FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Savings and Loan Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Home Owners’ Loan Act (12 U.S.C. 1461 et seq.) (HOLA), Regulation LL (12 CFR part 238), and Regulation MM (12 CFR part 239), and all other applicable statutes and regulations to become a savings and loan holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a savings association and nonbanking companies owned by the savings and loan holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the HOLA (12 U.S.C. 1467a(e)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 10(c)(4)(B) of the HOLA (12 U.S.C. 1467a(c)(4)(B)). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than August 31, 2017.

A. Federal Reserve Bank of Chicago
(Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. Pedcor Capital, LLC, Pedcor Bancorp, and American Capital Bancorp, of Carmel, Indiana; to become a savings and loan holding company upon the conversion of International City Bank, Long Beach, California, to a federal savings bank.

B. Federal Reserve Bank of Chicago
(Yao-Chin Chao, Assistant Secretary of the Board.)

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 et seq.) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than September 1, 2017.

A. Federal Reserve Bank of Chicago
(Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. Hometown Community Bancorp, Inc. and Hometown Community Bancorp, Inc. ESOP, both of Morton, Illinois; to acquire 100 percent of the voting shares of Arthur Bancshares Corp. and thereby indirectly acquire State Bank of Arthur, both of Arthur, Illinois.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1673–NC]

RIN 0938–AS97

Medicare Program; FY 2018 Inpatient Psychiatric Facilities Prospective Payment System—Rate Update

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

ACTION: Notice with comment period.

SUMMARY: This notice with comment period updates the prospective payment rates for Medicare inpatient hospital services provided by inpatient psychiatric facilities (IPFs), which include freestanding IPFs and psychiatric units of an acute care hospital or critical access hospital. These changes are applicable to IPF discharges occurring during the fiscal year (FY) beginning October 1, 2017 through September 30, 2018 (FY 2018).

DATES: The updated IPF prospective payment rates are effective for discharges occurring on or after October 1, 2017 through September 30, 2018.

Comment Date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on October 6, 2017.

ADDRESSES: In commenting, refer to file code CMS–1673–NC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

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

2. By regular mail. You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1673–NC, P.O. Box 8010, Baltimore, MD 21244–1800.

Please allow sufficient time for mailed comments to be received before the close of the comment period.
Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

Availability of Certain Tables Exclusively Through the Internet on the CMS Web site

Tables setting forth the fiscal year (FY) 2018 Wage Index for Urban Areas Based on Core-Based Statistical Area (CBSA) Labor Market Areas and the Wage Index Based on CBSA Labor Market Areas for Rural Areas are available exclusively through the Internet, on the CMS Web site at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/IPFPSS/WageIndex.html.

In addition, tables showing the complete listing of ICD–10 Clinical Modification (CM) and Procedure Coding System (PCS) codes underlying the FY 2018 Inpatient Psychiatric Facilities (IPF) Prospective Payment System (PPS) for 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.

Addendum B to this notice with comment period only shows the table of changes to the ICD–10–CM/PCS codes which affect FY 2018 IPF PPS comorbidity categories.

To assist readers in referencing sections contained in this document, we are providing the following table of contents.

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Acronyms

Because of the many terms to which we refer by acronym in this notice with comment period, we are listing the acronyms used and their corresponding meanings in alphabetical order below:

ADC: Average Daily Census
BLS: Bureau of Labor Statistics
CAH: Critical Access Hospital
CBSA: Core-Based Statistical Area
CCR: Cost-to-Charge Ratio
CPI: Consumer Price Index
II. Background

A. Overview of the Legislative Requirements for the IPF PPS

Section 124 of the Medicare, Medicaid, and SCHIP (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 certified psychiatric units including an adequate patient classification system that reflects the differences in patient resource use and costs among psychiatric hospitals and psychiatric units.

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 distinct part psychiatric units of critical access hospitals (CAHs).

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

Section 1886(s)(1) of the Act titled “Reference to Establishment and Implementation of System,” refers to section 124 of the BBRA, which relates to the establishment of the IPF PPS.
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, 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 ECT. During the IPF PPS mandatory 3-year transition period, stop-loss payments were also provided; however, since the transition ended in 2008, these payments are no longer available.

A complete discussion of the regression analysis that established the IPF PPS adjustment factors appears 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:

1. Calculate the federal per diem base rate to be budget-neutral for the 18-month period of January 1, 2005 through June 30, 2006.
2. Use a July 1 through June 30 annual update cycle.
3. Allow the IPF PPS first update to be effective for discharges on or after July 1, 2006 through June 30, 2007.
4. In FY 2012, we proposed and finalized switching the IPF PPS payment rate update from a rate year 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 FY 2012 IPF PPS covered a 15-month period from July 1, 2011 through September 30, 2012. For further discussion of the 15-month market basket update for FY 2012 and changing the payment rate update period to coincide with a FY period, we refer readers to the FY 2012 IPF PPS proposed rule (76 FR 4998) and the FY 2012 IPF PPS final rule (76 FR 26432).

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 subpart N of part 412 of the Medicare regulations. The November 2004 IPF PPS final rule set forth the per diem federal rates 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.

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The patient-level adjustments include age, Diagnosis-Related Group (DRG) assignment, 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).

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1. Calculate the federal per diem base rate to be budget-neutral for the 18-month period of January 1, 2005 through June 30, 2006.
2. Use a July 1 through June 30 annual update cycle.
3. Allow the IPF PPS first update to be effective for discharges on or after July 1, 2006 through June 30, 2007.
4. In FY 2012, we proposed and finalized switching the IPF PPS payment rate update from a rate year 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 FY 2012 IPF PPS covered a 15-month period from July 1, 2011 through September 30, 2012. For further discussion of the 15-month market basket update for FY 2012 and changing the payment rate update period to coincide with a FY period, we refer readers to the FY 2012 IPF PPS proposed rule (76 FR 4998) and the FY 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 appeared in the November 15, 2004 Federal Register (69 FR 66922). In developing the IPF PPS, 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, 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 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 (71 FR 27041).

In the May 6, 2011 IPF PPS final rule (76 FR 26432), we changed the payment rate update period to a FY that coincides with a FY update. Therefore, update notices 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 in order to be effective on October 1. For further discussion on changing the IPF PPS payment rate update period to a FY that coincides with a FY, see the IPF PPS final rule published in the Federal Register on May 6, 2011 (76 FR 26434 through 26435).
updates to the IPF PPS, see 42 CFR 412.428.

Our most recent IPF PPS annual update occurred in an August 1, 2016, Federal Register notice (81 FR 50502) (hereinafter referred to as the August 2016 IPF PPS notice), which updated the IPF PPS payment rates for FY 2017. That notice updated the IPF PPS per diem payment rates that were published in the August 2015 IPF PPS final rule (80 FR 46652) in accordance with our established policies.

III. Provisions of the FY 2018 IPF PPS Notice

A. Updated FY 2018 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, long-term care hospitals (LTCHs), cancer hospitals, and children’s hospitals. Although “market basket” technically describes the mix of goods and services used in providing health care at a given point in time, this term is also commonly used to denote the input price index (that is, cost category weights and price proxies) derived from that market basket. Accordingly, the term “market basket,” as used in this document, refers to an input price index.

Beginning with the May 2006 IPF PPS final rule (71 FR 27046 through 27054), IPF PPS payments were updated using a 2002-based rehabilitation, psychiatric, and long-term care (RPL) market basket reflecting the operating and capital cost structures for freestanding IRFs, freestanding IPFs, and LTCHs. Cancer and children’s hospitals were excluded from the RPL market basket because their payments are based entirely on reasonable costs subject to rate-of-increase limits established under the authority of section 1886(b) of the Act and not through a PPS. Also, the 2002 cost structures for cancer and children’s hospitals are noticeably different than the cost structures of freestanding IRFs, freestanding IPFs, and LTCHs. See the May 2006 IPF PPS final rule (71 FR 27046 through 27054) for a complete discussion of the 2002-based RPL market basket.

Beginning with the FY 2012 IPF PPS final rule (76 FR 26432), IPF PPS payments were updated using a 2008-based RPL market basket reflecting the operating and capital cost structures for freestanding IRFs, freestanding IPFs, and LTCHs. The major changes for FY 2012 included: Updating the base year from FY 2002 to FY 2008; using a more specific composite chemical price proxy; breaking the professional fees cost category into two separate categories (Labor-related and Non-labor-related); and adding two additional cost categories (Administrative and Facilities Support Services, and Financial Services), which were previously included in the residual All Other Services cost categories. The FY 2012 IPF PPS proposed rule (76 FR 4998) and FY 2012 final rule (76 FR 26432) contain a complete discussion of the development of the 2008-based RPL market basket.

In the FY 2016 IPF PPS proposed rule, we proposed to create a 2012-based IPF market basket, using Medicare cost report data for both freestanding and hospital-based IPFs. We first expressed our interest in exploring the possibility of creating a stand-alone IPF market basket in the May 1, 2009 IPF PPS notice (74 FR 20376). In the FY 2016 PPS proposed rule, we solicited comments on the 2012-based IPF market basket. After consideration of these public comments, we finalized the creation and adoption of a 2012-based IPF market basket with a modification to the Wages and Salaries and Employee Benefits cost methodologies based on public comments. We believe that the use of the 2012-based IPF market basket to update IPF PPS payments is a technical improvement as it is based on Medicare Cost Report data from both freestanding and hospital-based IPFs. Furthermore, the 2012-based IPF market basket does not include costs from either IRF or LTCH providers, which were included in the 2008-based RPL market basket. 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).

2. FY 2018 IPF Market Basket Update

For FY 2018 (beginning October 1, 2017 and ending September 30, 2018), we use an estimate of the 2012-based IPF market basket increase factor to update the IPF PPS base payment rate. Consistent with historical practice, we estimate 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). Based on IGI’s second quarter 2017 forecast, the MFP adjustment for FY 2018 (the 10-year moving average of MFP for the period ending FY 2018) is projected to be 0.6 percent. We reduced the 2.6 percent IPF market basket update by this 0.6 percentage point productivity adjustment, as mandated by the Act. For more information on the productivity adjustment, please see the discussion in the FY 2016 IPF PPS final rule (80 FR 46675).

In addition, for FY 2018 the 2012-based IPF PPS market basket update is further reduced by 0.75 percentage point as required by section 1886(s)(2)(A)(ii) and 1886(s)(3)(E) of the Act. This results in an estimated FY 2018 IPF PPS payment rate update of 1.25 percent (2.6 – 0.6 – 0.75 = 1.25).

3. IPF Labor-Related Share

Due to variations in geographic wage levels and other labor-related costs, we believe that payment rates under the IPF PPS should continue to be adjusted by a geographic wage index, which would apply to the labor-related portion of the federal per diem base rate (hereafter referred to as the labor-related share). The labor-related share is determined by identifying the national average proportion of total costs that are related to, influenced by, or vary with the local labor market. We 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 are continuing 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 2018. Using IGI’s second quarter 2017 forecast for the 2012-based IPF market basket, the IPF labor-related share for FY 2018 is the sum of the FY 2018 relative importance
of each labor-related cost category. Please see the FY 2016 IPF PPS final rule for more information on the labor-related share and its calculation (80 FR 46676 through 46679). For FY 2018, the updated labor-related share based on IGI’s second quarter 2017 forecast of the 2012-based IPF PPS market basket is 75.0 percent.

B. Updates to the IPF PPS Rates for FY Beginning October 1, 2017

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 69926).

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 69926).

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 May 2006 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 August 2013 IPF PPS update notice (78 FR 46738 through 46739). These documents are available on the CMS Web site at https://www.cms.gov/Regulations-and-Guidance/Guidance/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 update to the ICD–10–PCS code set for FY 2018.

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

The current (FY 2017) federal per diem base rate is $761.37 and the ECT payment per treatment is $327.78. For FY 2018, we applied a payment rate update of 1.25 percent (that is, the 2012-based IPF market basket increase for FY 2018 of 2.6 percent less the productivity adjustment of 0.6 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 1.0006 (as discussed in section III.D.1.e of this notice with comment period) to the FY 2017 federal per diem base rate of $761.37, yielding a federal per diem base rate of $771.35 for FY 2018. Similarly, we applied the 1.25 percent payment rate update and the 1.0006 wage index budget-neutrality factor to the FY 2017 ECT payment per treatment, yielding an ECT payment per treatment of $332.08 for FY 2018.

Section 1886(s)(4)(A)(i) of the Act requires that, for FY 2014 and each subsequent FY, 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 FY 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 failed to submit quality reporting data under the Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program, we are applying a −0.75 percent payment rate update (that is, 1.25 percent 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 1.0006 to the FY 2017 federal per diem base rate of $761.37, yielding a federal per diem base rate of $756.11 for FY 2018. Similarly, for IPFs that failed to submit quality reporting data under the IPFQR Program, we are applying the −0.75 percent annual payment rate update and the 1.0006 wage index budget-neutrality factor to the FY 2017 ECT payment per treatment of $327.78, yielding an ECT payment per treatment of $325.52 for FY 2018.

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 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 2018. However, we have used more recent claims data to simulate payments to 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. MS–DRG Assignment

We believe it is important to maintain the same diagnostic coding and DRG classification for IPFs that are 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 (CMS DRGs) that were utilized at the time under the IPPS. In the May 2008 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 2008 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 May 2008 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 the FY 2018 update, we are not making any changes to the IPF MS–DRG adjustment factors.

In FY 2015 rulemaking (79 FR 45945 through 45947), we proposed and 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 Web site at https://www.cms.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html.

For FY 2018, we will continue to make a payment adjustment for psychiatric diagnoses that group to one of the existing 17 IPF MS–DRGs listed in Addendum A of this notice with comment period. Psychiatric principal diagnoses that do not group to one of the 17 designated DRGs will still receive the federal per diem base rate and all other applicable adjustments, but the payment would not include a DRG adjustment.

The diagnoses for each IPF MS–DRG will be updated as of October 1, 2017, using the final FY 2018 ICD–10–CM/PCS code sets. The FY 2018 IPPS Final Rule with comment period includes tables of the changes to the ICD–10–CM/PCS code sets which underlie the FY 2018 IPF MS–DRGs. Both the FY 2018 IPPS final rule and the tables of changes to the ICD–10–CM/PCS code sets which underlie the FY 2018 MS–DRGs are available on the IPPS Web site 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 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.

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 the May 2011 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 comorbidity condition payment adjustment under the IPF PPS for FY 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 apply. In a “code first” situation, 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
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 the FY 2015 IPPS 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 2018, we will use the same comorbidity adjustment factors in effect in FY 2017, which are found in Addendum A of this notice with comment period.

We have updated the ICD–10–CM/PCS codes which are associated with the existing IPPS comorbidity categories, based upon the FY 2018 update to the ICD–10–CM/PCS code set. The FY 2018 ICD–10–CM/PCS updates included additions or deletions which affected the comorbidity categories for Oncology (both the Treatment and Procedures lists). These updates are detailed in Addendum B of this notice.

In accordance with the policy established in the FY 2015 IPPS final rule (79 FR 45949 through 45952), we reviewed all new FY 2018 ICD–10–CM codes to remove site unspecified codes from the new FY 2018 ICD–10–CM/PCS codes in instances where more specific codes are available. There were no new FY 2018 ICD–10–CM/PCS codes that were site unspecified. Please see Addendum B of this notice with comment period for a table of changes to the ICD–10–CM/PCS codes which affect FY 2018 IPPS comorbidity categories.

3. Patient Age Adjustments

As explained in the November 2004 IPPS final rule (69 FR 66946) that the regression analysis indicated that per diem cost declines as the LOS increases. The variable per diem adjustments to the federal per diem base rate account for ancillary and administrative costs that occur disproportionately in the first days after admission to an IPF. 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 the 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 notice with comment period.

For FY 2018, we will use the variable per diem adjustment factors currently in effect as shown in Addendum A of this notice with comment period. A complete discussion of the variable per diem adjustments appears in the November 2004 IPPS final rule (69 FR 66946).

D. Updates to the IPPS Facility-Level Adjustments

The IPPS 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 May 2006 IPPS final rule (71 FR 27061) and in the May 2008 (73 FR 25719) and May 2009 (74 FR 20373) IPPS notices, 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 2018

Since the inception of the IPPS, 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 May 2006 IPPS final rule for FY 2007 (71 FR 27061 through 27067), under the IPPS, 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, please see the CY 2013 IPPS/LTCH PPS final rule (77 FR 53365 through 53374). For FY 2018, we will continue to apply the most recent hospital wage index (the FY 2017 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 2013) without any geographic reclassifications, floors, or other adjustments. We apply the FY 2018 IPPS wage index to payments beginning October 1, 2017.

We apply the wage index adjustment to the labor-related portion of the federal rate, which changed from 75.1 percent in FY 2017 to 75.0 percent in FY 2018. This percentage reflects the labor-related share of the 2012-based IPPS market basket for FY 2018 (see section III.A.3 of this notice with comment period).

3. OMB Bulletins

OMB publishes bulletins regarding Core-Based Statistical Area (CBSA) changes, including changes to CBSA numbers and titles. In the May 2006 IPPS final rule for FY 2007 (71 FR 27061 through 27067), we adopted the changes discussed in the Office of Management and Budget (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 FY 2007, we did not provide a separate transition for the CBSA-based wage index since the IPPS was already in a transition period from TEFRA payments to IPPS payments.

In the May 2008 IPPS 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 PPS 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_default/

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 PPS 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/information-for-agencies/bulletins/

Because the FY 2014 pre-floor, pre-reclassified hospital wage index was finalized prior to the issuance of this Bulletin, the FY 2015 IPF PPS 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, 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, which was based on the FY 2014 wage index value by almost 14 percent.

In the November 2004 IPF PPS final rule, we provided a 17 percent payment adjustment for rural locations appears in the IPPS adoption of urban new CBSA 21420 called Enid, OK. The county of Bedford City, VA, a component of the Lynchburg, VA CBSA 31340, changed to town status and is added to Bedford County. Therefore, the county of Bedford City (SSA State county code 49090, FIPS State County Code 51019). However, the CBSA remains Lynchburg, VA, 31340.

The name of Macon, GA, CBSA 31420, as well as a principal city of the Macon-Warner Robins, GA combined statistical area, is now Macon-Bibb County, GA. The CBSA code remains as 31420. 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 and Long-Term Care Hospital (LTCH) PPS final rule (81 FR 56913), these updated labor market area definitions from OMB Bulletin 15–01 were implemented under the IPPS beginning on October 1, 2016 (FY 2017). Therefore, we are implementing these revisions for the IPF PPS beginning October 1, 2016. Consistent with our historical practice of modeling IPF PPS adoption of the labor market area delineations after IPPS adoption of these delineations.

In FY 2016, we applied a 1-year transition period when implementing the OMB delineations described in the February 28, 2013 OMB Bulletin No. 13–01, as this bulletin contained a number of significant changes that resulted in substantial payment implications for some IPF providers. That 1-year transition consisted of a blended wage index for all providers, consisting of a blend of fifty percent of the FY 2016 IPF wage index using the existing OMB delineations and fifty percent of the FY 2016 IPF wage index using the updated OMB delineations from the February 28, 2013 OMB Bulletin (80 FR 46682 through 46689). For FY 2018, we are incorporating the CBSA changes published in the July 15, 2015 OMB Bulletin No. 15–01 into the FY 2018 IPF wage index without a transition period, as we anticipate that these changes will affect a single IPF provider located in Garfield County, OK, and will increase the provider’s wage index value by almost 14 percent.

In summary, as the changes made in the July 15, 2015 OMB Bulletin 15–01 are minor and do not have a large effect on a substantial number of providers, we are adopting these updates without any transition period. Therefore, the FY 2018 IPF wage index and subsequent IPF wage indices will be based solely on the new OMB CBSA delineations in OMB Bulletin No. 15–01, without any transitions. The final FY 2018 IPF wage index is located on the CMS Web site at https://www.cms.gov/Medicare-Medicare-Fee-for-Service-Payment/InpatientPsychFaciIPPS/WageIndex.html.

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 2018, we will 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).

As noted in section III.D.1.c of this notice with comment period, we adopted the February 28, 2013 OMB updates to CBSA delineations in the FY 2016 IPF PPS transitional wage index.
Adoption of the updated CBSAs changed the status of 37 IPF providers designated as “rural” in FY 2015 to “urban” for FY 2016 and subsequent FYs. As such, these 37 newly urban providers no longer receive the 17 percent rural adjustment.

In the FY 2016 IPF PPS final rule, we implemented a budget-neutral 3-year phase-out of the rural adjustment for the existing FY 2015 rural IPFs that became urban in FY 2016 and that experienced a loss in payments due to changes from the new CBSA delineations (80 FR 46689 to 46690). This policy allowed rural IPFs that were classified as urban in FY 2016 to receive two-thirds of the IPF PPS rural adjustment for FY 2016. For FY 2017, these IPFs will receive one-third of the IPF PPS rural adjustment. For FY 2018 (and subsequent years), these IPFs will not receive any rural adjustment. FY 2018 is the third year of the 3-year rural adjustment phase-out. Therefore, these IPFs that were classified as rural in FY 2015, but were changed to urban in FY 2016 as a result of the February 28, 2013 OMB CBSA changes, will receive no rural adjustment in FY 2018 or subsequent years.

Additionally, as noted previously in section III.D.1.c. of this notice with comment period, the July 15, 2015 OMB Bulletin No. 15–01 changed Garfield County, Oklahoma from rural status to urban status, under new CBSA 21420. There is a single IPF in this county, which will lose the 17 percent rural adjustment in FY 2018. However, as noted in subsection III.D.1.c. of this notice with comment period, this provider will experience an increase of nearly 14 percent in their FY 2018 wage index value. As this provider is not expected to experience as steep of a reduction in payments as did the majority of IPFs for which a phase-out of the rural adjustment was implemented in FY 2016 (80 FR 46689 through 46690), we do not believe it is appropriate or necessary to adopt a rural phase-out policy for this provider.

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 2018, we will 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 2018 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 2013 hospital cost report data) and the labor-related share in a budget-neutral manner:

1. Simulate estimated IPF PPS payments, using the FY 2017 IPF wage index values (available on the CMS Web site) and labor-related share (as published in the FY 2017 IPF PPS notice (81 FR 50506, and 50508 to 50509)).

2. Simulate estimated IPF PPS payments using the FY 2018 IPF wage index values (available on the CMS Web site) and labor-related share (based on the latest available data as discussed previously).

3. Divide the amount calculated in step 1 by the amount calculated in step 2. The resulting quotient is the FY 2018 budget-neutral wage adjustment factor of 1.0006.

4. Apply the FY 2018 budget-neutral wage adjustment factor from step 3 to the FY 2017 IPF PPS per diem rate after the application of the market basket update described in section III.A.2 of this notice with comment period, to determine the FY 2018 IPF PPS per diem 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 cost variable was 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 one plus the ratio of the number of FTE residents training in the IPF (subject to limitations described below) to the IPF’s ADC.

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 January 27, 2011 IPF PPS proposed rule (76 FR 50518 through 5020) and the May 6, 2011 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 May 2008 IPF PPS notice (73 FR 23721). As with other adjustment factors derived through the regression analysis, we do not plan to rerun the teaching adjustment factors in the regression analysis until we more fully analyze IPF PPS data. Therefore, in this FY 2018 notice, we will continue to retain the coefficient value of 0.5150 for the teaching adjustment to the federal per diem base rate.

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 county 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 (before being reduced by locality payments) are published on the Office of Personnel Management (OPM) Web site (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. We published the proposed COLA factors in the January 2011 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 IPPS in the FY 2015 IPPS final rule (79 FR 45958 through 45960). We adopted this new COLA methodology for the IPPS 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 IPP COLAs for FY 2015 through FY 2017 were the same as those applied under the IPPS in those years. For the FY 2018 IPPS/LTCH PPS, we are continuing to adopt the COLA factors implemented in the FY 2018 IPPS/LTCH PPS final rule using the methodology finalized in the FY 2013 IPPS/LTCH final rule and implemented for the FY 2014 IPPS update. Also, as finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53700 and 53701), the COLA updates are determined every four years, when the IPPS market basket labor-related share is updated during rebasing. Because the labor-related share of the IPPS market basket is being updated for FY 2018, the COLA factors are being updated in FY 2018 IPPS/LTCH rulemaking. As such, we are also updating the IPP PPS COLA factors for FY 2018.

Specifically, the FY 2018 IPPS/LTCH PPS final rule updates the 2009 OPM COLA factors (as these are the last COLA factors OPM published prior to transitioning from COLAs to locality pay) by a comparison of the growth in the Consumer Price Indices (CPIs) for Anchorage, AK, and Honolulu, HI, relative to the growth in the CPI for the average U.S. city as published by the Bureau of Labor Statistics (BLS). Because BLS publishes CPI data for only Anchorage and Honolulu, using the methodology we finalized in the FY 2013 IPPS/LTCH PPS final rule, we use the comparison of the growth in the overall CPI relative to the growth in the CPI for those cities to update the COLA factors for all areas in Alaska and Hawaii, respectively. We believe that the relative price differences between these cities and the United States (as measured by the CPIs mentioned previously) are appropriate proxies for the relative price differences between the "other areas" of Alaska and Hawaii and the United States.

BLS publishes the CPI for All Items for Anchorage, Honolulu, and for the average U.S. city. However, consistent with the methodology finalized in the FY 2013 IPPS/LTCH PPS final rule, in the FY 2018 IPPS/LTCH PPS final rule, reweighted CPIs were created for each of the respective areas to reflect the underlying composition of the IPPS market basket nonlabor-related share. The current composition of the CPI for All Items for all of the respective areas is approximately 40 percent commodities and 60 percent services. However, the IPPS nonlabor-related share is comprised of a different mix of commodities and services. Therefore, reweighted indexes were created for Anchorage, Honolulu, and the average U.S. city and use the respective CPI commodities index and CPI services index using the approximate 55 percent commodities/45 percent services shares obtained from the updated 2014-based IPPS market basket.

Reweighted indexes were created using BLS data for 2009 through 2016, which is the most recent data available at the time of the FY 2018 IPPS/LTCH final rule. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50985 through 50987), reweighted indexes were created based on the FY 2010-based IPPS market basket (which was adopted for the FY 2014 IPPS update) and BLS data for 2009 through 2012 (the most recent BLS data at the time of the FY 2014 IPPS/LTCH PPS rulemaking). We continue to believe this methodology is appropriate for IPFs because we continue to make a COLA for IPFs located in Alaska and Hawaii by multiplying the nonlabor-related portion of the per diem amount by a COLA factor.

Under the COLA factor update methodology established in the FY 2013 IPPS/LTCH final rule, CMS exercised its discretionary authority to adjust payments to hospitals located in Alaska and Hawaii by incorporating a 25 percent cap on the CPI-updated COLA factors. We note that OPM’s COLA factors were calculated with a statutorily mandated cap of 25 percent, and the IPPS has exercised discretionary authority to adjust Alaska and Hawaii payments by incorporating this cap.

Because the IPP PPS adopted the IPPS COLA factor update methodology in FY 2015 rulemaking, the IPP PPS also continues to use such a cap for FY 2018. This would improve payment equity for IPFs located in Alaska and Hawaii by continuing to make a COLA for IPFs located in Alaska and Hawaii by multiplying the nonlabor-related portion of the per diem...
amount for IPFs located in Alaska and Hawaii 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        |
| 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           |
| Rest of Alaska                                | 1.25             | 1.25           |
| Hawaii:                                       |                  |                |
| 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           |

As noted in the FY 2018 IPPS/LTCH PPS final rule, the reweighted CPI for Anchorage, AK grew faster than the reweighted CPI for the average U.S. city over the 2009 to 2016 time period, at 12.4 percent and 10.5 percent, respectively. As a result, for FY 2018, COLA factors for the City of Anchorage, City of Fairbanks, and City of Juneau were calculated to be 1.25 compared to the FY 2017 COLA factor of 1.23. For FY 2018, a COLA factor of 1.27 was calculated for the Rest of Alaska compared to the FY 2017 COLA factor of 1.25. However, as stated previously, we are applying the methodology finalized in the FY 2013 IPPS/LTCH final rule and adopted in IPF PPS FY 2015 rulemaking to incorporate a cap of 1.25 for the rest of Alaska.

Similarly, the reweighted CPI for Honolulu, HI grew faster than the reweighted CPI for the average U.S. city over the 2009 to 2016 time period, at 13.7 percent and 10.5 percent, respectively. As a result, for FY 2018, COLA factors were calculated for the City and County of Honolulu, County of Kauai, County of Maui, and County of Kalawao to be 1.29, compared to the FY 2017 COLA factor of 1.25 (which was based on OPM’s published COLA factors for 2009, as described previously). However, as stated previously, we are applying the methodology finalized in the FY 2013 IPPS/LTCH PPS final rule and adopted in IPPS FY 2015 rulemaking to incorporate a cap of 1.25 for these areas. In addition, the COLA factor for the County of Hawaii for FY 2018 was calculated to be 1.21 compared to the FY 2017 COLA factor of 1.19.

The IPF PPS COLA factors for FY 2018 are also shown in Addendum A of this notice with comment period.

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 freestanding psychiatric hospital with a qualifying ED or a distinct part psychiatric unit of an acute care hospital or a CAH, for preadmission services otherwise payable under the Medicare 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 below. 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 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 or CAH’s 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 2018, 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 appears in the November 2004 IPF PPS final rule (69 FR 66959 through 66960) and the May 2006 IPF PPS final rule (71 FR 27070 through 27072).

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...
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 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 December 2016 update of FY 2016 IPF claims) and rate increases, we believe it is necessary to update the fixed dollar loss threshold amount in order to maintain an outlier percentage that equals 2 percent of total estimated IPF PPS payments. To update the IPF outlier threshold amount for FY 2018, we used FY 2016 claims data and the same methodology that we used to set the initial threshold amount in the May 2006 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 2017. Based on an analysis of these updated data, we estimate that IPF outlier payments as a percentage of total estimated payments are approximately 2.26 percent in FY 2017. Therefore, we will update the outlier threshold amount to $11,425 to maintain estimated outlier payments at 2 percent of total estimated aggregate IPF payments for FY 2018.

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 June 2003 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 in order to ensure that aberrant CCR data did not result in inappropriate outlier payments. As we indicated in the November 2004 IPPS final rule (69 FR 66961), because we believe that the IPF outlier policy is susceptible to the same payment vulnerabilities as the IPPS, 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 IPPS final rule: We calculated two national ceilings, one for IPFs located in rural areas and one for IPFs located in urban areas. We 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 2017 Provider Specific File. 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 2018 is 1.9634 for rural IPFs, and 1.7071 for urban IPFs, based on CBSA-based geographic designations. If an IPF’s CCR is above a 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 are updating the FY 2018 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 2018, to be used in each of the three situations listed previously, using the most recent CCRs entered in the CY 2017 Provider Specific File, we used a national median CCR of 0.5930 for rural IPFs and a national median CCR of 0.4420 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 IPPS final rule (69 FR 66961 through 66964).

IV. Update on IPPS Refinements

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

We have delayed making refinements to the IPPS until we have completed a thorough analysis of IPPS data on which to base those refinements. Specifically, we will delay updating the adjustment factors derived from the regression analysis until we have IPPS 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 IPPS industry practices so that we may refine the IPPS in the future, as appropriate.

As we noted in the FY 2016 IPPS final rule (80 FR 46693 to 46694), our preliminary analysis of 2012 to 2013 IPPS 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 per diem payment rate includes the cost of all ancillary services, including drugs and laboratory services. 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 are continuing to analyze data from claims and cost reports that do not include ancillary charges or costs, and will be sharing our findings with the Center for Program Integrity and the 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. Since we are not making refinements for FY 2018, we will continue to use the existing adjustment factors.

V. Waiver of Notice and Comment

We ordinarily publish a notice of proposed rulemaking in the Federal Register to provide a period for public comment before the provisions of a rule take effect. We can waive this procedure, however, if we find good cause that notice and comment procedures are impracticable, unnecessary, or contrary to the public interest and we incorporate a statement of finding and its reasons in the notice. We find it is unnecessary to undertake notice and comment rulemaking for this action because the updates in this notice with comment period do not reflect any substantive change in policy, but merely reflect the application of previously established methodologies. Therefore, under 5 U.S.C 553(b)(3)(B), for good cause, we waive notice and comment procedures.

VI. Request for Information on CMS Flexibilities and Efficiencies

CMS is committed to transforming the health care delivery system—and the Medicare program—by putting an additional focus on patient-centered care and working with providers, physicians, and patients to improve outcomes. We seek to reduce burdens for hospitals, physicians, and patients, improve the quality of care, decrease costs, and ensure that patients and their providers and physicians are making the best health care choices possible. These are the reasons we are including this Request for Information in this notice with comment period.

As we work to maintain flexibility and efficiency throughout the Medicare program, we would like to start a national conversation about improvements that can be made to the health care delivery system that reduce unnecessary burdens for clinicians, other providers, and patients and their families. We aim to increase quality of care, lower costs improve program integrity, and make the health care system more effective, simple and accessible.

We would like to take this opportunity to invite the public to submit their ideas for regulatory, subregulatory, policy, practice, and procedural changes to better accomplish these goals. Ideas could include payment system redesign, elimination or streamlining of reporting, monitoring and documentation requirements, aligning Medicare requirements and processes with those from Medicaid and other payers, operational flexibility, feedback mechanisms and data sharing that would enhance patient care, support of the physician-patient relationship in care delivery, and facilitation of individual preferences. Responses to this Request for Information could also include recommendations regarding when and how CMS issues regulations and policies and how CMS can simplify rules and policies for beneficiaries, clinicians, physicians, providers, and suppliers. Where practicable, data and specific examples would be helpful. If the proposals involve novel legal questions, analysis regarding CMS’ authority is welcome for CMS’ consideration. We are particularly interested in ideas for incentivizing organizations and the full range of relevant professionals and paraprofessionals to provide screening, assessment and evidence-based treatment for individuals with opioid use disorder and other substance use disorders, including reimbursement methodologies, care coordination, systems and services integration, use of paraprofessionals including community paramedics and other strategies. We are requesting commenters to provide clear and concise responses. All submitted data and specific examples that could be implemented within the law.

We note that this is a Request for Information only. Respondents are encouraged to provide complete but concise responses. This Request for Information is issued solely for information and planning purposes; it does not constitute a Request for Proposal (RFP), applications, proposal abstracts, or quotations. This Request for Information does not commit the U.S. Government to contract for any supplies or services or make a grant award. Further, CMS is not seeking proposals through this Request for Information and will not accept unsolicited proposals. Responders are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to this Request for Information; all costs associated with responding to this Request for Information will be solely at the interested party’s expense. We note that not responding to this Request for Information does not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor this Request for Information announcement for additional information pertaining to this request. In addition, we note that CMS will not respond to questions about the policy issues raised in this Request for Information. CMS will not respond to comment submissions in response to this Request for Information in the FY 2018 Inpatient Psychiatric Facilities Prospective Payment System—Rate Update notice with comment period. Rather, CMS will actively consider all input as we develop future regulatory proposals or future subregulatory policy guidance. CMS may or may not choose to contact individual responders. Such communications would be for the sole purpose of clarifying statements in the responders’ written responses. Contractor support personnel may be used to review responses to this Request for Information. Responses to this notice with comment period are not offers and cannot be accepted by the Government to form a binding contract or issue a grant. Information obtained as a result of this Request for Information may be used by the Government for program planning on a nonattribution basis. Respondents should not include any information that might be considered proprietary or confidential. This Request for Information should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submitted U.S. Government property and will not be returned. CMS may publicly post the
public comments received, or a summary of those public comments.

VII. Collection of Information Requirements

This notice does not impose any new or revised information collection requirements or burden pertaining to collecting, reporting, recordkeeping, or disclosing information. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

VIII. Response to Comments

Because of the large number of public comments we normally receive on Federal Register documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the “DATES” section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

IX. Regulatory Impact Analysis

A. Statement of Need

This notice with comment period updates the prospective payment rates for Medicare inpatient hospital services provided by IPFs for discharges occurring during FY 2018 (October 1, 2017 through September 30, 2018). We are applying the 2012-based IPF market basket increase of 2.6 percent, less the productivity adjustment of 0.6 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 total FY 2018 payment rate update of 1.25 percent. In this notice with comment period, we are also updating the IPF labor-related share and updating the IPF wage index for FY 2018. The rural adjustment phase-out for the small number of rural providers which became urban providers in FY 2016 as a result of FY 2016 changes to CBDA delineations is now in its third and final year, and we are applying the rural adjustment for the affected providers in FY 2018, or in subsequent years.

B. Overall Impact

We have examined the impacts of this notice with comment period 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 302 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 principle of Executive Order. This notice with comment period is not designated as economically “significant” under section 3(f)(1) of Executive Order 12866.

We estimate that the total impact of these changes for FY 2018 payments compared to FY 2017 payments will be a net increase of approximately $45 million. This reflects a $55 million increase from the update to the payment rates (+$115 million from the unadjusted second quarter 2017 IGI forecast of the 2012-based IPF market basket of 2.6 percent, -$25 million for the productivity adjustment of 0.6 percentage point, and -$35 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 2.26 percent in FY 2017 to 2.0 percent of total estimated IPF payments in FY 2018. 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).

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 2, we estimate that the overall revenue impact of this notice with comment period on all IPFs is to increase Medicare payments by approximately 0.99 percent. As a result, since the estimated impact of this notice with comment period is a net increase in revenue across almost all categories of IPFs, the Secretary has determined that this notice with comment period will have a positive revenue impact on a substantial number of small entities. MACs are not considered to be small entities. Individuals and states are not included in the definition of a small entity.

In addition, section 1102(b) of the Social Security 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 detail below, the rates and policies set forth in this notice with comment period will not have an adverse impact on the rural hospitals based on the data of the 277 rural units and 67 rural hospitals in our database of 1,621 IPFs for which data were available. Therefore, the Secretary has determined that this notice with comment period 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 2017, that threshold is approximately $148 million. This notice with comment period will not impose spending costs on state, local, or tribal governments in the aggregate, or by the private sector of $148 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. As stated previously, this notice with comment period will not have a substantial effect on state and local governments.

C. Anticipated Effects

In this section, we discuss the historical background of the IPF PPS and the impact of this notice with comment period on the Federal Medicare budget and on IPFs.

1. Budgetary Impact

As discussed in the November 2004 and May 2006 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 May 2008 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 notice with comment period, 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 notice with comment period will be due to the market basket update for FY 2018 of 2.6 percent (see section III.A.2 of this notice with comment period) less the productivity adjustment of 0.6 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 2018 impact will be a net increase of $45 million in payments to IPF providers. This reflects an estimated $55 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 2018. 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 III.B.2 of this notice with comment period).

2. Impact on Providers

To show the impact on providers of the changes to the IPF PPS discussed in this notice with comment period, we compare estimated payments under the IPF PPS rates and factors for FY 2018 versus those under FY 2017. We determined the percent change of estimated FY 2018 IPF PPS payments compared to FY 2017 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 2018, 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 2018 changes in this notice with comment period, our analysis begins with a FY 2017 baseline simulation model based on FY 2016 IPF payments inflated to the midpoint of FY 2017 using HHS Global Inc.’s most recent forecast of the market basket update (see section III.A.2 of this notice with comment period); the estimated outlier payments in FY 2017; the FY 2016 pre-floor, pre-reclassified hospital wage index; the FY 2017 labor-related share; and the FY 2017 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 update to the outlier fixed dollar loss threshold amount.
- The FY 2017 pre-floor, pre-reclassified hospital wage index.
- The FY 2018 labor-related share.
- The market basket update for FY 2018 of 2.6 percent less the productivity adjustment of 0.6 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 payment rate update of 1.25 percent.

Our final column comparison illustrates the percent change in payments from FY 2017 (that is, October 1, 2016, to September 30, 2017) to FY 2018 (that is, October 1, 2017, to September 30, 2018) including all the changes in this notice with comment period.

<table>
<thead>
<tr>
<th>Facility by type</th>
<th>Number of facilities</th>
<th>Outlier</th>
<th>CBSA wage index and labor share</th>
<th>Payment update 1</th>
<th>Total percent change 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Facilities</td>
<td>1,621</td>
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<td>Total Urban</td>
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<td>Total Rural</td>
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<td>Urban unit</td>
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<td>0.67</td>
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<tr>
<td>Urban hospital</td>
<td>450</td>
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<tr>
<td>Rural unit</td>
<td>277</td>
<td>−0.31</td>
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<tr>
<td>Rural hospital</td>
<td>67</td>
<td>−0.14</td>
<td>0.34</td>
<td>1.25</td>
<td>1.45</td>
</tr>
</tbody>
</table>

By Type of Ownership:
3. Results

Table 2 displays the results of our analysis. The table groups IPFs into the categories listed below 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

### TABLE 2—IPF PPS IMPACTS FOR FY 2018—Continued

<table>
<thead>
<tr>
<th>Facility by type</th>
<th>Number of facilities</th>
<th>Outlier</th>
<th>CBSA wage index and labor share</th>
<th>Payment update</th>
<th>Total percent change</th>
</tr>
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<tbody>
<tr>
<td><strong>Freestanding IPFs:</strong></td>
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<tr>
<td>Urban Psychiatric Hospitals:</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Government</td>
<td>121</td>
<td>-0.32</td>
<td>-0.09</td>
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<td>0.83</td>
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<tr>
<td>Non-Profit</td>
<td>97</td>
<td>-0.13</td>
<td>0.49</td>
<td>1.25</td>
<td>1.61</td>
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<tr>
<td>For-Profit</td>
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<td>0.04</td>
<td>1.25</td>
<td>1.26</td>
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<tr>
<td>Rural Psychiatric Hospitals:</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Government</td>
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<td>For-Profit</td>
<td>21</td>
<td>-0.14</td>
<td>0.11</td>
<td>1.25</td>
<td>1.22</td>
</tr>
<tr>
<td><strong>IPF Units:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Urban:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Government</td>
<td>118</td>
<td>-0.61</td>
<td>-0.36</td>
<td>1.25</td>
<td>0.27</td>
</tr>
<tr>
<td>Non-Profit</td>
<td>535</td>
<td>-0.38</td>
<td>-0.29</td>
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</tr>
<tr>
<td>For-Profit</td>
<td>174</td>
<td>-0.19</td>
<td>0.17</td>
<td>1.25</td>
<td>1.22</td>
</tr>
<tr>
<td>Rural:</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Government</td>
<td>68</td>
<td>-0.31</td>
<td>0.35</td>
<td>1.25</td>
<td>1.29</td>
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<tr>
<td>Non-Profit</td>
<td>147</td>
<td>-0.31</td>
<td>0.50</td>
<td>1.25</td>
<td>1.44</td>
</tr>
<tr>
<td>For-Profit</td>
<td>62</td>
<td>-0.30</td>
<td>0.19</td>
<td>1.25</td>
<td>1.14</td>
</tr>
<tr>
<td><strong>By Teaching Status:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-teaching</td>
<td>1,436</td>
<td>-0.22</td>
<td>0.04</td>
<td>1.25</td>
<td>1.06</td>
</tr>
<tr>
<td>Less than 10% interns and residents to beds</td>
<td>104</td>
<td>-0.37</td>
<td>-0.12</td>
<td>1.25</td>
<td>0.75</td>
</tr>
<tr>
<td>10% to 30% interns and residents to beds</td>
<td>60</td>
<td>-0.54</td>
<td>-0.39</td>
<td>1.25</td>
<td>0.31</td>
</tr>
<tr>
<td>More than 30% interns and residents to beds</td>
<td>21</td>
<td>-0.49</td>
<td>0.17</td>
<td>1.25</td>
<td>0.93</td>
</tr>
<tr>
<td><strong>By Region:</strong></td>
<td></td>
<td></td>
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<tr>
<td>New England</td>
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<td>-0.31</td>
<td>-0.46</td>
<td>1.25</td>
<td>0.47</td>
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<tr>
<td>Mid-Atlantic</td>
<td>233</td>
<td>-0.34</td>
<td>0.04</td>
<td>1.25</td>
<td>0.94</td>
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<tr>
<td>South Atlantic</td>
<td>240</td>
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<td>-0.25</td>
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<td>0.85</td>
</tr>
<tr>
<td>East North Central</td>
<td>269</td>
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<td>-0.03</td>
<td>1.25</td>
<td>0.99</td>
</tr>
<tr>
<td>East South Central</td>
<td>165</td>
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<td>-0.08</td>
<td>1.25</td>
<td>0.93</td>
</tr>
<tr>
<td>West North Central</td>
<td>133</td>
<td>-0.34</td>
<td>-0.05</td>
<td>1.25</td>
<td>0.85</td>
</tr>
<tr>
<td>West South Central</td>
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<td>-0.20</td>
<td>0.13</td>
<td>1.25</td>
<td>1.18</td>
</tr>
<tr>
<td>Mountain</td>
<td>105</td>
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<td>0.17</td>
<td>1.25</td>
<td>1.25</td>
</tr>
<tr>
<td>Pacific</td>
<td>126</td>
<td>-0.37</td>
<td>0.62</td>
<td>1.25</td>
<td>1.50</td>
</tr>
<tr>
<td><strong>By Bed Size:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Psychiatric Hospitals</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Beds: 0–24</td>
<td>86</td>
<td>-0.09</td>
<td>0.27</td>
<td>1.25</td>
<td>1.43</td>
</tr>
<tr>
<td>Beds: 25–49</td>
<td>74</td>
<td>-0.12</td>
<td>-0.04</td>
<td>1.25</td>
<td>1.09</td>
</tr>
<tr>
<td>Beds: 50–75</td>
<td>88</td>
<td>-0.14</td>
<td>0.24</td>
<td>1.25</td>
<td>1.35</td>
</tr>
<tr>
<td>Beds: 76+</td>
<td>269</td>
<td>-0.08</td>
<td>0.15</td>
<td>1.25</td>
<td>1.32</td>
</tr>
<tr>
<td>Psychiatric Units</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Beds: 0–24</td>
<td>640</td>
<td>-0.40</td>
<td>-0.01</td>
<td>1.25</td>
<td>0.83</td>
</tr>
<tr>
<td>Beds: 25–49</td>
<td>288</td>
<td>-0.34</td>
<td>-0.12</td>
<td>1.25</td>
<td>0.78</td>
</tr>
<tr>
<td>Beds: 50–75</td>
<td>112</td>
<td>-0.35</td>
<td>-0.30</td>
<td>1.25</td>
<td>0.60</td>
</tr>
<tr>
<td>Beds: 76+</td>
<td>64</td>
<td>-0.32</td>
<td>-0.08</td>
<td>1.25</td>
<td>0.84</td>
</tr>
</tbody>
</table>

1 This column reflects the payment update impact of the IPF market basket update for FY 2018 of 2.6 percent, a 0.6 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 2017 to FY 2018 include all of the changes presented in this notice. Note, the products of these impacts may be different from the percentage changes shown here due to rounding effects.

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The overall impact of this outlier adjustment update (as shown in column 3 of Table 2), across all hospital groups, is to decrease total estimated payments to IPFs by 0.26 percent. The largest...
decrease in payments is estimated to be a 0.61 percent decrease in payments 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 2017 IPF wage index to the FY 2018 IPF wage index, which includes the LRS update from 75.1 percent in FY 2017 to 75.0 percent in FY 2018. 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 distributitional effects among different categories of IPFs. For example, we estimate the largest increase in payments to be 0.90 percent for rural government psychiatric hospitals, and the largest decrease in payments to be 0.46 percent for New England IPFs.

Column 5 presents the estimated effects of the update to the IPF PPS payment rates of 1.25 percent, which are based on the 2012-based IPF market basket update of 2.6 percent, less the productivity adjustment of 0.6 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 changes reflected in this notice with comment period for FY 2018 to the estimates for FY 2017 (without these changes). The average estimated increase for all IPFs is approximately 0.99 percent. This estimated net increase includes the effects of the 2.6 percent market basket update reduced by the productivity adjustment of 0.6 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 0.26 percent decrease in estimated IPF outlier payments as a percent of total payments from the update to the outlier fixed dollar loss threshold amount.

IPF payments are estimated to increase by 0.93 percent in urban areas and 1.37 percent in rural areas. Overall, IPFs are estimated to experience a net increase in payments as a result of the updates in this notice with comment period. The estimated payment increase is estimated at 2.02 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 2018 IPF PPS, but we continue to expect that paying prospectively for IPF services will enhance the efficiency of the Medicare program.

5. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this notice with comment period, we should estimate the cost associated with regulatory review. Due to the uncertainty involved in accurately quantifying the number of entities that will review the notice with comment period, we assume that the total number of unique commenters on the most recent IPF proposed rule from FY 2016 will be the number of reviewers of this notice with comment period. We acknowledge that this assumption may underestimate or overstate the costs of reviewing this notice with comment period. It is possible that not all commenters reviewed the FY 2016 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 notice with comment period. We welcome any comments on the approach in estimating the number of entities which will review this notice with comment period.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this notice with comment period, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the notice with comment period. We seek comments on this assumption.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this notice with comment period is $105.16 per hour, including overhead and fringe benefits (https://www.bls.gov/oes/current/oes_nat.htm). Assuming an average reading speed, we estimate that it would take approximately 0.62 hours for the staff to review half of this notice with comment period. For each IPF that reviews the notice with comment period, the estimated cost is $65.20 (0.62 hours $105.16). Therefore, we estimate that the total cost of reviewing this notice with comment period is $4,955.20 ($65.20 × 76 reviewers).

6. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, titled “Reducing Regulation and Controlling Regulatory Costs,” was issued on January 30, 2017 (82 FR 9339, February 3, 2017). It has been determined that this notice with comment period is a transfer notice that does not impose more than de minimis costs and thus is not a regulatory action for the purposes of E.O. 13771.

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 FY 2018 2012-based IPF PPS market basket update of 2.6 percent, reduced by the statutorily required multifactor productivity adjustment of 0.6 percentage point and the other adjustment of 0.75 percentage point, along with the wage index budget neutrality adjustment to update the payment rates; finalizing a FY 2018 IPF PPS wage index which is fully based upon the OMB CBSA designations found in OMB Bulletin 15–01; and continuing with the third and final year of the 3-year phase-out of the rural adjustment for IPF providers which changed from rural to urban status in FY 2016 as a result of adopting the updated OMB CBSA delineations from OMB Bulletin 13–01, which were used in the FY 2016 IPF PPS transitional wage index.

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 3, we have prepared an accounting statement showing the classification of the expenditures associated with the updates to the IPF PPS wage index and payment rates in this notice with comment period. This table provides our best estimate of the increase in Medicare payments under the IPF PPS as a result of the changes presented in this notice with comment period and based on the data for 1,621 IPFs in our database.
TABLE 3—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES

<table>
<thead>
<tr>
<th>Category</th>
<th>Transfers</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Change in Estimated Transfers from FY 2017 IPF PPS to FY 2018 IPF PPS</strong></td>
<td></td>
</tr>
</tbody>
</table>

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


Seema Verma,
Administrator, Centers for Medicare & Medicaid Services.

Dated: July 24, 2017.

Thomas E. Price,
Secretary, Department of Health and Human Services.

[FR Doc. 2017–16430 Filed 8–2–17; 4:15 pm]
BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–1063]

Oncologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) announces a forthcoming public advisory committee meeting of the Oncologic Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA’s regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The public meeting will be held on September 19, 2017, from 8:30 a.m. to 1 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2017–N–1063. The docket will close on September 18, 2017. Submit either electronic or written comments on this public meeting by September 18, 2017.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 18, 2017. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of September 18, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Comments received on or before September 5, 2017, will be provided to the committee. Comments received after that date will be taken into consideration by the Agency.

Electronic Submissions

Submit electronic comments in the following way:

• Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

• Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2017–N–1063 for “Oncologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management