discharge and Tobacco Use Treatment at Discharge (TOB–3 and TOB–3a, NQF #1656) measure from the IPFQR Program beginning with the FY 2020 payment determination under our measure removal Factor 8. The costs associated with a measure outweigh the

benefit of its continued use in the program.

The Tobacco Use Treatment Provided or Offered at Discharge and Tobacco Use Treatment at Discharge (TOB–3 and TOB–3a, NQF #1656) measure assesses whether patients were referred to or refused evidence-based outpatient counseling and received or refused a prescription for FDA-approved cessation medication upon discharge and also identifies those IPF patients who were referred to evidence-based outpatient counseling and received a prescription for FDA-approved cessation medication upon discharge. This measure requires facilities to chart-abstract measure data on a sample of IPF patient records, in accordance with established sampling policies (FY 2016 IPF PPS final rule, 80 FR 46717 through 46719). When we introduced the measure to the IPFQR Program, the benefits of this measure were great, because facility performance was not consistent and the measure provided a means of distinguishing facility performance and incentivizing facilities to improve rates of providing treatment for this common comorbidity.

However, when we proposed to remove this measure we believed the benefit of keeping the Tobacco Use Treatment Provided or Offered at Discharge (TOB–3 and TOB–3a, NQF #1656) measure in the IPFQR Program had become limited because we believed that the same measure data is captured in the data elements required by the Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) (NQF #0647) measure, which was more recently added to the IPFQR Program (80 FR 46701 through 46706). The transition record created to meet the requirements for inclusion in the numerator of the Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) (NQF #0647) measure includes elements on major procedures and tests performed during inpatient stay, summary of results, a current medication list, and post-discharge patient instructions. To meet the inclusion criteria for the numerator of this measure, the post-discharge patient instructions must provide information on all recommended actions for the patient after discharge. These post-discharge patient instructions may include tobacco use treatment, if provided, and therefore, we believed they would capture the same information as the numerator of the Tobacco Use Treatment Provided or Offered at Discharge (TOB–3 and TOB–3a, NQF #1656) measure. Additionally, because the transition record created to meet the requirements for inclusion in the numerator of the Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) (NQF #0647) measure must include a current medication list, we believed this medication list would capture a prescription for an FDA approved cessation medication at discharge, if provided, the second element of tobacco use treatment measured by the Tobacco Use Treatment Provided or Offered at Discharge (TOB–3 and TOB–3a, NQF #1656) measure.

Furthermore, as we stated in section VI.F.1.a of this final rule, costs are multi-faceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining the program. For example, it may be costly for health care providers to maintain general administrative knowledge to report these measures. Additionally, CMS must expend resources in maintaining information collection systems, analyzing reported data, and providing public reporting of the collected information. For this measure, provider and clinician information collection burden and related cost and burden associated with the submitting of quality measures to CMS is high because it is a chart-abstracted measure. Additionally, CMS incurs costs associated with the program oversight of the measure, including public display.

Therefore, we believed that the benefits provided by the Tobacco Use Treatment Provided or Offered at Discharge (TOB–3 and TOB–3a, NQF #1656) measure had been reduced to the point that they are now outweighed by the costs of the measure. As such, we proposed to remove the Tobacco Use Treatment Provided or Offered at Discharge and Tobacco Use Treatment at Discharge (TOB–3 and TOB–3a, NQF #1656) measure from the IPFQR Program beginning with the FY 2020 payment determination and subsequent years.

Comment: Several commenters supported the proposal to remove the Tobacco Use Treatment Provided or Offered at Discharge and Tobacco Use Treatment Provided at Discharge (TOB–3 and TOB–3a) measure and agreed with CMS's rationale for removing this measure. One commenter further observed that tobacco use is secondary to the reason for the hospitalization and therefore tobacco use treatment should not be a focus of the IPFQR Program. Another commenter observed that because tobacco use is such a common comorbidity in this patient population this care is already embedded in clinical practices.

Response: We continue to believe that addressing a patient's tobacco use is a part of providing high quality care. As stated in previous rules (see for example, the FY 2015 IPF PPS final rule (79 FR 45972) and the FY 2016 IPF PPS final rule (80 FR 46698)) we believe that reporting information regarding tobacco cessation treatment provides meaningful distinctions between IPFs because of the prevalence of tobacco use in this patient population and the increase in premature morbidity and mortality associated with tobacco use. Furthermore, we believe that limiting the program to only measures or conditions that specifically apply to the psychiatric population creates a false demarcation between psychiatric and non-psychiatric care. Data collected for the FY 2018 payment determination show mean performance on Tobacco Use Treatment Provided or Offered at Discharge (TOB–3) to be 40.8 percent and mean performance on Tobacco Use Treatment Provided at Discharge (TOB–3a) to be 9.5 percent. Therefore, we believe that this tobacco use treatment is not currently embedded in clinical procedures. Despite this, we proposed to remove this measure because we believed that equivalent information was captured through the transition measure. However, we no longer believe that this is the case, as discussed below, and therefore, we are not finalizing removal of this measure from the IPFQR Program.

Comment: Numerous commenters expressed that the Transition Record Received by Discharged Patients (Patients Discharged to Home or Other Site of Care) (NQF #0647) measure is not a sufficient replacement for the Tobacco Use Treatment Provided or Offered at Discharge and Tobacco Use Treatment Provided at Discharge (TOB–3 and TOB–3a, NQF #1656) measure. Specifically, some commenters observed that the discharge record created as part of the Transition Record Received by Discharged Patients (Patients Discharged to Home or Other Site of Care) (NQF #0647) measure does not report data on smoking cessation, so removing the Tobacco Use Treatment Provided or Offered at Discharge and Tobacco Use Treatment at Discharge (TOB–3 and TOB–3a, NQF #1656) measure may cause some clinicians to cease providing this care. Other commenters observed that data reported for the Transition Record Received by Discharged Patients (Patients

Discharged to Home or Other Site of Care) (NQF #0647) measure does not enable patients and their families to assess facilities with respect to tobacco cessation referrals and treatment at discharge. One commenter further observed that the transition record measure may only capture FDA-approved cessation medications and not evidence based outpatient counseling. Another commenter observed that discharge records often do not include information about tobacco use screening or referral or prescriptions for treatment.

Response: When we proposed to remove the Tobacco Use Treatment Provided or Offered at Discharge and Tobacco Use Treatment Provided at Discharge (TOB–3 and TOB–3a, NQF #1656) measure from the IPFQR Program, we believed that providers would include referral or prescriptions for tobacco cessation treatment in the transition record developed for the Transition Record Received by Discharged Patients (Patients Discharged to Home or Other Site of Care) (NQF #0647) measure, and therefore, this measure would continue to encourage providers to provide tobacco cessation treatment. However, in reviewing the comments we received, we realized that providers will only document this treatment if it is provided, but will consider the transition record to be complete even if no tobacco cessation treatment is provided to patients for whom this treatment is appropriate. Therefore, the Transition Record Received by Discharged Patients (Patients Discharged to Home or Other Site of Care) (NQF #0647) measure will not meet the program objective of encouraging IPFs to provide tobacco cessation treatment. Furthermore, this measure will not meet the program objectives of providing information on tobacco cessation treatment to patients and their families because high performance on the Transition Record Received by Discharged Patients (Patients Discharged to Home or Other Site of Care) (NQF #0647) measure does not indicate that the appropriate tobacco cessation treatments were provided.

We continue to believe that a prescription for an FDA-approved cessation medication should be included in the medication list, and a referral to evidence-based cessation treatment should be included in post-discharge patient instructions if providers offer these services. We note that the Transition Record Received by Discharged Patients (Patients Discharged to Home or Other Site of Care) (NQF #0647) measure continues to meet its originally intended objective of assessing whether patients were provided a discharge record. However, the measure design does not provide specific detail on the data provided within this discharge record. Because of this, we now believe that the Transition Record Received by Discharged Patients (Patients Discharged to Home or Other Site of Care) (NQF #0647) measure may not provide sufficient incentive to providers to offer tobacco cessation care, nor does this measure capture data specific to providing or offering upon discharge tobacco cessation treatment in a way that is meaningful for patients and their caregivers. Because of this, we do not believe the measure encourages providers to provide tobacco cessation treatment or provides information for consumers to identify whether this treatment was provided. Thus, the benefits of the Tobacco Use Treatment Provided or Offered at Discharge and Tobacco Use Treatment Provided at Discharge (TOB–3 and TOB–3a, NQF #1656) measure are greater than we initially believed when we proposed to remove this measure in the proposed rule. With this new understanding of the continued benefits of the TOB–3 and TOB–3a (NQF #1656) measure in the IPFQR Program, we now believe that the benefits outweigh the costs of the measure.

Comment: Many commenters opposed the removal of Tobacco Use Treatment Provided or Offered at Discharge and Tobacco Use Treatment at Discharge (TOB–3 and TOB–3a, NQF #1656) measure. Many commenters expressed concern that psychiatric patients are over-represented in the population using tobacco and that these patients die earlier and more frequently from tobacco-related illness, and therefore this program should ensure they are offered resources to quit.

Response: We agree with commenters that psychiatric patients are over-represented in the population of tobacco users and that these patients die earlier and more frequently from tobacco-related illness. Furthermore, we agree with commenters that it is appropriate for the IPFQR Program to encourage IPFs to offer tobacco cessation resources to patients who use tobacco. When we proposed to remove the Tobacco Use Treatment Provided or Offered at Discharge and Tobacco Use Treatment Provided at Discharge (TOB–3 and TOB–3a, NQF #1656) measure from the IPFQR Program we believed that the Transition Record Received by Discharged Patients (Patients Discharged to Home or Other Site of Care) (NQF #0647) measure would continue to encourage IPFs to provide these resources. However, as described above we now recognize that the Tobacco Use Treatment Provided or Offered at Discharge and Tobacco Use Treatment Provided at Discharge (TOB–3 and TOB–3a, NQF #1656) measure may not adequately encourage IPFs to offer tobacco cessation resources to patients who use tobacco and see greater value of the TOB–3 and TOB–3a (NQF #1656) measure.

Comment: One commenter observed that the removal of the Tobacco Use Screening (TOB–1, NQF #1651) measure from the IPFQR Program broadens the potential denominator for the Tobacco Use Treatment Provided or Offered at Discharge and Tobacco Use Treatment Provided at Discharge (TOB–3 and TOB–3a, NQF #1656) measure (by not requiring screening on the day of admission) and therefore makes this measure more meaningful by encouraging IPFs to offer tobacco cessation treatment and referrals to a greater number of patients who use tobacco and therefore increases the importance of retaining TOB–3 and TOB–3a (NQF #156).

Response: We thank the commenter for their input and share the commenter's interest in encouraging IPFs to offer tobacco cessation treatment and referrals to as many tobacco users as possible through the potentially expanded denominator of TOB–3 and TOB–3a (NQF #1656).

Comment: One commenter expressed concerns that CMS may expand the requirements of the Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) (NQF #0647) measure to better replace Tobacco Use Treatment Provided or Offered at Discharge and Tobacco Use Treatment at Discharge measure (TOB–3 and TOB–3a, NQF #1656).

Response: We wish to clarify that we did not intend for the Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) (NQF #0647) measure to act as a replacement for Tobacco Use Treatment Provided or Offered at Discharge and Tobacco Use Treatment at Discharge (TOB–3 and TOB–3a, NQF #1656) measure. In the FY 2019 IPF PPS Proposed Rule (83 FR 21121 through 21122), we stated that because the transition record created to meet the requirements of the Transition Record Received by Discharged Patients (Patients Discharged to Home or Other Site of Care) (NQF #0647) measure includes elements on major procedures and tests performed during inpatient stay, summary of results, a current

medication list, and post-discharge instructions, it would include any prescriptions for FDA-approved cessation medications and tobacco use treatment in the latter two sections, if appropriate. We further stated that because we believed this data was being captured by another measure that the benefit of TOB–3 and TOB–3a had been reduced. We did not state that it was our intent to expand the Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) (NQF #0647) measure's requirements based on the proposal to remove the Tobacco Use Treatment Provided or Offered at Discharge and Tobacco Use Treatment at Discharge (TOB–3 and TOB–3a, NQF #1656) measure. However, as discussed below, we are not finalizing our proposal to remove Tobacco Use Treatment Provided or Offered at Discharge and Tobacco Use Treatment at Discharge (TOB–3 and TOB–3a, NQF #1656) measure.

Comment: One commenter expressed concern that the Transition Record Received by Discharged Patients (Patients Discharged to Home or Other Site of Care) (NQF #0647) measure is not NQF endorsed, and therefore the commenter does not have the same confidence regarding measure specifications and testing as with respect to Tobacco Use Treatment Provided or Offered at Discharge and Tobacco Use Treatment at Discharge (TOB–3 and TOB–3a, NQF #1656) measure.

Response: We acknowledge that the Transition Record Received by Discharged Patients (Patients Discharged to Home or Other Site of Care) (NQF #0647) measure has been NQF-endorsed in the past and recently lost that endorsement status. We note that this measure was NQF-endorsed at the time of adoption into the IPFQR Program. The NQF standing committee that assessed the measure for continuing endorsement assessed that the measure did not meet the performance gap subcriterion for maintaining endorsement.[12] However, information regarding this measure including information on the measure specifications and testing that was performed to obtain NQF-endorsement continues to be available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=69980.* Even though the Transition Record Received by Discharged Patients (Patients Discharged to Home or Other Site of Care) (NQF #0647) measure is no longer NQF endorsed, we believe that it provide valuable information for patients regarding care coordination, discharge planning, and communication from providers. We note that in the FY 2017 IPPS/LTCH PPS final rule, we reiterated a listserv announcement which delayed implementation of this measure until the FY 2019 payment determination (81 FR 57238). Therefore, we do not have sufficient data to identify whether NQF's finding of lack of evidence of a performance gap applies to the IPF setting.

For these reasons, we believe that the measure is a valuable component of the IPFQR Program measure set; however, as discussed above, we are not finalizing removal of the Tobacco Use Treatment Provided or Offered at Discharge and Tobacco Use Treatment at Discharge (TOB–3 and TOB–3a, NQF #1656) measure as proposed because we no longer believe that the Transition Record Received by Discharged Patients (Patients Discharged to Home or Other Site of Care) (NQF #0647) measure reduces the benefits of the Tobacco Use Treatment Provided or Offered at Discharge and Tobacco Use Treatment at Discharge (TOB–3 and TOB–3a, NQF #1656) measure to a level such that these benefits are outweighed by the costs.

Comment: Many commenters observed that the high societal costs of healthcare and mortality associated with smoking outweigh the burden of collecting this measure data. One commenter expressed the belief that providing tobacco cessation prescriptions and referrals at discharge is less expensive than CMS's estimated cost of this measure.

Response: We note that our estimate of the costs associated with the Tobacco Use Treatment Provided or Offered at Discharge and Tobacco Use Treatment at Discharge (TOB–3 and TOB–3a, NQF #1656) measure provided in the proposed rule focused primarily on the information collection burden or other reporting costs related to participating in the program, not the cost of providing care to the patient. However, we agree that data indicate that the societal costs associated with tobacco use are very high.[13] For reasons discussed above, we are not finalizing removal of the Tobacco Use Treatment Provided or Offered at Discharge and Tobacco Use Treatment at Discharge (TOB–3 and TOB–3a, NQF #1656) measure. This will allow us to continue to encourage providers to provide tobacco cessation treatment at discharge through the IPFQR Program measure set, thereby addressing this common and costly comorbidity.

Comment: Another commenter observed that this measure is a recent addition to the IPFQR Program and therefore there has not been sufficient time to track progress on this measure.

Response: We acknowledge that the Tobacco Use Treatment Provided or Offered at Discharge and Tobacco Use Treatment at Discharge (TOB–3 and TOB–3a, NQF #1656) measure is a relatively recent addition to the IPFQR Program measure set, adopted in the FY 2016 IPF PPS final rule beginning with the FY 2018 payment determination (80 FR 46696 through 46699). As discussed above, we are not finalizing removal of the Tobacco Use Treatment Provided or Offered at Discharge and Tobacco Use Treatment at Discharge (TOB–3 and TOB–3a, NQF #1656) measure as proposed. This will allow us to continue evaluating the benefit of maintaining this measure in the IPFQR Program, as well as enabling us to more accurately establish historical measure performance trends.

Final Decision: After careful consideration of the comments we received, we are not finalizing our proposal to remove the Tobacco Use Treatment Provided or Offered at Discharge and Tobacco Use Treatment at Discharge (TOB–3 and TOB–3a, NQF #1656) measure from the IPFQR Program. This measure will continue to be part of the IPFQR Program measure set for FY 2019 payment determination and subsequent years.

b. Topped-Out Measures

In the FY 2018 IPPS/LTCH PPS final rule, we finalized criteria for evaluating whether measures within the IPFQR Program measure set are topped-out (82 FR 38463). We stated that a measure is topped-out if there is statistically indistinguishable performance at the 75th and 90th percentiles and the TCV is less than or equal to 0.10. Based on our analysis of IPFQR Program measure data for January 1, 2015 through December 31, 2015, IPF performance on the following three measures is topped-out.

i. Tobacco Use Screening (TOB–1, NQF #1651) Measure

In the FY 2019 IPF PPS proposed rule (83 FR 21122), we proposed to remove

[12] NQF, Care Coordination Measures Technical Report, Pages 24–26, Available at: *http://www.qualityforum.org/Projects/c-d/Care_Coordination_2016-2017/Final_Report.aspx.*

[13] Centers for Disease Control and Prevention. Annual Smoking-Attributable Mortality, Years of Potential Life Lost, and Productivity Losses—United States, 2000–2004.'' Morb Mortal Wkly Rep. 2008. 57(45): 1226–1228. Available at: *http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5745a3.htm.* 29Fiore.

the Tobacco Use Screening (TOB–1, NQF #1651) measure from the IPFQR Program beginning with FY 2020 payment determination under our previously finalized measure removal Factor 1. Measure performance among IPFs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped-out'' measures). Based on our analysis of IPFQR Program measure data for January 1, 2015 through December 31, 2015 (that is, FY 2017 payment determination data), IPF performance on Tobacco Use Screening (TOB–1, NQF #1651) measure is statistically indistinguishable at the 75th and 90th percentiles and the TCV is less than or equal to 0.10. This analysis is captured in Table 4:

TABLE 4—TOPPED-OUT ANALYSIS RESULTS FOR TOBACCO USE SCREENING

Measure	Mean	Median	75th Percentile	90th Percentile	TCV	Topped-out
TOB–1	93.32	98.79	100	100	0.066	Yes.

The Tobacco Use Screening (TOB–1, NQF #1651) measure meets both of the statistical criteria for topped-out status. Our analysis shows that tobacco use screening is widely in practice and there is little room for improvement. We believe that IPFs will continue this practice even after the measure is removed because we believe that the high performance on this measure shows that this practice has become an embedded part of clinical workflows. For these reasons, we believe that the utility of the Tobacco Use Screening (TOB–1, NQF #1651) measure in the program is limited because measure performance among IPFs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made. Therefore, we proposed to remove the Tobacco Use Screening (TOB–1) measure from the IPFQR Program beginning with the FY 2020 payment determination.

Comment: Several commenters supported the proposal to remove Tobacco Use Screening (TOB–1, NQF #1651) measure.

Response: We thank these commenters for their support.

Comment: Several commenters recommended also removing the Tobacco Use Brief Intervention Provided or Offered and Tobacco Use Brief Intervention Provided (TOB–2 and TOB–2a, NQF #1654) measure because it cannot be effectively collected without the data from the Tobacco Use Screening (TOB–1, NQF #1651) measure; and therefore, removing the Tobacco Use Screening (TOB–1, NQF #1651) measure does not reduce provider burden. Another commenter supported the proposal to remove the Tobacco Use Screening (TOB–1, NQF #1651) measure without removing the Tobacco Use Brief Intervention Provided or Offered and Tobacco Use Brief Intervention Provided (TOB–2 and TOB–2a, NQF #1654) measure.

Response: We proposed to remove the Tobacco Use Screening (TOB–1, NQF #1651) measure because it is topped-out, which indicates the majority of facilities are conducting this screening. The Tobacco Use Brief Intervention Provided or Offered and Tobacco Use Brief Intervention Provided (TOB–2 and TOB–2a, NQF #1654) measure, by contrast, is not topped-out. As a result, we believe there is continued benefit to collecting and publicly reporting data on facility performance on TOB–2 and TOB–2a.

The cost reduction associated with removing the Tobacco Use Screening (TOB–1, NQF #1651) measure is associated with no longer requiring facilities to abstract and report data, which decreases the information collection burden and the administrative costs for CMS and facilities, as well as potentially reduces inconvenience to patients by allowing screening at a time when it is most clinically appropriate to do so, even if that is not within one day of admission. Further, we note that screening patients for tobacco use remains a part of clinical best practice because of the high prevalence of tobacco use in this patient population and the associated morbidity and mortality. Therefore, we believe it is appropriate for providers to continue to provide tobacco use screening which will ensure that the data necessary to collect and report the Tobacco Use Brief Intervention Provided or Offered and Tobacco Use Brief Intervention Provided (TOB–2 and TOB–2a, NQF #1654) measure will still be available.

Comment: Many commenters opposed removing the Tobacco Use Screening (TOB–1, NQF #1651) measure because of the high prevalence of tobacco use in this patient population. These commenters expressed that tobacco use screening is an important part of psychiatric care and expressed concern that removal of the Tobacco Use Screening (TOB–1, NQF #1651) measure may cause facility performance to decline. Some commenters cited a recent CDC report that says only approximately 50 percent of mental health facilities screen for tobacco use.

Response: We agree with commenters that tobacco use is high in this patient population, and that this has a high societal cost, as well as a high burden of morbidity and mortality for these patients. However, we disagree that the cited CDC report which indicates that only approximately 50 percent of mental health facilities screen for tobacco use indicates that the Tobacco Use Screening (TOB–1, NQF #1651) measure is not topped-out. This report, available at *https://www.cdc.gov/mmwr/volumes/67/wr/mm6718a3.htm?s_cid=mm6718a3_w* assesses the use of tobacco screening in all mental health facilities, whereas the Tobacco Use Screening (TOB–1, NQF #1651) measure only assesses screening at admission within inpatient facilities. Therefore, we believe that the data accurately indicate this measure is topped-out are accurate, and that the measure has served its purpose to encourage facilities to institute policies and procedures that ensure patients are screened for tobacco use.

Comment: Some commenters stated the cost of healthcare associated with tobacco-related illness is lower than the cost of reporting this measure. Another commenter asserted that the administrative costs to CMS do not outweigh the benefits of this measure.

Response: We note that we proposed to remove this measure due to its topped-out status. Our topped-out analysis shows that tobacco screening use is widely in practice, and we believe that IPFs will continue to perform these screenings even after the measure is removed because we believe that the high performance on this measure shows that this practice has become an embedded part of clinical workflows—the foundation laid by this measure will continue. Therefore, we believe that removing this measure will not affect the benefit to IPF patients associated with tobacco use screening in the IPF setting.

Comment: One commenter supported the proposal to remove the Tobacco Use

Screening (TOB–1, NQF #1651) measure because the commenter believes that this measure's restriction to screening within the first day of admission lessens the efficacy of the Tobacco Use Screening (TOB–1, NQF #1651) measure and therefore, removes some patients who may benefit from tobacco use interventions from the denominator of the Tobacco Use Brief Intervention Provided or Offered and Tobacco Use Brief Intervention Provided (TOB–2 and TOB–2a, NQF #1654) measure. One commenter suggested that CMS modify the measure to capture more accurate or complete tobacco use screening data.

Response: We thank the commenter for support of our proposal to remove the Tobacco Use Screening (TOB–1, NQF #1651) measure from the IPFQR Program. We agree that there may be other ways to capture tobacco use screening data which would capture more accurate or complete tobacco use screening data, or which would eliminate restrictions which may affect the denominator of the measure. We welcome suggestions for new measures. We also encourage commenters with suggestions for improving measure specifications (available for this measure at *http://www.qualityforum.org/QPS/1651*) reach out directly to the appropriate measure steward.

Comment: One commenter recommended that CMS ensure screening measures, including those for tobacco use, are really duplicative, topped-out, or part of best practices prior to removing such measures.

Response: Based on our analysis of the data as provided in section VI.F.2.b.i of this final rule and in the FY 2019 IPF PPS proposed rule (83 FR 21122), this measure meets our criteria for ''topped-out'' status. As stated above, based on our analysis of IPFQR Program measure data for January 1, 2015 through December 31, 2015 (that is, FY 2017 payment determination data), IPF performance on the Tobacco Use Screening (TOB–1, NQF #1651) measure is statistically indistinguishable at the 75th and 90th percentiles and the TCV is less than or equal to 0.10. Furthermore, for reasons described above, we believe that this process has become embedded in clinical workflows and supporting infrastructure and therefore is also part of widespread best practice.

Final Decision: After careful consideration of the comments we received, we are finalizing our proposal as proposed to remove the Tobacco Use Screening (TOB–1, NQF #1651) measure for FY 2020 payment determination and subsequent years.

ii. Hours of Physical Restraint Use (HBIPS–2, NQF #0640) Measure and Hours of Seclusion Use (HBIPS–3, NQF #0641) Measure

In the FY 2019 IPF PPS proposed rule (83 FR 21122 through 21123), we proposed to remove two measures: (1) The Hours of Physical Restraint Use, (HBIPS–2) (NQF #0640) measure; and (2) the Hours of Seclusion Use (HBIPS–3) (NQF #0641) measure from the IPFQR Program for the FY 2020 payment determination and subsequent years under our previously finalized measure removal Factor 1. Measure performance among IPFs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped-out'' measures). Our finalized policy states that a measure is topped out if there is statistically indistinguishable performance at the 75th and 90th percentiles and the TCV is less than or equal to 0.10. This policy is designed to compare performance at the 75th and 90th percentile of top performing facilities. Because lower results are better for the Hours of Physical Restraint Use (HBIPS–2, NQF #0640) measure and Hours of Seclusion Use (HBIPS–3, NQF #0641) measure, the top performing facilities are those at the 25th and 10th percentile. Therefore, we evaluated the 25th and 10th percentile of measure results, which is equivalent to the 75th and 90th percentile of facility performance.

Due to the design of these measures—that lower results are better—we could not apply the second criterion, a TCV that is less than or equal to 0.10. The coefficient of variation is calculated by dividing the standard deviation by the mean. Because the mean is near zero for these measures, this leads to division by a number near zero, which results in a large coefficient of variation, and therefore a large TCV. This means that for measures with a target performance of zero, the second topped-out criterion ''the truncated coefficient of variation is less than or equal to 0.10'' is not applicable. While different than our established topped-out criteria, we believe that our approach for evaluating data for these measures is appropriate because it applies the relevant criterion in a way that assesses performance among the top performing facilities.

Our analysis for Hours of Physical Restraint Use (HBIPS–2, NQF #0640) measure is captured in Table 5:

TABLE 5—TOPPED-OUT ANALYSIS RESULTS FOR HOURS OF PHYSICAL RESTRAINT USE

Payment determination year	Mean	Median	25th Percentile measure results (75th percentile of facility performance)	10th Percentile measure results (90th percentile of facility performance)	TCV	Topped-out
2014	2.2	0.0	0.0	0.0	N/A	Yes.
2015	1.8	0.1	0.0	0.0	N/A	Yes.
2016	0.9	0.1	0.0	0.0	N/A	Yes.
2017	1.4	0.1	0.0	0.0	N/A	Yes.
2018	0.6	0.1	0.0	0.0	N/A	Yes.

Our analysis for Hours of Seclusion Use (HBIPS–3, NQF #0641) measure is captured in Table 6.

TABLE 6—TOPPED-OUT ANALYSIS RESULTS FOR HOURS OF SECLUSION USE

Payment determination year	Mean	Median	25th Percentile measure results (75th percentile of facility performance)	10th Percentile measure results (90th percentile of facility performance)	TCV	Topped-out
2014	0.8	0.0	0.0	0.0	N/A	Yes.
2015	1.1	0.0	0.0	0.0	N/A	Yes.
2016	0.5	0.0	0.0	0.0	N/A	Yes.
2017	1.1	0.0	0.0	0.0	N/A	Yes.
2018	0.4	0.0	0.0	0.0	N/A	Yes.

We continue to believe that the use of physical restraints and seclusion as clinical interventions are important patient safety issues because of the severity of these interventions. However, we note that Hours of Physical Restraint Use (HBIPS–2) measure and Hours of Seclusion Use (HBIPS–3) measure have only been one element of the coordinated approach to minimizing the use of physical restraint and seclusion. They are not the primary method by which CMS monitors or assesses the appropriateness of their use. IPFs are subject to the Conditions of Participation (COP) concerning patient's rights, which include an extensive section on the use of seclusion and restraints (42 CFR 482.13(e), (f), and (g)). Unannounced surveys by state surveyors and surveys by CMS-approved accreditation organizations (for example, The Joint Commission (TJC)) for deeming purposes are the primary means by which CMS enforces these provisions, which assess compliance with these requirements on a case-by-case basis. This focus on the appropriate use of these interventions has led to consistently high performance on these measures for several years. Our ''topped-out'' analyses of the measures shows that meaningful distinctions and improvements in performance can no longer be made through continued use of these measures in the IPFQR Program, and thus, utility in the program is limited. However, we believe that the continued monitoring of the use of seclusion and restraint by surveyors will continue to protect against patient harm related to inappropriate use of seclusion and restraint.

Therefore, we proposed to remove from the IPFQR Program beginning with the FY 2020 payment determination both measures: (1) The Hours of Physical Restraint Use (HBIPS–2) measure; and (2) the Hours of Seclusion use (HBIPS–3) measure.

Comment: Several commenters supported the removal of the Hours of Physical Restraint Use (HBIPS–2, NQF #0640) measure and the Hours of Seclusion Use (HBIPS–3, NQF #0641) measure and agreed with CMS's rationale that sufficient standards remain in place to ensure continued performance. One commenter expressed that these measures are difficult to report and therefore very burdensome.

Response: We appreciate the support for removing these measures.

Comment: One commenter requested that CMS provide more data on how it determined these measures were topped-out and develop and publicize a ''lifecycle'' for removing topped-out measures similar to that in use in the MIPS QPP. Another commenter recommended that CMS develop measures that address these topics and allow comparison across and within facilities by accounting for risk factors rather than removing HBIPS–2 and HBIPS–3 without replacing these measures. Some commenters recommended that CMS make the data collected from facilities and then published by CMS regarding these interventions more meaningful by stratifying the data.

Response: We thank these commenters for their comments. We refer readers to Tables 5 and 6, which demonstrate the calculations we used to identify that these measures meet the applicable statistical criteria for being topped-out—that is, there is statistically indistinguishable difference in performance between the 75th and 90th percentiles of facilities. We believe that the commenter is referring to the four year timeline which requires a measure to be identified as topped-out for three consecutive years prior to proposal for removal through notice and comment rulemaking in the fourth year in the MIPS QPP (82 FR 53637 through 53640). We do not have a similar ''lifecycle'' policy in the IPFQR Program for removing topped-out measures or other measures that we have determined are no longer appropriate for the IPFQR Program. Instead, according to IPFQR Program policy, which aligns with policies in other quality reporting programs,[14] we evaluate each measure according to the measure removal and retention factors in order to make case-by-case decisions about the appropriate course of action for each measure. We will consider the suggestion for a ''lifecycle'' and for the refinement of existing measures and/or development of new measures that address use of physical restraints and use of seclusion within the IPF setting as we continue planning for the IPFQR Program.

We note that as described in section VI.D of this final rule regarding social risk factors, we continue to seek to identify ways to account for social risk within the IPFQR Program. We will consider the suggestions for stratifying data regarding these measures as part of this analysis.

Comment: Numerous commenters opposed the removal of the Hours of Physical Restraint Use (HBIPS–2, NQF #0640) measure and the Hours of Seclusion Use (HBIPS–3, NQF #0641) measure because they are critical patient safety measures of interventions that can traumatize already vulnerable patients. Many commenters expressed concern that removing these measures would result in a deterioration in facility performance on these topics which could harm patients. Some commenters expressed that because these are patient safety measures, any variation in these measures provides meaningful data, and therefore, the topped-out criteria are not applicable.

Response: We thank these commenters for their input. We do not have data indicating that removing these measures will cause a deterioration in IPF performance in use of seclusion and/or restraints. We initially believed the topped-out status of these measures justified their removal from the IPFQR Program, despite our continued belief that use of physical restraints and seclusion are critical patient safety issues and that it is important for CMS

[14] For example, the Hospital IQR Program also evaluates measures on a case-by-case basis using finalized measure removal factors (79 FR 50203) and (80 FR 49641 through 49642).

to encourage IPFs to minimize their use of these interventions. After reviewing comments (the vast majority of which, from a diverse group of stakeholders, opposed removing these measures) we decided to keep these measures, despite their topped-out status, in order to allow these critical patient data to continue to be publicly reported for use by patients and their families/caregivers in selecting an IPF for their care and by IPFs in quality improvement activities. We further believe retaining these measures will better ensure IPFs continue to proactively track and continually strive for performance improvement on these measures.

Comment: Other commenters observed that these measures remind providers of the importance of these topics and provide more ability to directly monitor performance than COP surveys. Some commenters expressed that COP surveys serve a different purpose (that is, ensure compliance with regulations) than quality measures, which serve to incentivize high performance and that provide consumer information.

Response: While we continue to believe that surveys ensuring adherence to the COPs are an important tool in achieving and maintaining low rates of seclusion and restraint use, we agree with commenters that these COP surveys do not provide benchmark data, information to consumers, or a continual reminder of the importance of maintaining low rates, of the same way the Hours of Physical Restraint Use (HBIPS–2, NQF #0640) measure and the Hours of Seclusion Use (HBIPS–3, NQF #0641) measure do.

We would like to clarify that the IFPQR Program, as a pay-for-reporting quality program, does not provide direct incentives (that is, payment impacts) for high or low performance on program measures. However, we agree that use of the Hours of Physical Restraint Use (HBIPS–2, NQF #0640) measure and Hours of Seclusion Use (HBIPS–3, NQF #0641) measure in the IPFQR Program provides indirect incentives to strive for high performance on these measures because the program publicly reports measure rates for all participating IPFs, which allows patients, their caregivers, and IPFs to compare performance across IPFs. As stated above, we have decided to keep these measures in the program despite their topped-out status.

Comment: Some commenters recommend that CMS retain these measures because these measures allow hospitals to compare their performance to other hospitals.

Response: As stated above, we have decided to keep these measures in the program despite their topped-out status. We agree with these commenters that public reporting of these measures allows hospitals to compare their performance to other commenters. This is a valuable function of these quality measures that is not achieved by COP surveys, for example.

Final Decision: After careful consideration of the comments we received, we are not finalizing our proposal to remove the Hours of Physical Restraint Use (HBIPS–2, NQF #0640) measure and the Hours of Seclusion Use (HBIPS–3, NQF #0641) measure from the IPFQR Program. These two measures will continue to be part of the IPFQR Program measure set for the FY 2019 payment determination and subsequent years.

G. Previously Finalized and Newly Finalized Measure Sets for the FY 2020 Payment Determination and Subsequent Years

1. Previously Finalized Measures for the FY 2020 Payment Determination and Subsequent Years

We previously finalized 18 measures for the FY 2020 payment determination and subsequent years. These measures are set forth in Table 7.

TABLE 7—PREVIOUSLY FINALIZED MEASURES FOR THE FY 2020 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

NQF No.	Measure ID	Measure
0640	HBIPS–2	Hours of Physical Restraint Use.
0641	HBIPS–3	Hours of Seclusion Use.
560	HBIPS–5	Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification.
576	FUH	Follow-up After Hospitalization for Mental Illness.
1661	SUB–1	Alcohol Use Screening.
1663	SUB–2 and SUB–2a	Alcohol Use Brief Intervention Provided or Offered and SUB–2a Alcohol Use Brief Intervention.
1664	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.
1651	TOB–1	Tobacco Use Screening.
1654	TOB–2 and TOB–2a	Tobacco Use Treatment Provided or Offered and TOB–2a Tobacco Use Treatment.
1656	TOB–3 and TOB–3a	Tobacco Use Treatment Provided or Offered at Discharge and Tobacco Use Treatment at Discharge.
1659	IMM–2	Influenza Immunization.
0431	N/A	Influenza Vaccination Coverage Among Healthcare Personnel.
647	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).
648	N/A	Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care).
N/A	N/A	Screening for Metabolic Disorders.
2860	N/A	Thirty-Day All-Cause Unplanned Readmission Following Psychiatric Hospitalization in an Inpatient Psychiatric Facility.
N/A	N/A	Assessment of Patient Experience of Care.
N/A	N/A	Use of an Electronic Health Record.

2. Measure Set for the FY 2020 Payment Determination and Subsequent Years

With the measure removals we are finalizing in section VI.F.2 of this final rule, five of the previously finalized measures described in Table 7 will be removed for the FY 2020 payment determination and subsequent years. The remaining thirteen measures are set forth in Table 8.

TABLE 8—MEASURE SET FOR THE FY 2020 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

NQF No.	Measure ID	Measure
0640	HBIPS–2	Hours of Physical Restraint Use.
0641	HBIPS–3	Hours of Seclusion Use.
560	HBIPS–5	Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification.
576	FUH	Follow-up After Hospitalization for Mental Illness.
1663	SUB–2 and SUB–2a	Alcohol Use Brief Intervention Provided or Offered and SUB–2a Alcohol Use Brief Intervention.
1664	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.
1654	TOB–2 and TOB–2a	Tobacco Use Treatment Provided or Offered and TOB–2a Tobacco Use Treatment.
1656	TOB–3 and TOB–3a	Tobacco Use Treatment Provided or Offered at Discharge and Tobacco Use Treatment at Discharge.
1659	IMM–2	Influenza Immunization.
647	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).
648	N/A	Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care).
N/A	N/A	Screening for Metabolic Disorders.
2860	N/A	Thirty-Day All-Cause Unplanned Readmission Following Psychiatric Hospitalization in an Inpatient Psychiatric Facility.

H. Possible IPFQR Program Measures and Measure Topics for Future Consideration

As we have previously indicated (79 FR 45974 through 45975), we seek to develop a comprehensive set of quality measures to be available for widespread use for informed decision-making and quality improvement in the IPF setting. We are considering development of process and outcomes measures related to treatment and management of depression. In our assessment of the current IPFQR measure set under the Meaningful Measures Initiative, described in section VI.E of this final rule, we recognized the importance of developing a measure that fits into the meaningful measure areas of Prevention, Treatment, and Management of Mental Health and Patient Experience and Functional Outcomes, as we believe that the lack of such a measure indicates a gap in the current IPFQR Program measure set.

Specifically, we are considering: (1) Future development and adoption of a process measure that measures administration of a standardized depression assessment instrument (for example, the Patient Health Questionnaire (PHQ)–9) [15] at admission and discharge for patients admitted with depression; and (2) future development and adoption of a patient reported outcome measure, which assesses change in patient reported function based on the change in results on the standardized depression assessment instrument between admission and discharge.

We ultimately wish to adopt a patient reported outcome measure related to treatment and management of depression; however, such a measure would require consistent administration of a standardized assessment instrument at admission and discharge. To ensure that facilities are consistently using a standardized assessment instrument, we believe that it may be necessary to first adopt a process measure that assesses facility administration of a standardized depression assessment, such as the PHQ–9, at both admission and discharge for adult inpatient admissions, thereby, encouraging facilities that do not currently consistently use such an instrument to use one. In the future, we could replace this measure with a patient reported outcome measure that we would develop to compare the patient's responses to the standardized depression assessment instrument at admission with the patient's results on the same assessment instrument at discharge. We believe this potential future patient reported outcome measure for patients with depression would address the meaningful measure areas of Prevention, Treatment, and Management of Mental Health, and Patient Experience and Functional Outcomes.

We solicited public comments on: (1) Future development and adoption of a process measure that measures the number of facilities that administer a standardized assessment instrument; (2) future development and adoption of an outcome measure related to treatment and management of depression; and (3) any other possible new measures or new measure topics.

Comment: Several commenters supported the concept of developing a measure or measures for evaluation of treatment of depression; these commenters also provided suggestions for development of such measures. One suggestion was to coordinate with other measure developers to ensure alignment of measures. Some commenters expressed that IPFs already use standardized depression instruments and therefore a process measure to assess this would be topped-out almost immediately. Other commenters observed that the measure would need to be well-specified to ensure that it is clear which patients would be included and when a depression screening would be appropriate. Another commenter suggested development of an attestation

[15] The PHQ–9 is publicly available at: *http://www.phqscreeners.com/sites/g/files/g10016261/f/201412/PHQ-9_English.pdf.*

measure to determine any outcome measurement techniques already in use by facilities. Another commenter requested that CMS ensure that any assessment instrument selected for use in a measure program be available to all IPFs without imposing additional costs on IPFs. Some commenters recommended that CMS develop a depression measure that allows providers to select between several standardized depression assessment instruments to best meet the clinical needs of their specific patient population or to tailor the instrument to sub-populations. Some commenters recommended that CMS survey IPFs to determine the most appropriate assessment instrument, without using a process measure to collect this data. One commenter observed that there are several issues with the depression patient reported outcome measure that CMS described. These issues are: (1) There may not be sufficient time between admission and discharge for improvement of symptoms, therefore CMS should consider a minimum duration in the denominator; (2) discharge is a stressful time for patients which may lead to biased data, therefore CMS should consider a low burden method to collect data 2–4 weeks post-discharge; and (3) high acuity patients may not be able to be screened at admission therefore excluding data from a highly applicable patient population. These commenters therefore recommended that CMS should assess how to include patients with psychosis, agitation, and cognitive difficulties in any future measures for the evaluation of treatment of depression.

Response: We thank these commenters and will consider their recommendations if we develop a process measure or a patient reported outcome measure for depression management. If we do develop such measures, we will follow our standard measure development process including seeking input through a technical expert panel (TEP), seeking public comment, placing the measure on the Measures Under Consideration (MUC) list to receive input from the Measure Application Partnership (MAP), and proposing the measure through notice and comment rulemaking.

Comment: Commenters provided several recommendations regarding measures that would be appropriate to develop or adopt for the IPFQR Program. The topics suggested by commenters included:

- Sexual assault screening;
- Family and caregiver engagement;
- Patient experience of care;
- Clinical improvement outcomes;
- Access to care;
- Inpatient assaults and violence;
- Suicide evaluation and reduction;
- Additional indicators to decrease use of seclusion and physical restraints (such as patient surveys and assessment of staff ability to de-escalate);
- eCQM versions of the tobacco use screening and treatment measures;
- eCQM versions of the alcohol use screening and treatment measures;
- eCQM version of Influenza Immunization measure (IMM–2);
- Patient reported outcome measures that address specific conditions, comorbidities, or lengths of stay;
- Safety planning for patients with suicidal ideation and/or impulsive self-destructive tendencies;
- Immunization focused measures including an immunization composite measure and a measure of Pneumococcal Vaccination for Older Adults; and
- Measures that encourage facilities to identify community supports and help patients become more accountable for their own health.

One commenter observed that CMS could expedite adoption of a standardized patient experience of care survey by collecting this data through a voluntary data collection prior to adopting such a measure in the program. Another commenter recommended that CMS not adopt structural measures in the future. Some commenters requested the CMS only adopt measures that have been endorsed by the NQF specifically for the IPF setting and that specifically address psychiatric care. One commenter also recommended that CMS engage in a collaborative measure development process, preferably modeled on the one undertaken in developing the HBIPS measures.

Response: We thank these commenters for their recommendations and will consider this input as we develop and refine the IPFQR Program measure set.

I. Public Display and Review Requirements

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53653 through 53654), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50897 through 50898), and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57248 through 57249). In this final rule, we are not making any changes to these policies. However, we note that in section VI.D of this final rule, we discuss potential considerations to provide stratified data by patient dual eligibility status in IPF confidential feedback reports and considerations to make stratified data publicly available on the Hospital Compare website (*https://www.medicare.gov/hospitalcompare/psych-measures.html*) in the future.

J. Form, Manner, and Timing of Quality Data Submission for the FY 2020 Payment Determination and Subsequent Years

1. Procedural Requirements for the FY 2020 Payment Determination and Subsequent Years

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53654 through 53655), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50898 through 50899), and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38471 through 38472) for our previously finalized procedural requirements. We did not propose any changes to these policies in the FY 2019 IPF PPS proposed rule.

2. Data Submission Requirements for the FY 2020 Payment Determination and Subsequent Years

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53655 through 53657), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50899 through 50900), and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38472 through 38473) for our previously finalized data submission requirements. We did not propose any changes to the data submission requirements in the FY 2019 IPF PPS proposed rule.

3. Reporting Requirements for the FY 2020 Payment Determination and Subsequent Years

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53656 through 53657), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50900 through 50901), and the FY 2015 IPF PPS final rule (79 FR 45976 through 45977) for our previously finalized reporting requirements. In this final rule, we are not making any changes to these policies; however, we requested public comment on our consideration to potentially require patient-level measure data in the future. This is discussed in more detail below.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53655 through 53656), we finalized that for the FY 2014 payment determination and subsequent years, IPFs must submit aggregated numerator and denominator data for all age groups for all measures on an annual basis, and that the data input forms on the QualityNet website for such submission will require aggregate data for each separate quarter. In the FY 2016 IPF PPS final rule (80 FR 46715 through 46717), we finalized that for the FY 2017

payment determination and subsequent years, facilities would only be required to report data for chart-abstracted measures on an aggregate basis by year, rather than by quarter. In addition, we finalized that facilities would no longer be required to report by age group.

Although we are not making any changes to these requirements in this final rule, we recognize that reporting aggregate measure data increases the possibility of human error, such as making typographical errors while entering data, which cannot be detected by CMS or by data submission systems. Unlike patient-level data reporting, aggregate measure data reporting does not allow for data accuracy validation (77 FR 53655 through 53656). Therefore, the ability to detect error is lower for aggregate measure data reporting than for patient-level data reporting. For this reason, we are considering requiring patient-level data reporting (that is, data regarding each patient included in a measure and whether the patient was included in each the numerator and denominator of the measure) of IPFQR Program measure data in the future. We note that in the FY 2013 IPPS/LTCH PPS final rule, we previously indicated that we would consider requiring patient-level data in the future and that we would use notice and comment rulemaking to establish any requirements (77 FR 53656).

In the FY 2019 IPF PPS proposed rule (83 FR 21125) we solicited public comments on the consideration for requiring patient-level measure data in the future.

Comment: Several commenters expressed support for patient-level data collection because it provides greater confidence in the data's validity and reliability. Some commenters suggested that, as CMS explores patient-level data reporting, CMS should use a system that has already been tested and used for IPF data reporting to avoid creating additional burden. Another commenter recommended that CMS collaborate with IPFs to ensure that the system used to report patient-level data is not burdensome.

Response: We thank these commenters for their support and recommendations. We will consider these suggestions as we explore patient-level data reporting for the IPFQR Program.

4. Quality Measure Sampling Requirements

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53657 through 53658), we finalized that participating IPFs must meet specific population, sample size, and minimum reporting case threshold requirements for individual measures as specified in TJC's Specifications Manual [16] for the FY 2014 payment determination and subsequent years. The Specifications Manual is updated at least twice a year (and may be updated more often as necessary), and IPFs must follow the requirements in the most recent manual. We finalized that the target population for the measures includes all patients, not solely Medicare beneficiaries, to improve quality of care. We believe it is important to require IPFs to submit measures on all patients because quality improvement is of industry-wide importance and should not be focused exclusively on a certain subset of patients. We noted that the Specifications Manual gives IPFs the option of sampling their data quarterly or monthly. We also finalized our policy that IPFs that have no data to report for a given measure must enter zero for the population and sample counts. For example, an IPF that has no hours of physical restraint use to report for a given quarter is still required to submit a zero for its quarterly aggregate population for the Hours of Physical Restraint Use (HBIPS–2, NQF #0640) measure in order to meet the reporting requirement. We note that at the time we finalized this policy, the only measures in the IPFQR Program were HBIPS measures (77 FR 53652).

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50901 through 50902), we stated that for the existing HBIPS measures, we continue to apply our finalized policies for population, sampling, and minimum case threshold as discussed above. However, in that rule, we finalized a new policy for new measures. For new measures finalized for the FY 2016 payment determination and subsequent years, we finalized that IPFs must follow sampling and population requirements as specified by the appropriate measure steward (78 FR 50901 through 50902).

In that rule, we also made clear that the Follow-Up After Hospitalization for Mental Illness (FUH, NQF #0576) measure is not eligible for sampling because CMS calculates the measure using administrative claims data, and sampling is not applicable to claims-based measures. We finalized that IPFs must follow the population requirements outlined at: *http://www.ncqa.org/portals/0/Follow-Up%20After%20Hospitalization%20for%20Mental%20Illness.pdf*.

In the FY 2014 IPPS/LTCH PPS final rule, some commenters noted that different sampling requirements in the measures could increase burden on facilities because these differences will require IPFs to have varying policies and procedures in place for each measure (78 FR 50901). Therefore, in the FY 2016 IPF PPS final rule (80 FR 46717 through 46719), in order to provide facilities greater flexibility, we expanded our sampling policy to allow sampling either through: (1) Previously finalized requirements for individual measures as discussed above; or (2) through the use of a uniform sampling methodology beginning with the FY 2018 payment determination. We finalized a uniform sampling methodology that could be applied to both measures that allow sampling and for certain other measures (specifically measures not previously included in TJC's Specifications Manuals, such as Screening for Metabolic Disorders, Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification, HBIPS–5). Specifically, we finalized use of The Joint Commission/CMS Global Initial Patient Population sampling methodology found at: *https://www.qualitynet.org/dcs/BlobServer?blobkey=id&blobnocache=true&blobwhere=1228890321190&blobheader=multipart%2Foctet-stream&blobheadername1=Content-Disposition&blobheadervalue1=attachment%3Bfilename%3D2+9_Global_v4_4.pdf&blobcol=urldata&blobtable=MungoBlobs*. This uniform sampling methodology allows IPFs to utilize one sampling methodology and apply it to all IPFQR Program measures for which sampling is allowed. The Joint Commission/CMS Global Initial Patient Population sampling methodology, as developed, ensures that enough data are represented in the sample to determine accurate measure rates (80 FR 46718).

Therefore currently, IPFs can choose from two options to sample quality measures: (1) Sampling and population requirements as specified by the appropriate measure steward; or (2) a uniform sampling methodology (that is, The Joint Commission/CMS Global Initial Patient Population methodology). These population and sampling options currently apply to the following measures in the IPFQR Program measure set:

- Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification (HBIPS–5, NQF #0560).
- Alcohol Use Screening (SUB–1, NQF #1661) (removed in this final rule).
- Alcohol Use Screening and Brief Intervention Provided or Offered and

[16] *https://manual.jointcommission.org/releases/TJC2017B2/*.

Alcohol Use Brief Intervention (SUB–2 and SUB–2a, NQF #1663).

- Alcohol & Other Drug Use Disorder Treatment Provided or Offered at Discharge and Alcohol & Other Drug Use Disorder Treatment at Discharge (SUB–3 and SUB–3a, NQF #1664).
- Tobacco Use Screening (TOB–1, NQF #1651) (removed in this final rule).
- Tobacco Use Treatment Provided or Offered and Tobacco Use Treatment Provided (TOB–2 and TOB–2a, NQF #1654).
- Tobacco Use Treatment Provided or Offered at Discharge and Tobacco Use Treatment at Discharge (TOB–3 and TOB–3a, NQF #1656).
- Influenza Immunization (IMM–2, NQF #1659).
- Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) (NQF #0647).
- Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) (NQF #0648).
- Screening for Metabolic Disorders.

We did not propose any changes to our quality measure sampling policies in the FY 2019 IPF PPS proposed rule.

5. Non-Measure Data Collection

In the FY 2015 IPF PPS final rule (79 FR 45973), we finalized that IPFs must submit aggregate population counts for Medicare and non-Medicare discharges by age group, diagnostic group, and quarter for the FY 2017 payment determination and subsequent years. We also finalized that IPFs must report the sample size counts (that is, number of patients included in the sample) for measures for which sampling is performed. Because these data (that is, (1) the aggregate population counts for Medicare and non-Medicare discharges by age group, diagnostic group, and quarter, as well as (2) sample size count for sampled measures) relate to the IPF's entire patient population, rather than the IPF's performance on specific measures, we refer to this data collectively as ''non-measure data.'' When adopting this requirement we expressed our belief that it is vital for IPFs to accurately determine and submit this non-measure data to CMS in order for CMS to assess IPFs' data reporting completeness for their total population, both Medicare and non-Medicare (79 FR 45973). We also stated that in addition to helping to better assess the quality and completeness of measure data, we expected that this information would improve our ability to assess the relevance and impact of potential future measures.

In the FY 2016 IPF PPS final rule (80 FR 46717), we finalized a change to the frequency with which we collect this non-measure data, such that beginning with the FY 2017 payment determination and subsequent years, we require non-measure data to be submitted as an aggregate, yearly count rather than by quarter. Therefore, there are currently five components to the non-measure data that facilities are required to submit on an annual basis: (1) Total annual discharges; (2) annual discharges stratified by age; (3) annual discharges stratified by diagnostic category; (4) annual discharges stratified by Medicare versus non-Medicare payer; (5) the sample size counts for measures for which sampling is performed.

However, the requirement to submit the sample size counts has created confusion for some facilities (for example, for facilities that used more than one sampling methodology such as applying the global sample to some measures and measure specific sampling procedures to others). In an effort to reduce confusion and information collection burden, and in line with our Meaningful Measures and Patients over Paperwork Initiatives, we proposed to no longer require facilities to report the sample size counts for measures for which sampling is performed (that is, item (5) listed above) beginning with the FY 2020 payment determination and subsequent years.

Our data indicate that most facilities avail themselves of the global sampling option (as discussed in section VI.J.4 of this final rule). We believe that for most facilities which use sampling, the size of the global sample can be compiled by other means, since information on the global sample size can still be inferred from the denominator values that are already reported as part of measure data submission. This is because for measures in which the denominator represents the entire patient population (except for any denominator exclusions) the denominator is a good approximation for the global sample size count. Any denominator exclusions represent only a small proportion of the patient population and would not significantly affect the global sample size approximation. Since the global sample applies to all measures for which sampling is performed, the global sample size is consistent across all measures for which sampling is performed, and therefore, can be inferred from the denominator of any measure for which the denominator represents the entire patient population (such as the Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) (NQF #0647) measure. We note that this proposal does not in any way change or affect our requirements concerning quality measure sampling outlined in section VI.J.4 of this final rule and would only change the information that IPFs report to CMS on the size of samples used.

Therefore, we proposed to no longer require facilities to report sample size counts for measures for which sampling is performed as discussed above for the FY 2020 payment determination and subsequent years.

Comment: One commenter supported our proposal to no longer require facilities to report sample size counts.

Response: We thank this commenter for the support.

Final Decision: After careful consideration of the comment we received, we are finalizing our proposal to no longer require facilities to report sample size counts for measures for which sampling is performed as discussed above for the FY 2020 payment determination and subsequent years.

6. Data Accuracy and Completeness Acknowledgement (DACA) Requirements

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53658) for our previously finalized DACA requirements. We did not propose any changes to the DACA requirements in the FY 2019 IPF PPS proposed rule.

K. Reconsideration and Appeals Procedures

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53658 through 53659) and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50903) for our previously finalized reconsideration and appeals procedures. We did not propose any changes to these procedures in the FY 2019 IPF PPS proposed rule.

L. Extraordinary Circumstances Exceptions (ECE) Policy

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53659 through 53660), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50903), the FY 2015 IPF PPS final rule (79 FR 45978), and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38473 through 38474) for our previously finalized ECE policies. We did not propose any changes to these policies in the FY 2019 IPF PPS proposed rule.

VII. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to publish a 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval.

To fairly evaluate whether an information collection should be approved by OMB, PRA section 3506(c)(2)(A) 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 burden estimates.
- The quality, utility, and clarity of the information to be collected.
- Our effort to minimize the information collection burden on the affected public, including the use of automated collection techniques.

We solicited public comment on each of the PRA section 3506(c)(2)(A)-required issues for the following information collection requirements (ICRs).

We did not receive such comments. We note that we are updating the information collection estimates based on the policies we are finalizing in this final rule, specifically (1) the adoption of a new measure removal factor, (2) the removal of five (5) measures, and (3) the removal of the requirement that facilities report sample size counts. This differs from the policies proposed in the FY 2019 IPF PPS proposed rule, in which we proposed to remove eight (8) measures.

A. Collection of Information Requirements for the IPFQR Program

1. Wage Estimates

Consistent with the FY 2017 IPPS/LTCH PPS final rule (81 FR 57265 through 57266) and our FY 2016 IPF PPS final rule (80 FR 46720), to derive average costs, we used data from the United States Bureau of Labor Statistics (BLS) National Occupational Employment and Wage Estimates for all salary estimates (in this case the May 2016 report) and applied this wage rate to the year in which the savings would accrue (in this case FY 2018).[17] The BLS is ''the principal Federal agency responsible for measuring labor market activity, working conditions, and price changes in the economy.'' [18] Acting as an independent agency, the BLS provides objective information for not only the government, but also for the public. The BLS describes Medical Records and Health Information Technicians as those responsible for organizing and managing health information data. We believe it is reasonable to assume that these individuals would be tasked with abstracting clinical data for these measures. The most recent data from the BLS reflects a median hourly wage of $18.29 for a Medical Records and Health Information Technician.[19] We note that we have already incorporated this updated wage data into other quality reporting programs, for example the Hospital Inpatient Quality Reporting (IQR) Program uses this wage to calculate its burden estimates (82 FR 38501). Therefore, in the FY 2019 IPF PPS proposed rule (83 FR 21127), we updated our wage estimate to reflect this hourly wage for the IPFQR Program.

Table 9 presents the median hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE 9—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation title	Occupation code	Median hourly wage ($/hr)	Fringe benefits and overhead ($/hr)	Adjusted hourly wage ($/hr)
Medical Records and Health Information Technician	29–2071	18.29	18.29	36.58

Under OMB Circular A–76, in calculating direct labor, agencies should not only include salaries and wages, but also ''other entitlements'' such as fringe benefits.[20] As indicated in Table 9 and consistent with our past approach, we have chosen to calculate the cost of overhead at 100 percent of the median hourly wage (81 FR 57266). This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and methods of estimating these costs vary widely from study to study. We believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

2. ICRs Regarding the IPFQR Program

For a detailed discussion of the information collection burden for the program requirements that we have previously adopted, we refer readers to the burden approved under OMB control number 0938–1171 (CMS–10432) and the following rules:

- The FY 2013 IPPS/LTCH PPS final rule (77 FR 53673);
- The FY 2014 IPPS/LTCH PPS final rule (78 FR 50964);
- The FY 2015 IPF PPS final rule (79 FR 45978 through 45980);
- The FY 2016 IPF PPS final rule (80 FR 46720 through 46721);
- The FY 2017 IPPS/LTCH PPS final rule (81 FR 57265 through 57266); and
- The FY 2018 IPPS/LTCH PPS final rule (82 FR 38507 through 38508).

The requirements and burden estimates were submitted to OMB for approval under control number 0938–1171 (CMS–10432). We solicited public comments for the information collection in its entirety in the FY 2019 IPF PPS proposed rule (83 FR 21128). That is, we solicited comments both for the proposed rule's changes and for the requirements and burden that are currently approved under the 0938–1171 control number. Both can be found in the 0938–1171 PRA package's Supporting Statement.

In this final rule, we discuss only the changes in burden resulting from the provisions we are finalizing in this final rule. We will attribute the costs associated with the provisions in this final rule to the FY in which these costs begin; for the purposes of all of the provisions included here, that year is FY 2018. All of these provisions we discuss in section VI. of this final rule apply to data collected in CY 2018 and reported in FY 2019 for the FY 2020 payment determination.

a. Adoption of a New Measure Removal Factor

In section VI.F.1. of this final rule, we are adopting a new measure removal factor, Factor 8, ''the costs associated with a measure outweigh the benefit of its continued use in the program.'' As discussed in the FY 2018 IPPS/LTCH

[17] *http://www.bls.gov/oes/current/oes_nat.htm.*

[18] *http://www.bls.gov/bls/infohome.htm.*

[19] *https://www.bls.gov/oes/current/oes292071.htm.*

[20] *http://www.whitehouse.gov/omb/circulars_a076_a76_incl_tech_correction.*

PPS final rule (82 FR 38507 through 38508), the adoption of measure removal factors does not affect the data submission requirements for IPFs. These factors are intended to improve transparency of our measure review and evaluation process, and have no effect on the data collection or submission requirements for IPFs. Therefore, we do not believe that there is any change of burden associated with the new measure removal factor.

We solicited PRA-related comments in the FY 2019 IPF PPS proposed rule (83 FR 21128). We did not receive any comments on this estimate. Consequently we are finalizing our PRA-related estimates as proposed.

b. Removal of Five Measures

In the FY 2019 IPF PPS proposed rule (83 FR 21128 through 21129) we estimated the information collection burden for our proposals to remove eight measures. However, in section VI.F.2. of this final rule, we are only finalizing the removal of five measures. We are not finalizing our proposal to remove the Tobacco Use Treatment Provided or Offered at Discharge and Tobacco Use Treatment Provided at Discharge (TOB–3 and TOB–3a, NQF #1656) measure because the benefits of this measure are greater than we initially believed when we proposed to remove it. We are not finalizing our proposal to remove the Hours of Physical Restraint Use (HBIPS–2, NQF #0640) measure, and the Hours of Seclusion Use (HBIPS–3, NQF #0641) measure to allow these critical patient data to continue to be publicly reported for use by patients and their families/caregivers in selecting an IPF for their care and by IPFs in quality improvement activities. Therefore here, we are updating our estimates for change in information collection burden to reflect our final policies.

In section VI.F.2 of this final rule, we are finalizing our proposals to remove the following five measures for FY 2020 payment determination and subsequent years:

- Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431);
- SUB–1—Alcohol Use Screening (NQF #1661);
- Assessment of Patient Experience of Care;
- Use of an Electronic Health Record; and
- TOB–1—Tobacco Use Screening (NQF #1651).

For the FY 2020 payment determination, CY 2018 data would be reported during the summer of CY 2019. Therefore, for the FY 2020 payment determination, we are correlating the burden reduction to the FY 2018 burden calculation. We believe that approximately 1,734 [21] IPFs will participate in the IPFQR Program for requirements occurring in FY 2018 and subsequent years. Based on data from CY 2017, we believe that each IPF will submit measure data based on approximately 1,213 [22] discharges per year.

i. Chart-Abstracted Measures

We previously estimated that the reporting burden for chart-abstracted measures is 15 minutes (0.25 hours) per measure per case (81 FR 57265). We based this estimate on data collected by other quality reporting programs (81 FR 57265) and this data continues to indicate that the time required to chart-abstract data is approximately 15 minutes (0.25 hours) per measure per case; therefore, we continue to use that time estimate to calculate the burden pertaining to this final rule. Of the measures we are removing from the program, the following two are chart-abstracted:

- Alcohol Use Screening (SUB–1, NQF #1661) measure; and.
- Tobacco Use Screening (TOB–1, NQF #1651) measure.

Both measures fall under our previously finalized ''global sample'' (80 FR 46717 through 46718) under which, we allow facilities to apply the same sampling methodology to all measures eligible for sampling. In the FY 2016 IPF PPS final rule (80 FR 46718), we finalized that facilities with between 609 and 3,056 cases and choose to participate in the global sample would be required to report data for 609 cases. Because facilities are only required to submit data on a number specified by the global sampling methodology, rather than abstracting data for all patients or applying measure specific sampling methodologies, we believe that the number of cases under the global sample is a good approximation of facility burden associated with these measures. Therefore, for the average IPF discharge rate of 1,213 discharges, the global sample requires abstraction of 609 records. We estimate that removing these two measures will result in a decrease of 304.5 hours per IPF (2 measures × 609 cases/measure × 0.25 hours/case) or 528,003 hours across all IPFs (304.5 hours/IPF × 1,734 IPFs). The decrease in costs is approximately $11,138 per IPF ($36.58/hour × 304.5 hours) or $19,314,350 across all IPFs ($11,138/IPF × 1,734 IPFs).

We solicited PRA-related comments in the FY 2019 IPF PPS proposed rule (83 FR 21128). We did not receive any comments. Consequently, we are finalizing our amended estimates based on finalized policies (that is, based on removal of two chart-abstracted measures as opposed to five chart abstracted measures).

ii. National Healthcare Safety Network (NHSN) Measure

We previously estimated that the reporting burden for the one IPFQR measure for which data is collected via the NHSN, the Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) measure, is 15 minutes (0.25 hours) per measure per case and that the average IPF will report on 40 cases per year (79 FR 45979). Therefore, we estimate that removing this measure will result in a decrease in burden of 10 hours per IPF (40 cases × 0.25 hours/case) or 17,340 hours across all IPFs (40 cases × 0.25 hours/case × 1,734 IPFs). The decrease in costs is approximately $366 per IPF (10 hours × $36.58/hour) or $634,297 across all IPFs ($366/IPF × 1,734 IPFs).

We also anticipate cost reduction unrelated to the information collection burden associated with these proposals, and refer readers to section IX.C.5.b of this final rule for a discussion of these costs.

We solicited PRA-related comments in the FY 2019 IPF PPS proposed rule (83 FR 21128 through 21129). We did not receive any comments. Consequently, we are finalizing these estimates as proposed.

iii. Attestation Measures

We previously estimated that the Assessment of Patient Experience of Care measure and the Use of an Electronic Health Record (EHR) measure have no measurable information collection burden because both of these measures require only attestation (79 FR 45979). Therefore, we do not anticipate a reduction in IPF information collection burden associated with the removal of these measures. However, we anticipate cost reduction unrelated to the information collection burden associated with these provisions, and refer readers to section IX.C.5.b of this final rule for a discussion.

We solicited PRA-related comment in the FY 2019 IPF PPS proposed rule (83 FR 21129). We did not receive any comments. Consequently, we are finalizing these estimates as proposed.

[21] In the FY 2017 IPPS/LTCH PPS final rule we estimated 1,684 IPFs and are adjusting that estimate by +50 to account for more recent data.

[22] In the FY 2017 IPPS/LTCH PPS final rule we estimated 848 discharges per year and are adjusting that estimate by +365 to account for more recent data.

iv. Burden Related to the Removal of Five Measures

In summary, the information collection burden reduction associated with the removal of these five measures would be 545,343 hours at a cost of $19,948,647 (total) or $11,504 (per IPF) as summarized in Table 10.

TABLE 10—TOTAL INFORMATION COLLECTION BURDEN REDUCTION ASSOCIATED WITH THE REMOVAL OF FIVE MEASURES

Measure(s)	Hourly burden reduction per IPF	Total hourly burden reduction	Cost burden reduction per IPF	Total cost burden reduction
• (1) Alcohol Use Screening (NQF #1661)	304.5	528,003	$11,138	$19,314,350
• (2) Tobacco Use Screening (NQF #1651).	.....	.....	.....	.....
• (3) Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431)	10	17,340	366	634,297
• (4) Remove Assessment of Patient Experience of Care	0	0	0	0
• (5) Use of an Electronic Health Record (EHR).	.....	.....	.....	.....
Total Burden Reduction	314.5	545,343	11,504	19,948,647

We did not receive comments on this burden reduction estimate.

c. Removal of Sample Size Count Requirement

In section VI.J.4 of this final rule, we are removing the requirement to report the sample size count for measures for which sampling is performed beginning with the FY 2020 payment determination and subsequent years (that is, data collected during CY 2018 and reported during summer of CY 2019). Previously, we estimated that the total burden of reporting non-measure data to be 2.5 hours per IPF (79 FR 45979 through 45980). As discussed in section VI.J.5 of this final rule, the non-measure data encompasses five reporting requirements: (1) Total annual discharges; (2) annual discharges stratified by age; (3) annual discharges stratified by diagnostic category; (4) annual discharges stratified by Medicare versus non-Medicare payer; and (5) the sample size count for measures for which sampling is performed.

We estimate that, because the sample size count is one-fifth of the non-measure data collection, removing this requirement will reduce the non-measure collection burden by one-fifth, (that is, 20 percent) or 0.5 hours per facility (0.20×2.5 hours). This results in a reduction of information collection burden of 867 hours across all IPFs (0.5 hours per IPF $\times$ 1,734 IPFs). The decrease in costs is approximately $18 per IPF (0.5 hours $\times$ $36.58/hour) or $31,715 across all IPFs ($18 per IPF $\times$ 1,734 IPFs).

We solicited public comments on the information collection burden reduction estimate of 867 hours and $31,714.86 across all IPFs related to our proposal to no longer require facilities to report sample size counts beginning with the FY 2020 payment determination.

We did not receive comments on this estimate.

d. Summary of Annual Information Collection Burden Estimates for Requirements

Our policies to adopt a new measure removal factor, to remove five measures from the IPFQR Program, and to no longer require IPFs to report the size of their sample lead to a burden reduction of approximately 546,210 hours and $19,980,362, as described in Table 11.

Table 11: Reduction in Total IPFQR Program Information Collection Burden

Preamble Section(s)	Action	Respondents	Responses (per respondent)	Total Responses	Burden per Response (hours)*	Total Annual Burden (hours)	Labor Cost of Reporting ($/hr)	Total Cost ($)
VI.F.2	Remove Alcohol Use Screening and Tobacco Use Screening	1,734	609 per measure	2,112,012	0.25	528,003 (2 measures x 609 cases x 0.25 hr/case x 1,734 IPFs)	$36.58	$19,314,350
VI.F.2	Remove Influenza Vaccination Coverage Among Healthcare Personnel	1,734	40	69,360	0.25	17,340 (1 measure x 40 cases x 0.25 hr/case x 1,734 IPFs)	$36.58	$634,297
VI.F.2	Remove Assessment of Patient Experience of Care and Use of an Electronic Health Record (EHR)	1,734	1	1,734	0	0	$36.58	0
Subtotal (removing 5 measures)		*1,734*	*650*	*2,183,106*	*Varies*	*545,343*	*$36.58*	*$19,948,647*
VI.F.1	Adopt a new measure removal factor	N/A	N/A	N/A	N/A	0	N/A	0
VI.J.4	No longer require reporting of sample size counts	1,734	1	1,734	0.5	867	$36.58	$31,715
	Total	1734	651	2,184,840	Varies	546,210	$36.58	$19,980,362

VIII. Regulatory Impact Analysis

A. Statement of Need

This final rule finalizes updates to the prospective payment rates for Medicare inpatient hospital services provided by IPFs for discharges occurring during FY 2019 (October 1, 2018 through September 30, 2019). We are finalizing our proposal to apply the 2012-based IPF market basket increase of 2.9 percent, less the productivity adjustment of 0.8 percentage point as required by 1886(s)(2)(A)(i) of the Act, and further reduced by 0.75 percentage point as required by sections 1886(s)(2)(A)(ii) and 1886(s)(3)(E) of the Act, for a final total FY 2019 payment rate update of 1.35 percent. In this final rule, we are updating the IPF labor-related share and updating the IPF wage index for FY 2019. We are also finalizing our proposals to provide minor technical corrections to three IPF regulations, and making updates to the IPFQR Program.

B. Overall Impact

We have examined the impacts of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, 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), the Congressional Review Act (5 U.S.C. 804(2)) and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

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

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

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This final rule is not economically significant under Executive Order 12866.

We estimate that the total impact of these changes for FY 2019 payments compared to FY 2018 payments will be a net increase of approximately $50 million. This reflects a $60 million increase from the update to the payment rates (+$130 million from the second quarter 2018 IGI forecast of the 2012-based IPF market basket of 2.9 percent, −$40 million for the productivity adjustment of 0.8 percentage point, and −$30 million for the ''other adjustment'' of 0.75 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 decrease from 2.24 percent in FY 2018 to 2.00 percent of total estimated IPF payments in FY 2019. We also estimate a total decrease in burden of 315 hours per IPF or 546,210 hours across all IPFs (315 hours per IPF × 1,734 IPFs), resulting in a total decrease in financial burden of $11,522.70 per IPF (315 hours × $36.58) or $19,980,362 across all IPFs ($11,522.70 per IPF × 1,734 IPFs).

C. Anticipated Effects

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

1. Budgetary Impact

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

As discussed in section III.D.1 of this rule, we are using the wage index and labor-related share in a budget neutral manner by applying a wage index budget neutrality factor to the federal per diem base rate and ECT payment per treatment. Therefore, the budgetary impact to the Medicare program of this rule will be due to the market basket update for FY 2019 of 2.9 percent (see section III.A.2 of this final rule) less the productivity adjustment of 0.8 percentage point required by section 1886(s)(2)(A)(i) of the Act; further reduced by the ''other adjustment'' of 0.75 percentage point under sections 1886(s)(2)(A)(ii) and 1886(s)(3)(E) of the Act; and the update to the outlier fixed dollar loss threshold amount.

We estimate that the FY 2019 impact will be a net increase of $50 million in payments to IPF providers. This reflects an estimated $60 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 2019. This estimate does not include the implementation of the required 2.0 percentage point reduction of the market basket increase factor for any IPF that fails to meet the IPF quality reporting requirements (as discussed in section VI.A. of this final rule).

The RFA requires agencies to analyze options for regulatory relief of small entities if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most IPFs and most other providers and suppliers are small entities, either by nonprofit status or having revenues of $7.5 million to $38.5 million or less in any 1 year, depending on industry classification (for details, refer to the SBA Small Business Size Standards found at *http://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf*). Individuals and states are not included in the definition of a small entity.

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

The Department of Health and Human Services generally uses a revenue impact of 3 to 5 percent as a significance threshold under the RFA. As shown in Table 12, we estimate that the overall revenue impact of this final rule on all IPFs is to increase estimated Medicare payments by approximately 1.10 percent. As a result, since the estimated impact of this final rule is a net increase in revenue across almost all categories of IPFs, the Secretary has determined that this final rule will have a positive revenue impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. As discussed in section VIII.C.1. of this final rule, the rates and policies set forth in this final rule will not have an adverse impact on the rural hospitals based on the data of the 269 rural excluded psychiatric units and 67 rural psychiatric hospitals in our database of 1,622 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.

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 2018 that threshold is approximately $150 million. This final rule does not impose spending costs on state, local, or tribal governments in the aggregate, or by the private sector of $150 million or more.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. This final rule will not have a substantial effect on state and local governments.

2. Impact on Providers

To show the impact on providers of the changes to the IPF PPS discussed in this final rule, we compare estimated payments under the IPF PPS rates and factorsfor FY 2019 versus those under FY 2018. We determined the percent change of estimated FY 2019 IPF PPS payments compared to FY 2018 IPF PPS payments for each category of IPFs. In

addition, for each category of IPFs, we have included the estimated percent change in payments resulting from the update to the outlier fixed dollar loss threshold amount; the updated wage index data including the updated labor-related share; and the market basket update for FY 2019, as adjusted by the productivity adjustment according to section 1886(s)(2)(A)(i) of the Act, and the ''other adjustment'' according to sections 1886(s)(2)(A)(ii) and 1886(s)(3)(E) of the Act.

To illustrate the impacts of the FY 2019 changes in this final rule, our analysis begins with a FY 2018 baseline simulation model based on FY 2017 IPF payments inflated to the midpoint of FY 2018 using IHS Global Inc.'s most recent forecast of the market basket update (see section III.A.2 of this final rule); the estimated outlier payments in FY 2018; the FY 2017 pre-floor, pre-reclassified hospital wage index; the FY 2018 labor-related share; and the FY 2018 percentage amount of the rural adjustment. During the simulation, total outlier payments are maintained at 2 percent of total estimated IPF PPS payments.

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

- The final update to the outlier fixed dollar loss threshold amount.
- The FY 2018 pre-floor, pre-reclassified hospital wage index and the final FY 2019 labor-related share.
- The final market basket update for FY 2019 of 2.9 percent less the productivity adjustment of 0.8 percentage point in accordance with section 1886(s)(2)(A)(i) of the Act and further reduced by the ''other adjustment'' of 0.75 percentage point in accordance with sections 1886(s)(2)(A)(ii) and 1886(s)(3)(E) of the Act, for a final payment rate update of 1.35 percent.

Our final column comparison in Table 12 illustrates the percent change in payments from FY 2018 (that is, October 1, 2017, to September 30, 2018) to FY 2019 (that is, October 1, 2018, to September 30, 2019) including all the payment policy changes in this final rule.

Table 12: IPF Impacts for FY 2019

[Percent Change in columns 3 through 6]

Facility by Type	Number of Facilities	Outlier	CBSA Wage Index & Labor Share	Payment Update[1]	Total Percent Change[2]
(1)	(2)	(3)	(4)	(5)	(6)
All Facilities	1,622	-0.24	0.00	1.35	1.10
Total Urban	1,286	-0.24	0.04	1.35	1.14
Total Rural	336	-0.25	-0.27	1.35	0.83
Urban unit	815	-0.36	0.04	1.35	1.03
Urban hospital	471	-0.09	0.03	1.35	1.29
Rural unit	269	-0.31	-0.23	1.35	0.80
Rural hospital	67	-0.07	-0.35	1.35	0.92
By Type of Ownership:					
Freestanding IPFs					
Urban Psychiatric Hospitals					
Government	126	-0.25	0.13	1.35	1.23
Non-Profit	94	-0.09	0.08	1.35	1.34
For-Profit	251	-0.06	0.00	1.35	1.29
Rural Psychiatric Hospitals					
Government	32	-0.15	0.51	1.35	1.71
Non-Profit	16	-0.20	-0.21	1.35	0.94
For-Profit	19	-0.01	-0.81	1.35	0.53
IPF Units					
Urban					
Government	116	-0.63	-0.01	1.35	0.70
Non-Profit	529	-0.35	0.04	1.35	1.04
For-Profit	170	-0.22	0.08	1.35	1.21
Rural					
Government	71	-0.38	-0.12	1.35	0.84
Non-Profit	141	-0.30	-0.29	1.35	0.76

For-Profit	57	-0.28	-0.24	1.35	0.83
By Teaching Status:					
Non-teaching	1,429	-0.20	0.02	1.35	1.17
Less than 10% interns and residents to beds	109	-0.38	-0.12	1.35	0.84
10% to 30% interns and residents to beds	62	-0.59	-0.14	1.35	0.61
More than 30% interns and residents to beds	22	-0.51	-0.24	1.35	0.59
By Region:					
New England	105	-0.26	-0.05	1.35	1.04
Mid-Atlantic	234	-0.33	0.05	1.35	1.06
South Atlantic	246	-0.13	-0.05	1.35	1.16
East North Central	271	-0.20	-0.19	1.35	0.96
East South Central	162	-0.24	-0.07	1.35	1.04
West North Central	125	-0.34	0.38	1.35	1.39
West South Central	243	-0.23	0.10	1.35	1.22
Mountain	106	-0.15	0.07	1.35	1.27
Pacific	130	-0.34	-0.01	1.35	1.00
By Bed Size:					
Psychiatric Hospitals					
Beds: 0-24	87	-0.13	-0.31	1.35	0.90
Beds: 25-49	76	-0.05	0.03	1.35	1.33
Beds: 50-75	88	-0.14	-0.37	1.35	0.84
Beds: 76 +	287	-0.08	0.12	1.35	1.40
Psychiatric Units					
Beds: 0-24	624	-0.37	0.01	1.35	0.99
Beds: 25-49	287	-0.33	0.16	1.35	1.17
Beds: 50-75	114	-0.32	-0.12	1.35	0.90
Beds: 76 +	59	-0.39	-0.20	1.35	0.75

[1]This column reflects the payment update impact of the final IPF market basket update for FY 2019 of 2.9 percent, a 0.8 percentage point reduction for the productivity adjustment as required by section 1886(s)(2)(A)(i) of the Act, and a 0.75 percentage point reduction in accordance with sections 1886(s)(2)(A)(ii) and 1886(s)(3)(E) of the Act.

[2]Percent changes in estimated payments from FY 2018 to FY 2019 include all of the changes presented in this final rule. Note, the products of these impacts may be different from the percentage changes shown here due to rounding effects.

By Region:					
New England	105	-0.26	-0.05	1.35	1.04
Mid-Atlantic	234	-0.33	0.05	1.35	1.06
South Atlantic	246	-0.13	-0.05	1.35	1.16
East North Central	271	-0.20	-0.19	1.35	0.96
East South Central	162	-0.24	-0.07	1.35	1.04
West North Central	125	-0.34	0.38	1.35	1.39
West South Central	243	-0.23	0.10	1.35	1.22
Mountain	106	-0.15	0.07	1.35	1.27
Pacific	130	-0.34	-0.01	1.35	1.00
By Bed Size:					
Psychiatric Hospitals					
Beds: 0-24	87	-0.13	-0.31	1.35	0.90
Beds: 25-49	76	-0.05	0.03	1.35	1.33
Beds: 50-75	88	-0.14	-0.37	1.35	0.84
Beds: 76 +	287	-0.08	0.12	1.35	1.40
Psychiatric Units					
Beds: 0-24	624	-0.37	0.01	1.35	0.99
Beds: 25-49	287	-0.33	0.16	1.35	1.17
Beds: 50-75	114	-0.32	-0.12	1.35	0.90
Beds: 76 +	59	-0.39	-0.20	1.35	0.75

[1]This column reflects the payment update impact of the final IPF market basket update for FY 2019 of 2.9 percent, a 0.8 percentage point reduction for the productivity adjustment as required by section 1886(s)(2)(A)(i) of the Act, and a 0.75 percentage point reduction in accordance with sections 1886(s)(2)(A)(ii) and 1886(s)(3)(E) of the Act.

[2]Percent changes in estimated payments from FY 2018 to FY 2019 include all of the changes presented in this final rule. Note, the products of these impacts may be different from the percentage changes shown here due to rounding effects.

3. Impact Results

Table 12 displays the results of our analysis. The table groups IPFs into the categories listed here based on characteristics provided in the Provider of Services (POS) file, the IPF provider specific file, 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 1,622 IPFs included in this analysis. 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 2.24 percent in FY 2018. Thus, we are adjusting the outlier threshold amount in this final rule to set total estimated outlier payments equal to 2.0 percent of total payments in FY 2019. The estimated change in total IPF payments for FY 2019, therefore, includes an approximate 0.24 percent decrease in payments because the outlier portion of total payments is expected to decrease from approximately 2.24 percent to 2.0 percent.

The overall impact of this outlier adjustment update (as shown in column 3 of Table 12), across all hospital groups, is to decrease total estimated payments to IPFs by 0.24 percent. The largest decrease in payments is estimated to be 0.63 percent for urban government IPF units.

In column 4, we present the effects of the budget-neutral update to the IPF wage index and the Labor-Related Share (LRS). This represents the effect of using the most recent wage data available and taking into account the updated OMB delineations. That is, the impact represented in this column reflects the update from the FY 2018 IPF wage index to the final FY 2019 IPF wage index, which includes updating the LRS from 75.0 percent in FY 2018 to 74.8 percent in FY 2019. We note that there is no projected change in aggregate payments to IPFs, as indicated in the first row of column 4, however, there will be distributional effects among different categories of IPFs. For example, we estimate the largest increase in payments to be 0.51 percent for rural government psychiatric hospitals, and the largest decrease in payments to be 0.81 percent for for-profit rural psychiatric hospitals.

In column 5, we present the estimated effects of the final update to the IPF PPS payment rates of 1.35 percent, which are based on the final FY 2019 IPF market basket update of 2.9 percent, less the productivity adjustment of 0.8 percentage point in accordance with section 1886(s)(2)(A)(i) of the Act, and further reduced by 0.75 percentage point in accordance with sections 1886(s)(2)(A)(ii) and 1886(s)(3)(E) of the Act.

Finally, column 6 compares our estimates of the total final changes reflected in this final rule for FY 2019 to the estimates for FY 2018 (without these changes). The average estimated increase for all IPFs is approximately 1.10 percent. This estimated net increase includes the effects of the final 2.9 percent market basket update reduced by the productivity adjustment of 0.8 percentage point, as required by section 1886(s)(2)(A)(i) of the Act and further reduced by the ''other adjustment'' of 0.75 percentage point, as required by sections 1886(s)(2)(A)(ii) and 1886(s)(3)(E) of the Act. It also includes the overall estimated 0.24 percent decrease in estimated IPF outlier payments as a percent of total payments from the final update to the outlier fixed dollar loss threshold amount.

IPF payments are estimated to increase by 1.14 percent in urban areas and 0.83 percent in rural areas. Overall, IPFs are estimated to experience a net increase in payments as a result of the updates in this final rule. The largest payment increase is estimated at 1.71 percent for rural government psychiatric hospitals.

4. Effect on Beneficiaries

Under the IPF PPS, IPFs will receive payment based on the average resources consumed by patients for each day. We do not expect changes in the quality of care or access to services for Medicare beneficiaries under the FY 2019 IPF PPS, but we continue to expect that paying prospectively for IPF services will enhance the efficiency of the Medicare program.

5. Effects of Updates to the IPFQR Program

As discussed in section VI. of this final rule and in accordance with section 1886(s)(4)(A)(i) of the Act, we will implement a 2 percentage point reduction in the FY 2020 annual update to the standard Federal rate for IPFs that have failed to comply with the IPFQR Program requirements for FY 2020. In section VI of this final rule, we discuss how the 2 percentage point reduction will be applied. For FY 2018, of the 1,758 IPFs eligible for the IPFQR Program, 59 IPFs (3.4 percent) did not receive the full market basket update for failure to meet program requirements; of those 59, 24 chose not to participate in the program. We anticipate that even fewer IPFs would receive the reduction for FY 2020 as IPFs become more familiar with the requirements. Thus, we estimate that the policy to apply a 2 percentage point reduction to the annual update for the IPFs that have failed to comply with IPFQR Program requirements will have a negligible impact on overall IPF payments for FY 2020. We believe that there will be additional effects of the policies related to cost reduction for providers and data simplification for beneficiaries. We discuss these effects in more detail in the following sections.

a. Effects Related to Information Collection Burden

Based on the proposals finalized in this final rule, we estimate the total decrease in information collection burden to be 315 hours per IPF or 546,210 hours across all IPFs, resulting in a total decrease in financial burden of $11,522.70 per IPF or $19,980,362 across all IPFs. As discussed in section VII of this final rule, we will attribute the savings associated with the proposals to the year in which these savings begin; for the purposes of all the proposals in this proposed rule, that year is FY 2018. Further information on these estimates can be found in section VII. of this final rule.

b. Effects Other Than Burden Related to Information Collection

As stated in section VI.F.1.a and VII.A of this final rule, we anticipate that in addition to the reduction in information collection burden discussed above, there will be unrelated cost reduction associated with some of our proposals. One example of this cost reduction is that IPFs will no longer have to register with and maintain accounts with NHSN. Because of the administrative complexity of NHSN participation, we believe this will be a substantial reduction in costs. Furthermore, we believe that costs related to reviewing and tracking measure information in feedback reports will be reduced.

Finally, we believe that by no longer maintaining data submission mechanisms, public reporting infrastructure, and program materials for measures which are no longer providing significant benefit, we will be able to better utilize CMS's resources to support quality reporting and quality improvement initiatives among IPFs.

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

6. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this final rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the final rule, we assume that the total number of unique commenters on the most recent IPF proposed rule from FY 2019 will be the number of reviewers of this final rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this final rule. It is possible that not all commenters reviewed the FY 2019 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 past commenters would be a fair estimate of the number of reviewers of this final rule. We did not receive any 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 the final rule. We did not receive any comments on this assumption.

Using the May, 2017 mean (average) wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this final rule is $107.38 per hour, including overhead and fringe benefits (*https://www.bls.gov/oes/current/oes119111.htm*). Assuming an average reading speed of 250 words per minute, we estimate that it would take approximately 1.39 hours for the staff to review half of this final rule. For each IPF that reviews the final rule, the estimated cost is (1.39 hours × $107.38) or $149.26. Therefore, we estimate that the total cost of reviewing this final rule is $13,135 ($149.26 × 88 reviewers).

D. Alternatives Considered

The statute does not specify an update strategy for the IPF PPS and is broadly written to give the Secretary discretion in establishing an update methodology. Therefore, we are updating the IPF PPS using the methodology published in the November 2004 IPF PPS final rule; applying the final FY 2019 2012-based IPF PPS market basket update of 2.9

percent, reduced by the statutorily required multifactor productivity adjustment of 0.8 percentage point and the ''other adjustment'' of 0.75 percentage point, along with the final wage index budget neutrality adjustment to update the payment rates; finalizing a FY 2019 IPF wage index which is fully based upon the latest OMB CBSA designations; and implementing changes to the IPFQR Program.

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 13, we have prepared an accounting statement showing the classification of the expenditures associated with the final updates to the IPF wage index and payment rates in this final rule. Table 13 provides our best estimate of the decrease in provider costs and the increase in Medicare payments under the IPF PPS as a result of the changes presented in this final rule and based on the data for 1,622 IPFs in our database.

TABLE 13—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES

Category	Costs
Change in Estimated Impacts from FY 2018 IPF PPS to FY 2019 IPF PPS	
Annualized Monetized Costs	−$20 million.
Category	Transfers
Annualized Monetized Transfers	$50 million.
From Whom to Whom?	Federal Government to IPF Medicare Providers.

F. Regulatory Reform Analysis Under Executive Order 13771

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017. This final rule is considered an Executive Order 13771 deregulatory action. We estimate that this final rule generates $17.5 million in annualized cost savings, discounted at 7 percent relative to year 2016, over a perpetual time horizon. This $17.5 million is equal to the estimated $20.0 million in annual cost savings which would begin in 2018, discounted to 2016 for Executive Order 13771 accounting purposes using a 7 percent discount rate. Details on the estimated costs of this final rule can be found in the preceding analysis, as shown in Table 11.

G. Conclusion

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

IX. Request for Information on Promoting Interoperability and Electronic Healthcare Information Exchange Through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare- and Medicaid-Participating Providers and Suppliers

In the FY 2019 IPF PPS proposed rule, we included a Request for Information (RFI) related to promoting interoperability and electronic healthcare information exchange (83 FR 21135 through 21138). We received 12 comments on this RFI, and appreciate the input provided by commenters.

List of Subjects in 42 CFR Part 412

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

For reasons stated in the preamble of this document, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

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

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

■ 2. Section 412.27 is amended by revising paragraph (a) to read as follows:

§ 412.27 Excluded psychiatric units: Additional requirements.

* * * * *

(a) Admit only patients whose admission to the unit is required for active treatment, of an intensity that can be provided appropriately only in an inpatient hospital setting, of a psychiatric principal diagnosis that is listed in the International Classification of Diseases, Tenth Revision, Clinical Modification.

* * * * *

■ 3. Section 412.402 is amended by revising the definition of ''Principal diagnosis'' to read as follows:

§ 412.402 Definitions.

* * * * *

Principal diagnosis means the condition established after study to be chiefly responsible for occasioning the admission of the patient to the inpatient psychiatric facility. Principal diagnosis is also referred to as the primary diagnosis.

* * * * *

■ 4. Section 412.428 is amended by revising the section heading, the introductory text, and paragraphs (a) and (b) to read as follows:

§ 412.428 Publication of changes to the inpatient psychiatric facility prospective payment system.

CMS will issue annually in the **Federal Register** information pertaining to changes to the inpatient psychiatric facility prospective payment system. This information includes:

(a) A description of the methodology and data used to calculate the federal per diem base payment amount for the subsequent fiscal year.

(b)(1) For discharges occurring on or after January 1, 2005 but before July 1, 2006, the update, described in § 412.424(a)(2)(iii), for the federal portion of the inpatient psychiatric facility's payments is based on the 1997-based excluded hospital with capital market basket under the applicable percentage increase methodology described in section 1886(b)(3)(B)(ii) of the Act for each year.

(2)(i) For discharges occurring on or after July 1, 2006 but before October 1, 2015, the update for the federal portion of the inpatient psychiatric facility's payment is based on the rehabilitation, psychiatric, and long-term care market basket.

(ii) For discharges occurring on or after October 1, 2015, the update of the inpatient psychiatric facility's payment is based on the inpatient psychiatric facility market basket.

(3) For discharges occurring on or after January 1, 2005 but before October

1, 2005, the update, described in § 412.424(a)(2)(iii), for the reasonable cost portion of the inpatient psychiatric facility's payment is based on the 1997-based excluded hospital with capital market basket under the updated methodology described in section 1886(b)(3)(B)(ii) of the Act for each year.

(4) For discharges occurring on or after October 1, 2005 but before July 1, 2008, the update for the reasonable cost portion of the inpatient psychiatric facility's payment is based on the 2002-based excluded hospital market basket.

* * * * *

Dated: July 26, 2018.

Seema Verma,

Administrator,Centers for Medicare & Medicaid Services.

Dated: July 27, 2018.

Alex M. Azar II,

Secretary,Department of Health and Human Services.

[FR Doc. 2018–16518 Filed 7–31–18; 4:15 pm]

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