

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services****42 CFR Part 412**

[CMS-1608-F]

RIN 0938-AS09

Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2015**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.**ACTION:** Final rule.

SUMMARY: This final rule updates the prospective payment rates for inpatient rehabilitation facilities (IRFs) for federal fiscal year (FY) 2015 as required by the statute. This final rule finalizes a policy to collect data on the amount and mode (that is, Individual, Concurrent, Group, and Co-Treatment) of therapy provided in the IRF setting according to therapy discipline, revises the list of diagnosis and impairment group codes that presumptively meet the “60 percent rule” compliance criteria, provides a way for IRFs to indicate on the Inpatient Rehabilitation Facility-Patient Assessment Instrument (IRF-PAI) form whether the prior treatment and severity requirements have been met for arthritis cases to presumptively meet the “60 percent rule” compliance criteria, and revises and updates quality measures and reporting requirements under the IRF quality reporting program (QRP). This rule also delays the effective date for the revisions to the list of diagnosis codes that are used to determine presumptive compliance under the “60 percent rule” that were finalized in FY 2014 IRF PPS final rule and adopts the revisions to the list of diagnosis codes that are used to determine presumptive compliance under the “60 percent rule” that are finalized in this rule. This final rule also addresses the implementation of the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM), for the IRF prospective payment system (PPS), which will be effective when ICD-10-CM becomes the required medical data code set for use on Medicare claims and IRF-PAI submissions.

DATES: The updated IRF prospective payment rates are applicable for IRF

discharges occurring on or after October 1, 2014, and on or before September 30, 2015 (FY 2015). In addition, the revisions to the list of diagnosis codes that are used to determine presumptive compliance under the “60 percent rule” that were finalized in FY 2014 IRF PPS final rule (78 FR 47860) and the revisions to the lists of diagnosis codes and impairment group codes finalized in this rule are applicable for compliance review periods beginning on or after October 1, 2015. The change to the Inpatient Rehabilitation Facility-Patient Assessment Instrument (IRF-PAI) form to indicate whether the prior treatment and severity requirements have been met for arthritis cases to presumptively meet the “60 percent rule” compliance criteria is applicable October 1, 2015. The implementation of the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM), for the IRF prospective payment system (PPS), is applicable when ICD-10-CM becomes the required medical data code set for use on Medicare claims and IRF-PAI submissions. The updated quality measures and reporting requirements under the IRF QRP are applicable for IRF discharges occurring on or after October 1, 2014. The two new IRF quality measures will require data submission beginning with admissions and discharges occurring on or after January 1, 2015: (1) National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716); and (2) National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717).

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SUPPLEMENTARY INFORMATION: The IRF PPS Addenda along with other supporting documents and tables referenced in this final rule are available through the Internet on the CMS Web site at <http://www.cms.hhs.gov/>

Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/.

Executive Summary*A. Purpose*

This final rule updates the payment rates for IRFs for FY 2015 (that is, for discharges occurring on or after October 1, 2014, and on or before September 30, 2015) as required under section 1886(j)(3)(C) of the Social Security Act (the Act). Section 1886(j)(5) of the Act requires the Secretary to publish in the **Federal Register** on or before the August 1 that precedes the start of each fiscal year, the classification and weighting factors for the IRF PPS’s case-mix groups and a description of the methodology and data used in computing the prospective payment rates for that fiscal year. It also makes policy changes to programs associated with IRFs.

B. Summary of Major Provisions

In this final rule, we use the methods described in the FY 2014 IRF PPS final rule (78 FR 47860) to update the federal prospective payment rates for FY 2015 using updated FY 2013 IRF claims and the most recent available IRF cost report data. We are also finalizing a policy to collect data on the amount and mode (that is, Individual, Concurrent, Group, and Co-Treatment) of therapy provided in the IRF setting according to therapy discipline, revising the list of impairment group codes that presumptively meet the “60 percent rule” compliance criteria, providing a way for IRFs to indicate on the Inpatient Rehabilitation Facility-Patient Assessment Instrument (IRF-PAI) form whether the prior treatment and severity requirements have been met for arthritis cases to presumptively meet the “60 percent rule” compliance criteria, and revising and updating quality measures and reporting requirements under the IRF QRP. In this final rule, we also address the implementation of the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM), for the IRF prospective payment system (PPS), effective when ICD-10-CM becomes the required medical data code set for use on Medicare claims and IRF-PAI submissions.

C. Summary of Impacts

Provision description	Transfers
FY 2015 IRF PPS payment rate update	The overall economic impact of this final rule is an estimated \$180 million in increased payments from the Federal government to IRFs during FY 2015.
Provision description	Costs
New quality reporting program requirements	The total costs in FY 2015 for IRFs as a result of the new quality reporting requirements are estimated to be \$852,238
New Individual, Concurrent, Group, and Co-Treatment Therapy reporting requirements.	The total costs in FY 2016 for IRFs as a result of the new Individual, Concurrent, Group, and Co-Treatment reporting requirements are estimated to be \$1.2 million.

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

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Acronyms, Abbreviations, and Short Forms

Because of the many terms to which we refer by acronym, abbreviation, or short form in this final rule, we are listing the acronyms, abbreviation, and short forms used and their corresponding terms in alphabetical order below.

- The Act The Social Security Act
- ADC Average Daily Census
- The Affordable Care Act Patient Protection and Affordable Care Act (Pub. L. 111-148, enacted on March 23, 2010)
- AHIMA American Health Information Management Association
- ASCA Administrative Simplification Compliance Act (Pub. L. 107-105, enacted on December 27, 2002)
- BBA Balanced Budget Act of 1997 (Pub. L. 105-33, enacted on August 5, 1997)
- BLS U.S. Bureau of Labor Statistics
- CAH Critical Access Hospitals
- CAUTI Catheter-Associated Urinary Tract Infection
- CBSA Core-Based Statistical Area
- CCR Cost-to-Charge Ratio
- CDC The Centers for Disease Control and Prevention
- CDI *Clostridium difficile* Infection
- CFR Code of Federal Regulations
- CMG Case-Mix Group
- CMS Centers for Medicare & Medicaid Services
- DRA Deficit Reduction Act of 2005 (Pub. L. 109-171, enacted February 8, 2006)
- DSH Disproportionate Share Hospital
- DSH PP Disproportionate Share Patient Percentage
- EHR Electronic Health Record
- ESRD End-Stage Renal Disease
- FR **Federal Register**
- FY Federal Fiscal Year
- GEMS General Equivalence Mappings
- HAI Healthcare Associated Infection
- HCP Health Care Personnel
- HHS U.S. Department of Health & Human Services
- HIE Health Information Exchange

HIPAA Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191, enacted on August 21, 1996)

ICD–9–CM The International Classification of Diseases, 9th Revision, Clinical Modification

ICD–10–CM The International Classification of Diseases, 10th Revision, Clinical Modification

ICRs Information Collection Requirements

IGC Impairment Group Code

IGI IHS Global Insight

IPF Inpatient Psychiatric Facility

IPPS Inpatient Prospective Payment System

IQR Inpatient Quality Reporting Program

IRF Inpatient Rehabilitation Facility

IRF–PAI Inpatient Rehabilitation Facility–Patient Assessment Instrument

IRF PPS Inpatient Rehabilitation Facility Prospective Payment System

IRVEN Inpatient Rehabilitation Validation and Entry

LIP Low-Income Percentage

LPN Licensed Practical Nurse

LTCH Long-Term Care Hospital

MAC Medicare Administrative Contractor

MAP Measure Applications Partnership

MA (Medicare Part C) Medicare Advantage

MedPAC Medicare Payment Advisory Commission

MDS Minimum Data Set

MFP Multifactor Productivity

MMSEA Medicare, Medicaid, and SCHIP Extension Act of 2007 (Pub. L. 110–173, enacted on December 29, 2007)

MRSA Methicillin-Resistant *Staphylococcus aureus*

MUC Measures under Consideration

NHSN National Healthcare Safety Network

NPP National Priorities Partnership

NQF National Quality Forum

OMB Office of Management and Budget

ONC Office of the National Coordinator for Health Information Technology

PAI Patient Assessment Instrument

PPS Prospective Payment System

PRA Paperwork Reduction Act of 1995 (Pub. L. 104–13, enacted on May 22, 1995)

PRRB Provider Reimbursement Review Board

QM Quality Measure

QRP Quality Reporting Program

RIA Regulatory Impact Analysis

RIC Rehabilitation Impairment Category

RFA Regulatory Flexibility Act (Pub. L. 96–354, enacted on September 19, 1980)

RN Registered Nurse

RPL Rehabilitation, Psychiatric, and Long-Term Care market basket

SSI Supplemental Security Income

I. Background

A. Historical Overview of the Inpatient Rehabilitation Facility Prospective Payment System (IRF PPS)

Section 1886(j) of the Act provides for the implementation of a per-discharge prospective payment system (PPS) for inpatient rehabilitation hospitals and inpatient rehabilitation units of a hospital (collectively, hereinafter referred to as IRFs). Payments under the IRF PPS encompass inpatient operating and capital costs of furnishing covered

rehabilitation services (that is, routine, ancillary, and capital costs), but not direct graduate medical education costs, costs of approved nursing and allied health education activities, bad debts, and other services or items outside the scope of the IRF PPS. Although a complete discussion of the IRF PPS provisions appears in the original FY 2002 IRF PPS final rule (66 FR 41316) and the FY 2006 IRF PPS final rule (70 FR 47880), we are providing below a general description of the IRF PPS for fiscal years (FYs) 2002 through 2013.

Under the IRF PPS from FY 2002 through FY 2005, as described in the FY 2002 IRF PPS final rule (66 FR 41316), the federal prospective payment rates were computed across 100 distinct case-mix groups (CMGs). We constructed 95 CMGs using rehabilitation impairment categories (RICs), functional status (both motor and cognitive), and age (in some cases, cognitive status and age may not be a factor in defining a CMG). In addition, we constructed five special CMGs to account for very short stays and for patients who expire in the IRF.

For each of the CMGs, we developed relative weighting factors to account for a patient's clinical characteristics and expected resource needs. Thus, the weighting factors accounted for the relative difference in resource use across all CMGs. Within each CMG, we created tiers based on the estimated effects that certain comorbidities would have on resource use.

We established the federal PPS rates using a standardized payment conversion factor (formerly referred to as the budget-neutral conversion factor). For a detailed discussion of the budget-neutral conversion factor, please refer to our FY 2004 IRF PPS final rule (68 FR 45684 through 45685). In the FY 2006 IRF PPS final rule (70 FR 47880), we discussed in detail the methodology for determining the standard payment conversion factor.

We applied the relative weighting factors to the standard payment conversion factor to compute the unadjusted federal prospective payment rates under the IRF PPS from FYs 2002 through 2005. Within the structure of the payment system, we then made adjustments to account for interrupted stays, transfers, short stays, and deaths. Finally, we applied the applicable adjustments to account for geographic variations in wages (wage index), the percentage of low-income patients, location in a rural area (if applicable), and outlier payments (if applicable) to the IRFs' unadjusted federal prospective payment rates.

For cost reporting periods that began on or after January 1, 2002, and before

October 1, 2002, we determined the final prospective payment amounts using the transition methodology prescribed in section 1886(j)(1) of the Act. Under this provision, IRFs transitioning into the PPS were paid a blend of the federal IRF PPS rate and the payment that the IRFs would have received had the IRF PPS not been implemented. This provision also allowed IRFs to elect to bypass this blended payment and immediately be paid 100 percent of the federal IRF PPS rate. The transition methodology expired as of cost reporting periods beginning on or after October 1, 2002 (FY 2003), and payments for all IRFs now consist of 100 percent of the federal IRF PPS rate.

We established a CMS Web site as a primary information resource for the IRF PPS which is available at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/index.html>. The Web site may be accessed to download or view publications, software, data specifications, educational materials, and other information pertinent to the IRF PPS.

Section 1886(j) of the Act confers broad statutory authority upon the Secretary to propose refinements to the IRF PPS. In the FY 2006 IRF PPS final rule (70 FR 47880) and in correcting amendments to the FY 2006 IRF PPS final rule (70 FR 57166) that we published on September 30, 2005, we finalized a number of refinements to the IRF PPS case-mix classification system (the CMGs and the corresponding relative weights) and the case-level and facility-level adjustments. These refinements included the adoption of the Office of Management and Budget's (OMB) Core-Based Statistical Area (CBSA) market definitions, modifications to the CMGs, tier comorbidities, and CMG relative weights, implementation of a new teaching status adjustment for IRFs, revision and rebasing of the market basket index used to update IRF payments, and updates to the rural, low-income percentage (LIP), and high-cost outlier adjustments. Beginning with the FY 2006 IRF PPS final rule (70 FR 47908 through 47917), the market basket index used to update IRF payments is a market basket reflecting the operating and capital cost structures for freestanding IRFs, freestanding inpatient psychiatric facilities (IPFs), and long-term care hospitals (LTCHs) (hereafter referred to as the rehabilitation, psychiatric, and long-term care (RPL) market basket). Any reference to the FY 2006 IRF PPS final rule in this final rule also includes the provisions effective in the correcting

amendments. For a detailed discussion of the final key policy changes for FY 2006, please refer to the FY 2006 IRF PPS final rule (70 FR 47880 and 70 FR 57166).

In the FY 2007 IRF PPS final rule (71 FR 48354), we further refined the IRF PPS case-mix classification system (the CMG relative weights) and the case-level adjustments, to ensure that IRF PPS payments would continue to reflect as accurately as possible the costs of care. For a detailed discussion of the FY 2007 policy revisions, please refer to the FY 2007 IRF PPS final rule (71 FR 48354).

In the FY 2008 IRF PPS final rule (72 FR 44284), we updated the federal prospective payment rates and the outlier threshold, revised the IRF wage index policy, and clarified how we determine high-cost outlier payments for transfer cases. For more information on the policy changes implemented for FY 2008, please refer to the FY 2008 IRF PPS final rule (72 FR 44284), in which we published the final FY 2008 IRF federal prospective payment rates.

After publication of the FY 2008 IRF PPS final rule (72 FR 44284), section 115 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (Pub. L. 110–173, enacted on December 29, 2007) (MMSEA), amended section 1886(j)(3)(C) of the Act to apply a zero percent increase factor for FYs 2008 and 2009, effective for IRF discharges occurring on or after April 1, 2008. Section 1886(j)(3)(C) of the Act required the Secretary to develop an increase factor to update the IRF federal prospective payment rates for each FY. Based on the legislative change to the increase factor, we revised the FY 2008 federal prospective payment rates for IRF discharges occurring on or after April 1, 2008. Thus, the final FY 2008 IRF federal prospective payment rates that were published in the FY 2008 IRF PPS final rule (72 FR 44284) were effective for discharges occurring on or after October 1, 2007, and on or before March 31, 2008; and the revised FY 2008 IRF federal prospective payment rates were effective for discharges occurring on or after April 1, 2008, and on or before September 30, 2008. The revised FY 2008 federal prospective payment rates are available on the CMS Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Data-Files.html>.

In the FY 2009 IRF PPS final rule (73 FR 46370), we updated the CMG relative weights, the average length of stay values, and the outlier threshold; clarified IRF wage index policies regarding the treatment of “New

England deemed” counties and multi-campus hospitals; and revised the regulation text in response to section 115 of the MMSEA to set the IRF compliance percentage at 60 percent (the “60 percent rule”) and continue the practice of including comorbidities in the calculation of compliance percentages. We also applied a zero percent market basket increase factor for FY 2009 in accordance with section 115 of the MMSEA. For more information on the policy changes implemented for FY 2009, please refer to the FY 2009 IRF PPS final rule (73 FR 46370), in which we published the final FY 2009 IRF federal prospective payment rates.

In the FY 2010 IRF PPS final rule (74 FR 39762) and in correcting amendments to the FY 2010 IRF PPS final rule (74 FR 50712) that we published on October 1, 2009, we updated the federal prospective payment rates, the CMG relative weights, the average length of stay values, the rural, LIP, teaching status adjustment factors, and the outlier threshold; implemented new IRF coverage requirements for determining whether an IRF claim is reasonable and necessary; and revised the regulation text to require IRFs to submit patient assessments on Medicare Advantage (MA) (Medicare Part C) patients for use in the 60 percent rule calculations. Any reference to the FY 2010 IRF PPS final rule in this final rule also includes the provisions effective in the correcting amendments. For more information on the policy changes implemented for FY 2010, please refer to the FY 2010 IRF PPS final rule (74 FR 39762 and 74 FR 50712), in which we published the final FY 2010 IRF federal prospective payment rates.

After publication of the FY 2010 IRF PPS final rule (74 FR 39762), section 3401(d) of the Patient Protection and Affordable Care Act (Pub. L. 111–148, enacted on March 23, 2010), as amended by section 10319 of the same Act and by section 1105 of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152, enacted on March 30, 2010) (collectively, hereafter referred to as “The Affordable Care Act”), amended section 1886(j)(3)(C) of the Act and added section 1886(j)(3)(D) of the Act. Section 1886(j)(3)(C) of the Act requires the Secretary to estimate a multi-factor productivity adjustment to the market basket increase factor, and to apply other adjustments as defined by the Act. The productivity adjustment applies to FYs from 2012 forward. The other adjustments apply to FYs 2010 to 2019.

Sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(i) of the Act defined the

adjustments that were to be applied to the market basket increase factors in FYs 2010 and 2011. Under these provisions, the Secretary was required to reduce the market basket increase factor in FY 2010 by a 0.25 percentage point adjustment. Notwithstanding this provision, in accordance with section 3401(p) of the Affordable Care Act, the adjusted FY 2010 rate was only to be applied to discharges occurring on or after April 1, 2010. Based on the self-implementing legislative changes to section 1886(j)(3) of the Act, we adjusted the FY 2010 federal prospective payment rates as required, and applied these rates to IRF discharges occurring on or after April 1, 2010, and on or before September 30, 2010. Thus, the final FY 2010 IRF federal prospective payment rates that were published in the FY 2010 IRF PPS final rule (74 FR 39762) were used for discharges occurring on or after October 1, 2009, and on or before March 31, 2010, and the adjusted FY 2010 IRF federal prospective payment rates applied to discharges occurring on or after April 1, 2010, and on or before September 30, 2010. The adjusted FY 2010 federal prospective payment rates are available on the CMS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Data-Files.html>.

In addition, sections 1886(j)(3)(C) and (D) of the Act also affected the FY 2010 IRF outlier threshold amount because they required an adjustment to the FY 2010 RPL market basket increase factor, which changed the standard payment conversion factor for FY 2010. Specifically, the original FY 2010 IRF outlier threshold amount was determined based on the original estimated FY 2010 RPL market basket increase factor of 2.5 percent and the standard payment conversion factor of \$13,661. However, as adjusted, the IRF prospective payments are based on the adjusted RPL market basket increase factor of 2.25 percent and the revised standard payment conversion factor of \$13,627. To maintain estimated outlier payments for FY 2010 equal to the established standard of 3 percent of total estimated IRF PPS payments for FY 2010, we revised the IRF outlier threshold amount for FY 2010 for discharges occurring on or after April 1, 2010, and on or before September 30, 2010. The revised IRF outlier threshold amount for FY 2010 was \$10,721.

Sections 1886(j)(3)(c)(ii)(II) and 1886(j)(3)(D)(i) of the Act also required the Secretary to reduce the market basket increase factor in FY 2011 by a 0.25 percentage point adjustment. The FY 2011 IRF PPS notice (75 FR 42836)

and the correcting amendments to the FY 2011 IRF PPS notice (75 FR 70013) described the required adjustments to the FY 2011 and FY 2010 IRF PPS federal prospective payment rates and outlier threshold amount for IRF discharges occurring on or after April 1, 2010, and on or before September 30, 2011. It also updated the FY 2011 federal prospective payment rates, the CMG relative weights, and the average length of stay values. Any reference to the FY 2011 IRF PPS notice in this final rule also includes the provisions effective in the correcting amendments. For more information on the FY 2010 and FY 2011 adjustments or the updates for FY 2011, please refer to the FY 2011 IRF PPS notice (75 FR 42836 and 75 FR 70013).

In the FY 2012 IRF PPS final rule (76 FR 47836), we updated the IRF federal prospective payment rates, rebased and revised the RPL market basket, and established a new quality reporting program for IRFs in accordance with section 1886(j)(7) of the Act. We also revised regulation text for the purpose of updating and providing greater clarity. For more information on the policy changes implemented for FY 2012, please refer to the FY 2012 IRF PPS final rule (76 FR 47836), in which we published the final FY 2012 IRF federal prospective payment rates.

The FY 2013 IRF PPS notice (77 FR 44618) described the required adjustments to the FY 2013 federal prospective payment rates and outlier threshold amount for IRF discharges occurring on or after October 1, 2012, and on or before September 30, 2013. It also updated the FY 2013 federal prospective payment rates, the CMG relative weights, and the average length of stay values. For more information on the updates for FY 2013, please refer to the FY 2013 IRF PPS notice (77 FR 44618).

In the FY 2014 IRF PPS final rule (78 FR 47860), we updated the federal prospective payment rates, the CMG relative weights, and the outlier threshold amount. We also updated the facility-level adjustment factors using an enhanced estimation methodology, revised the list of diagnosis codes that count toward an IRF's 60 percent rule compliance calculation to determine "presumptive compliance," revised sections of the Inpatient Rehabilitation Facility-Patient Assessment Instrument (IRF-PAI), revised requirements for acute care hospitals that have IRF units, clarified the IRF regulation text regarding limitation of review, updated references to previously changed sections in the regulations text, and revised and updated quality measures

and reporting requirements under the IRF quality reporting program. For more information on the policy changes implemented for FY 2014, please refer to the FY 2014 IRF PPS final rule (78 FR 47860), in which we published the final FY 2014 IRF federal prospective payment rates.

B. Provisions of the Affordable Care Act Affecting the IRF PPS in FY 2012 and Beyond

The Affordable Care Act included several provisions that affect the IRF PPS in FYs 2012 and beyond. In addition to what was discussed above, section 3401(d) of the Affordable Care Act also added section 1886(j)(3)(C)(ii)(I) (providing for a "productivity adjustment" for fiscal year 2012 and each subsequent fiscal year). The productivity adjustment for FY 2015 is discussed in section VI.A. of this final rule. Section 3401(d) of the Affordable Care Act requires an additional 0.2 percentage point adjustment to the IRF increase factor for FY 2015, as discussed in section VI.A. of this final rule. Section 1886(j)(3)(C)(ii)(II) of the Act notes that the application of these adjustments to the market basket update may result in an update that is less than 0.0 for a fiscal year and in payment rates for a fiscal year being less than such payment rates for the preceding fiscal year.

Section 3004(b) of the Affordable Care Act also addressed the IRF PPS program. It reassigned the previously designated section 1886(j)(7) of the Act to section 1886(j)(8) and inserted a new section 1886(j)(7), which contains requirements for the Secretary to establish a quality reporting program for IRFs. Under that program, data must be submitted in a form and manner and at a time specified by the Secretary. Beginning in FY 2014, section 1886(j)(7)(A)(i) of the Act requires the application of a 2 percentage point reduction of the applicable market basket increase factor for IRFs that fail to comply with the quality data submission requirements. Application of the 2 percentage point reduction may result in an update that is less than 0.0 for a fiscal year and in payment rates for a fiscal year being less than such payment rates for the preceding fiscal year. Reporting-based reductions to the market basket increase factor will not be cumulative; they will only apply for the FY involved.

Under section 1886(j)(7)(D)(i) and (ii) of the Act, the Secretary is generally required to select quality measures for the IRF quality reporting program from those that have been endorsed by the consensus-based entity which holds a

performance measurement contract under section 1890(a) of the Act. This contract is currently held by the National Quality Forum (NQF). So long as due consideration is given to measures that have been endorsed or adopted by a consensus-based organization, section 1886(j)(7)(D)(ii) of the Act authorizes the Secretary to select non-endorsed measures for specified areas or medical topics when there are no feasible or practical endorsed measure(s).

Section 1886(j)(7)(E) of the Act requires the Secretary to establish procedures for making the IRF PPS quality reporting data available to the public. In so doing, the Secretary must ensure that IRFs have the opportunity to review any such data prior to its release to the public. Future rulemaking will address these public reporting obligations.

C. Operational Overview of the Current IRF PPS

As described in the FY 2002 IRF PPS final rule, upon the admission and discharge of a Medicare Part A Fee-for-Service patient, the IRF is required to complete the appropriate sections of a patient assessment instrument (PAI), designated as the IRF-PAI. In addition, beginning with IRF discharges occurring on or after October 1, 2009, the IRF is also required to complete the appropriate sections of the IRF-PAI upon the admission and discharge of each Medicare Part C (Medicare Advantage) patient, as described in the FY 2010 IRF PPS final rule. All required data must be electronically encoded into the IRF-PAI software product. Generally, the software product includes patient classification programming called the Grouper software. The Grouper software uses specific IRF-PAI data elements to classify (or group) patients into distinct CMGs and account for the existence of any relevant comorbidities.

The Grouper software produces a 5-character CMG number. The first character is an alphabetic character that indicates the comorbidity tier. The last 4 characters are numeric characters that represent the distinct CMG number. Free downloads of the Inpatient Rehabilitation Validation and Entry (IRVEN) software product, including the Grouper software, are available on the CMS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Software.html>.

Once a Medicare Fee-for-Service Part A patient is discharged, the IRF submits a Medicare claim as a Health Insurance Portability and Accountability Act of

1996 (Pub. L. 104–191, enacted on August 21, 1996) (HIPAA) compliant electronic claim or, if the Administrative Simplification Compliance Act of 2002 (Pub. L. 107–105, enacted on December 27, 2002) (ASCA) permits, a paper claim (a UB–04 or a CMS–1450 as appropriate) using the five-character CMG number and sends it to the appropriate Medicare Administrative Contractor (MAC). In addition, once a Medicare Advantage patient is discharged, in accordance with the Medicare Claims Processing Manual, chapter 3, section 20.3 (Pub. 100–04), hospitals (including IRFs) must submit an informational-only bill (TOB 111), which includes Condition Code 04 to their MAC. This will ensure that the Medicare Advantage days are included in the hospital's Supplemental Security Income (SSI) ratio (used in calculating the IRF low-income percentage adjustment) for Fiscal Year 2007 and beyond. Claims submitted to Medicare must comply with both ASCA and HIPAA.

Section 3 of the ASCA amends section 1862(a) of the Act by adding paragraph (22) which requires the Medicare program, subject to section 1862(h) of the Act, to deny payment under Part A or Part B for any expenses for items or services “for which a claim is submitted other than in an electronic form specified by the Secretary.” Section 1862(h) of the Act, in turn, provides that the Secretary shall waive such denial in situations in which there is no method available for the submission of claims in an electronic form or the entity submitting the claim is a small provider. In addition, the Secretary also has the authority to waive such denial “in such unusual cases as the Secretary finds appropriate.” For more information, see the “Medicare Program; Electronic Submission of Medicare Claims” final rule (70 FR 71008). Our instructions for the limited number of Medicare claims submitted on paper are available at <http://www.cms.gov/manuals/downloads/clm104c25.pdf>.

Section 3 of the ASCA operates in the context of the administrative simplification provisions of HIPAA, which include, among others, the requirements for transaction standards and code sets codified in 45 CFR, parts 160 and 162, subparts A and I through R (generally known as the Transactions Rule). The Transactions Rule requires covered entities, including covered health care providers, to conduct covered electronic transactions according to the applicable transaction standards. (See the CMS program claim memoranda at <http://www.cms.gov/ElectronicBillingEDITrans/> and listed in

the addenda to the Medicare Intermediary Manual, Part 3, section 3600).

The MAC processes the claim through its software system. This software system includes pricing programming called the “Pricer” software. The Pricer software uses the CMG number, along with other specific claim data elements and provider-specific data, to adjust the IRF's prospective payment for interrupted stays, transfers, short stays, and deaths, and then applies the applicable adjustments to account for the IRF's wage index, percentage of low-income patients, rural location, and outlier payments. For discharges occurring on or after October 1, 2005, the IRF PPS payment also reflects the teaching status adjustment that became effective as of FY 2006, as discussed in the FY 2006 IRF PPS final rule (70 FR 47880).

II. Summary of Provisions of the Proposed Rule

In the FY 2015 IRF PPS proposed rule (79 FR 26308), we proposed to update the IRF Federal prospective payment rates, to collect data on the amount and mode (that is, Individual, Group, and Co-Treatment) of therapies provided in the IRF setting according to therapy discipline, to revise the list of diagnosis and impairment group codes that presumptively meet the 60 percent rule compliance criteria, provide for a new item on the IRF–PAI form to indicate whether the prior treatment and severity requirements have been met for arthritis cases to presumptively meet the 60 percent rule compliance criteria, and to revise and update quality measures and reporting requirements under the IRF QRP. In the FY 2015 IRF PPS proposed rule (79 FR 26308), we also addressed the implementation of the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM), for the IRF prospective payment system (PPS), effective when ICD–10–CM becomes the required medical data code set for use on Medicare claims and IRF–PAI submissions.

The proposed updates to the IRF federal prospective payment rates for FY 2015 were as follows:

- Update the FY 2015 IRF PPS relative weights and average length of stay values using the most current and complete Medicare claims and cost report data in a budget-neutral manner, as discussed in section III of the FY 2015 IRF PPS proposed rule (79 FR 26308, 26314 through 26318).
- Discuss our rationale for freezing the IRF facility-level adjustment factors at FY 2014 levels, as discussed in

section IV of the FY 2015 IRF PPS proposed rule (79 FR 26308, 26318 through 26319).

- Update the FY 2015 IRF PPS payment rates by the proposed market basket increase factor, based upon the most current data available, with a 0.2 percentage point reduction as required by sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(iv) of the Act and a proposed productivity adjustment required by section 1886(j)(3)(C)(ii)(I) of the Act, as described in section V of the FY 2015 IRF PPS proposed rule (79 FR 26308, 26319 through 26321).

- Discuss the Secretary's Proposed Recommendation for updating IRF PPS payments for FY 2015, in accordance with the statutory requirements, as described in section V of the FY 2015 IRF PPS proposed rule (79 FR 26308 at 26321).

- Update the FY 2015 IRF PPS payment rates by the FY 2015 wage index and the labor-related share in a budget-neutral manner, as discussed in section V of the FY 2015 IRF PPS proposed rule (79 FR 26308, 26321 through 26322).

- Describe the calculation of the IRF Standard Payment Conversion Factor for FY 2015, as discussed in section V of the FY 2015 IRF PPS proposed rule (79 FR 26308 at 26322).

- Update the outlier threshold amount for FY 2015, as discussed in section VI of the FY 2015 IRF PPS proposed rule (79 FR 26308, 26324 through 26325).

- Update the cost-to-charge ratio (CCR) ceiling and urban/rural average CCRs for FY 2015, as discussed in section VI of the FY 2015 IRF PPS proposed rule (79 FR 26308 at 26325).

- Describe proposed revisions to the list of eligible diagnosis codes that are used to determine presumptive compliance under the 60 percent rule in section VII of the FY 2015 IRF PPS proposed rule (79 FR 26308 at 26327).

- Describe proposed revisions to the list of eligible impairment group codes that presumptively meet the 60 percent rule compliance criteria in section VII of the FY 2015 IRF PPS proposed rule (79 FR 26308, 26328 through 26329).

- Describe proposed data collection of the amount and mode (that is, of Individual, Group, and Co-Treatment) of therapies provided in IRFs according to occupational, speech, and physical therapy disciplines via the IRF–PAI in section VIII of the FY 2015 IRF PPS proposed rule (79 FR 26308, 26329 through 26330).

- Describe a proposed revision to the IRF–PAI to add a new data item for arthritis conditions in section IX of the

FY 2015 IRF PPS proposed rule (79 FR 26308, 26330 through 26331).

- Describe the conversion of the IRF PPS to ICD-10-CM, effective when ICD-10-CM becomes the required medical data code set for use on Medicare claims and IRF-PAI submissions, in section X of the FY 2015 IRF PPS proposed rule (79 FR 26308, 26331 through 26333).

- Describe proposed revisions and updates to quality measures and reporting requirements under the quality reporting program for IRFs in accordance with section 1886(j)(7) of the Act, as discussed in section XI of the FY 2015 IRF PPS proposed rule (79 FR 26308, 26333 through 26345).

III. Analysis and Responses to Public Comments

We received 66 timely responses from the public, many of which contained multiple comments on the FY 2015 IRF PPS proposed rule (79 FR 26308). We received comments from various trade associations, inpatient rehabilitation facilities, individual physicians, therapists, clinicians, health care industry organizations, law firms and health care consulting firms. The following sections, arranged by subject area, include a summary of the public comments that we received, and our responses.

IV. Update to the Case-Mix Group (CMG) Relative Weights and Average Length of Stay Values for FY 2015

As specified in § 412.620(b)(1), we calculate a relative weight for each CMG that is proportional to the resources needed by an average inpatient rehabilitation case in that CMG. For example, cases in a CMG with a relative weight of 2, on average, will cost twice as much as cases in a CMG with a relative weight of 1. Relative weights account for the variance in cost per discharge due to the variance in resource utilization among the payment groups, and their use helps to ensure that IRF PPS payments support beneficiary access to care, as well as provider efficiency.

In the FY 2015 IRF PPS proposed rule (79 FR 26308, 26314 through 26318), we proposed to update the CMG relative weights and average length of stay values for FY 2015. As required by statute, we always use the most recent available data to update the CMG relative weights and average lengths of stay. For FY 2015, we proposed to use the FY 2013 IRF claims and FY 2012 IRF cost report data. These data are the most current and complete data available at this time. Currently, only a small portion of the FY 2013 IRF cost report data are available for analysis, but the majority of the FY 2013 IRF claims data are available for analysis.

In the FY 2015 IRF PPS proposed rule (79 FR 26308, 26314 through 26318), we proposed to apply these data using the same methodologies that we have used to update the CMG relative weights and average length of stay values each fiscal year since we implemented an update to the methodology to use the more detailed cost-to-charge ratio (CCRs) data from the cost reports of IRF subprovider units of primary acute care hospitals, instead of CCR data from the associated primary care hospitals, to calculate IRFs' average costs per case, as discussed in the FY 2009 IRF PPS final rule (73 FR 46372). In calculating the CMG relative weights, we use a hospital-specific relative value method to estimate operating (routine and ancillary services) and capital costs of IRFs. The process used to calculate the CMG relative weights for this proposed rule is as follows:

Step 1. We estimate the effects that comorbidities have on costs.

Step 2. We adjust the cost of each Medicare discharge (case) to reflect the effects found in the first step.

Step 3. We use the adjusted costs from the second step to calculate CMG relative weights, using the hospital-specific relative value method.

Step 4. We normalize the FY 2015 CMG relative weights to the same average CMG relative weight from the CMG relative weights implemented in

the FY 2014 IRF PPS final rule (78 FR 47860).

Consistent with the methodology that we have used to update the IRF classification system in each instance in the past, we proposed to update the CMG relative weights for FY 2015 in such a way that total estimated aggregate payments to IRFs for FY 2015 are the same with or without the changes (that is, in a budget-neutral manner) by applying a budget neutrality factor to the standard payment amount. To calculate the appropriate budget neutrality factor for use in updating the FY 2015 CMG relative weights, we use the following steps:

Step 1. Calculate the estimated total amount of IRF PPS payments for FY 2015 (with no changes to the CMG relative weights).

Step 2. Calculate the estimated total amount of IRF PPS payments for FY 2015 by applying the changes to the CMG relative weights (as discussed above).

Step 3. Divide the amount calculated in step 1 by the amount calculated in step 2 to determine the budget neutrality factor (1.0000) that would maintain the same total estimated aggregate payments in FY 2015 with and without the changes to the CMG relative weights.

Step 4. Apply the budget neutrality factor (1.0000) to the FY 2014 IRF PPS standard payment amount after the application of the budget-neutral wage adjustment factor.

In section VI.F. of this final rule, we discuss the use of the existing methodology to calculate the standard payment conversion factor for FY 2015.

Table 1, "Relative Weights and Average Length of Stay Values for Case-Mix Groups," presents the CMGs, the comorbidity tiers, the corresponding relative weights, and the average length of stay values for each CMG and tier for FY 2015. The average length of stay for each CMG is used to determine when an IRF discharge meets the definition of a short-stay transfer, which results in a per diem case level adjustment.

TABLE 1—RELATIVE WEIGHTS AND AVERAGE LENGTH OF STAY VALUES FOR CASE-MIX GROUPS

CMG	CMG description (M=motor, C=cognitive, A=age)	Relative weight				Average length of stay			
		Tier 1	Tier 2	Tier 3	None	Tier 1	Tier 2	Tier 3	None
0101	Stroke M>51.05	0.7853	0.7150	0.6512	0.6248	9	10	8	8
0102	Stroke M>44.45 and M<51.05 and C>18.5.	0.9836	0.8955	0.8155	0.7826	11	11	10	10
0103	Stroke M>44.45 and M<51.05 and C<18.5.	1.1636	1.0594	0.9648	0.9258	12	14	12	12
0104	Stroke M>38.85 and M<44.45	1.2121	1.1036	1.0050	0.9644	13	13	12	12
0105	Stroke M>34.25 and M<38.85	1.4155	1.2888	1.1737	1.1262	14	14	14	14
0106	Stroke M>30.05 and M<34.25	1.6135	1.4691	1.3379	1.2838	16	16	15	15
0107	Stroke M>26.15 and M<30.05	1.8026	1.6412	1.4946	1.4342	17	19	17	17

TABLE 1—RELATIVE WEIGHTS AND AVERAGE LENGTH OF STAY VALUES FOR CASE-MIX GROUPS—Continued

CMG	CMG description (M=motor, C=cognitive, A=age)	Relative weight				Average length of stay			
		Tier 1	Tier 2	Tier 3	None	Tier 1	Tier 2	Tier 3	None
0108	Stroke M<26.15 and A>84.5 ..	2.2467	2.0456	1.8629	1.7876	22	24	21	21
0109	Stroke M>22.35 and M<26.15 and A<84.5.	2.0570	1.8728	1.7055	1.6366	19	20	19	19
0110	Stroke M<22.35 and A<84.5 ..	2.6928	2.4518	2.2328	2.1425	28	27	24	24
0201	Traumatic brain injury M>53.35 and C>23.5.	0.8145	0.6636	0.5954	0.5680	10	9	8	8
0202	Traumatic brain injury M>44.25 and M<53.35 and C>23.5.	1.0591	0.8629	0.7741	0.7385	12	10	9	10
0203	Traumatic brain injury M>44.25 and C<23.5.	1.2162	0.9909	0.8890	0.8481	13	12	12	11
0204	Traumatic brain injury M>40.65 and M<44.25.	1.3397	1.0915	0.9793	0.9342	12	13	12	12
0205	Traumatic brain injury M>28.75 and M<40.65.	1.5924	1.2974	1.1640	1.1104	14	15	14	14
0206	Traumatic brain injury M>22.05 and M<28.75.	1.9327	1.5747	1.4127	1.3477	19	18	16	16
0207	Traumatic brain injury M<22.05.	2.5640	2.0890	1.8741	1.7880	32	25	21	20
0301	Non-traumatic brain injury M>41.05.	1.1022	0.9324	0.8453	0.7798	10	11	10	10
0302	Non-traumatic brain injury M>35.05 and M<41.05.	1.3799	1.1673	1.0582	0.9762	13	13	12	12
0303	Non-traumatic brain injury M>26.15 and M<35.05.	1.6371	1.3849	1.2555	1.1583	16	15	14	14
0304	Non-traumatic brain injury M<26.15.	2.1541	1.8222	1.6520	1.5240	23	21	18	17
0401	Traumatic spinal cord injury M>48.45.	1.0264	0.8790	0.8131	0.7251	12	12	10	9
0402	Traumatic spinal cord injury M>30.35 and M<48.45.	1.4108	1.2081	1.1176	0.9966	15	14	14	13
0403	Traumatic spinal cord injury M>16.05 and M<30.35.	2.3059	1.9747	1.8268	1.6289	26	21	20	20
0404	Traumatic spinal cord injury M<16.05 and A>63.5.	4.0832	3.4967	3.2348	2.8845	54	40	33	33
0405	Traumatic spinal cord injury M<16.05 and A<63.5.	3.3355	2.8564	2.6425	2.3563	26	34	29	27
0501	Non-traumatic spinal cord in- jury M>51.35.	0.8418	0.6804	0.6237	0.5643	9	10	9	8
0502	Non-traumatic spinal cord in- jury M>40.15 and M<51.35.	1.1580	0.9359	0.8579	0.7763	11	12	10	10
0503	Non-traumatic spinal cord in- jury M>31.25 and M<40.15.	1.4373	1.1616	1.0648	0.9635	15	13	13	12
0504	Non-traumatic spinal cord in- jury M>29.25 and M<31.25.	1.6935	1.3687	1.2546	1.1352	17	15	15	14
0505	Non-traumatic spinal cord in- jury M>23.75 and M<29.25.	1.9365	1.5651	1.4346	1.2981	20	17	17	16
0506	Non-traumatic spinal cord in- jury M<23.75.	2.7066	2.1875	2.0052	1.8144	26	25	23	21
0601	Neurological M>47.75	1.0293	0.8149	0.7526	0.6862	9	10	9	9
0602	Neurological M>37.35 and M<47.75.	1.3283	1.0516	0.9713	0.8856	12	12	11	11
0603	Neurological M>25.85 and M<37.35.	1.6727	1.3243	1.2231	1.1152	15	15	13	13
0604	Neurological M<25.85	2.1908	1.7345	1.6020	1.4607	21	19	17	17
0701	Fracture of lower extremity M>42.15.	0.9700	0.8060	0.7727	0.7036	10	9	10	9
0702	Fracture of lower extremity M>34.15 and M<42.15.	1.2429	1.0327	0.9901	0.9016	13	12	12	11
0703	Fracture of lower extremity M>28.15 and M<34.15.	1.5056	1.2511	1.1994	1.0922	15	15	14	13
0704	Fracture of lower extremity M<28.15.	1.9359	1.6086	1.5421	1.4044	19	18	17	17
0801	Replacement of lower extrem- ity joint M>49.55.	0.7402	0.6068	0.5608	0.5172	8	8	7	7
0802	Replacement of lower extrem- ity joint M>37.05 and M<49.55.	0.9891	0.8109	0.7495	0.6912	10	10	9	9

TABLE 1—RELATIVE WEIGHTS AND AVERAGE LENGTH OF STAY VALUES FOR CASE-MIX GROUPS—Continued

CMG	CMG description (M=motor, C=cognitive, A=age)	Relative weight				Average length of stay			
		Tier 1	Tier 2	Tier 3	None	Tier 1	Tier 2	Tier 3	None
0803	Replacement of lower extremity joint M>28.65 and M<37.05 and A>83.5.	1.3374	1.0963	1.0133	0.9345	13	13	12	12
0804	Replacement of lower extremity joint M>28.65 and M<37.05 and A<83.5.	1.1821	0.9690	0.8956	0.8260	12	12	11	10
0805	Replacement of lower extremity joint M>22.05 and M<28.65.	1.4702	1.2053	1.1140	1.0274	14	14	13	12
0806	Replacement of lower extremity joint M<22.05.	1.7663	1.4479	1.3383	1.2342	16	17	15	14
0901	Other orthopedic M>44.75	0.9386	0.7581	0.7069	0.6392	10	9	9	8
0902	Other orthopedic M>34.35 and M<44.75.	1.2382	1.0000	0.9325	0.8432	12	12	11	10
0903	Other orthopedic M>24.15 and M<34.35.	1.5552	1.2561	1.1713	1.0591	15	15	14	13
0904	Other orthopedic M<24.15	1.9772	1.5968	1.4890	1.3464	19	18	17	16
1001	Amputation, lower extremity M>47.65.	1.0224	0.9300	0.8055	0.7365	11	12	10	10
1002	Amputation, lower extremity M>36.25 and M<47.65.	1.3168	1.1978	1.0374	0.9485	14	14	12	11
1003	Amputation, lower extremity M<36.25.	1.8778	1.7081	1.4794	1.3527	18	19	17	16
1101	Amputation, non-lower extremity M>36.35.	1.2643	1.0143	1.0050	0.8569	12	13	12	10
1102	Amputation, non-lower extremity M<36.35.	1.8936	1.5192	1.5052	1.2835	17	19	16	15
1201	Osteoarthritis M>37.65	1.0034	0.9522	0.8881	0.8256	10	11	11	10
1202	Osteoarthritis M>30.75 and M<37.65.	1.1916	1.1308	1.0547	0.9805	11	12	12	12
1203	Osteoarthritis M<30.75	1.5133	1.4360	1.3393	1.2452	13	16	15	15
1301	Rheumatoid, other arthritis M>36.35.	1.2220	0.9887	0.8677	0.8181	12	12	10	10
1302	Rheumatoid, other arthritis M>26.15 and M<36.35.	1.5913	1.2874	1.1299	1.0653	17	14	13	13
1303	Rheumatoid, other arthritis M<26.15.	2.0302	1.6425	1.4416	1.3591	18	19	16	15
1401	Cardiac M>48.85	0.9032	0.7324	0.6671	0.6051	9	10	8	8
1402	Cardiac M>38.55 and M<48.85.	1.1947	0.9689	0.8825	0.8004	12	11	11	10
1403	Cardiac M>31.15 and M<38.55.	1.4699	1.1920	1.0857	0.9847	14	13	12	12
1404	Cardiac M<31.15	1.8493	1.4998	1.3660	1.2390	18	17	15	14
1501	Pulmonary M>49.25	0.9998	0.8150	0.7537	0.7283	10	10	9	8
1502	Pulmonary M>39.05 and M<49.25.	1.2986	1.0586	0.9791	0.9461	13	11	11	10
1503	Pulmonary M>29.15 and M<39.05.	1.5918	1.2976	1.2001	1.1597	15	14	13	13
1504	Pulmonary M<29.15	1.9688	1.6049	1.4843	1.4343	20	17	15	15
1601	Pain syndrome M>37.15	0.9445	0.8763	0.8085	0.7620	10	10	9	10
1602	Pain syndrome M>26.75 and M<37.15.	1.2509	1.1606	1.0708	1.0092	13	13	13	12
1603	Pain syndrome M<26.75	1.5845	1.4703	1.3565	1.2784	14	17	16	15
1701	Major multiple trauma without brain or spinal cord injury M>39.25.	1.0432	0.9290	0.8566	0.7881	11	11	10	10
1702	Major multiple trauma without brain or spinal cord injury M>31.05 and M<39.25.	1.3109	1.1674	1.0764	0.9903	13	14	12	12
1703	Major multiple trauma without brain or spinal cord injury M>25.55 and M<31.05.	1.5378	1.3694	1.2627	1.1617	16	16	15	14
1704	Major multiple trauma without brain or spinal cord injury M<25.55.	1.9856	1.7682	1.6303	1.5000	20	20	18	17
1801	Major multiple trauma with brain or spinal cord injury M>40.85.	1.0662	0.9437	0.8082	0.7231	11	11	10	9

TABLE 1—RELATIVE WEIGHTS AND AVERAGE LENGTH OF STAY VALUES FOR CASE-MIX GROUPS—Continued

CMG	CMG description (M=motor, C=cognitive, A=age)	Relative weight				Average length of stay			
		Tier 1	Tier 2	Tier 3	None	Tier 1	Tier 2	Tier 3	None
1802	Major multiple trauma with brain or spinal cord injury M>23.05 and M<40.85.	1.6884	1.4945	1.2798	1.1451	17	16	15	14
1803	Major multiple trauma with brain or spinal cord injury M<23.05.	2.8097	2.4869	2.1297	1.9055	32	28	22	22
1901	Guillain Barre M>35.95	1.0421	0.9341	0.9263	0.8837	15	10	13	11
1902	Guillain Barre M>18.05 and M<35.95.	1.8757	1.6814	1.6672	1.5905	25	19	18	19
1903	Guillain Barre M<18.05	3.3752	3.0255	3.0000	2.8620	44	31	36	31
2001	Miscellaneous M>49.15	0.8827	0.7250	0.6681	0.6098	9	8	8	8
2002	Miscellaneous M>38.75 and M<49.15.	1.1872	0.9751	0.8986	0.8201	12	11	11	10
2003	Miscellaneous M>27.85 and M<38.75.	1.5061	1.2370	1.1400	1.0405	15	14	13	12
2004	Miscellaneous M<27.85	1.9507	1.6021	1.4765	1.3475	20	18	16	15
2101	Burns M>0	1.8405	1.6766	1.5548	1.3534	27	18	17	16
5001	Short-stay cases, length of stay is 3 days or fewer.	0.1549	2
5101	Expired, orthopedic, length of stay is 13 days or fewer.	0.6791	7
5102	Expired, orthopedic, length of stay is 14 days or more.	1.5539	16
5103	Expired, not orthopedic, length of stay is 15 days or fewer.	0.7274	8
5104	Expired, not orthopedic, length of stay is 16 days or more.	1.9477	21

Generally, updates to the CMG relative weights result in some increases and some decreases to the CMG relative weight values. Table 2 shows how we estimate that the application of the proposed revisions for FY 2015 would affect particular CMG relative weight

values, which would affect the overall distribution of payments within CMGs and tiers. Note that, because we propose to implement the CMG relative weight revisions in a budget-neutral manner (as described above), total estimated aggregate payments to IRFs for FY 2015

would not be affected as a result of the proposed CMG relative weight revisions. However, the revisions will affect the distribution of payments within CMGs and tiers.

TABLE 2—DISTRIBUTIONAL EFFECTS OF THE CHANGES TO THE CMG RELATIVE WEIGHTS
[FY 2014 values compared with FY 2015 values]

Percentage change	Number of cases affected	Percentage of cases affected
Increased by 15% or more	0	0.0
Increased by between 5% and 15%	1,023	0.3
Changed by less than 5%	382,960	99.4
Decreased by between 5% and 15%	1,288	0.3
Decreased by 15% or more	25	0.0

As Table 2 shows, more than 99 percent of all IRF cases are in CMGs and tiers that will experience less than a 5 percent change (either increase or decrease) in the CMG relative weight value as a result of the revisions for FY 2015. The largest estimated increase in the proposed CMG relative weight values that affects the largest number of IRF discharges is a 1.2 percent increase in the CMG relative weight value for CMG 0704—Fracture of lower extremity, with a motor score less than 28.15 in the

“no comorbidity” tier. In the FY 2013 claims data, 20,017 IRF discharges (5.2 percent of all IRF discharges) were classified into this CMG and tier.

The largest decrease in a CMG relative weight value affecting the largest number of IRF cases is a 0.8 percent decrease in the CMG relative weight for CMG 0604—Neurological, with a motor score less than 25.85 in the “no comorbidity” tier. In the FY 2013 IRF claims data, this change would have

affected 8,766 cases (2.3 percent of all IRF cases).

The changes in the average length of stay values for FY 2015, compared with the FY 2014 average length of stay values, are small and do not show any particular trends in IRF length of stay patterns.

We received 1 comment on the proposed update to the CMG relative weights and average length of stay values for FY 2015, which is summarized below.

Comment: The commenter requested that we provide more detail about the use of the CCR data in the CMG relative weight calculations. Additionally, the commenter requested that we outline the methodology used to calculate the average length of stay values in the IRF PPS rule.

Response: A key variable used to calculate the CMG relative weights is a facility's average cost per case, which is obtained by averaging the estimated cost per case for every patient discharged from the facility in a given fiscal year. To obtain the estimated cost per case for a given IRF patient, we start by pulling the appropriate charges from the Medicare claim for that patient. Then, we calculate the appropriate CCRs from the Medicare cost report submitted by the facility. The CCRs are then multiplied by the charges from the Medicare claim to obtain the estimated IRF cost for the case. This variable is used as the dependent variable in the regression analysis to estimate the CMG relative weights.

In conjunction with the publication of the IRF PPS FY 2014 final rule, we posted our methodology for calculating the average length of stay values on the IRF PPS Web site at <http://www.cms.gov/medicare-fee-for-service-payment/inpatientrehab/facpps/research.html>.

Final Decision: After careful consideration of the public comments, we are finalizing our proposal to update the CMG relative weight and average length of stay values for FY 2015. These updates are effective October 1, 2014.

V. Freezing the Facility-Level Adjustment Factors at FY 2014 Levels

A. Background on Facility-Level Adjustments

Section 1886(j)(3)(A)(v) of the Act confers broad authority upon the Secretary to adjust the per unit payment rate "by such . . . factors as the Secretary determines are necessary to properly reflect variations in necessary costs of treatment among rehabilitation facilities." For example, we adjust the federal prospective payment amount associated with a CMG to account for facility-level characteristics such as an IRF's LIP, teaching status, and location in a rural area, if applicable, as described in § 412.624(e).

In the FY 2010 IRF PPS final rule (74 FR 39762), we updated the adjustment factors for calculating the rural, LIP, and teaching status adjustments based on the most recent three consecutive years' worth of IRF claims data (at that time, FY 2006, FY 2007, and FY 2008) and the most recent available corresponding IRF

cost report data. As discussed in the FY 2010 IRF PPS proposed rule (74 FR 21060 through 21061), we observed relatively large year-to-year fluctuations in the underlying data used to compute the adjustment factors, especially the teaching status adjustment factor. Therefore, we implemented a 3-year moving average approach to updating the facility-level adjustment factors in the FY 2010 IRF PPS final rule (74 FR 39762) to provide greater stability and predictability of Medicare payments for IRFs.

Each year, we review the major components of the IRF PPS to maintain and enhance the accuracy of the payment system. For FY 2010, we implemented a change to our methodology that was designed to decrease the IRF PPS volatility by using a 3-year moving average to calculate the facility-level adjustment factors. For FY 2011, we issued a notice to update the payment rates, which did not include any policy changes or changes to the IRF facility-level adjustments. As we found that the implementation of the 3-year moving average did not fully address year-to-year fluctuations, in the FY 2012 IRF PPS proposed rule (76 FR 24214, 24225 through 24226), we analyzed the effects of having used a weighting methodology. The methodology assigned greater weight to some facilities than to others in the regression analysis used to estimate the facility-level adjustment factors. As we found that this weighting methodology inappropriately exaggerated the cost differences among different types of IRF facilities, we proposed to remove the weighting factor from our analysis and update the IRF facility-level adjustment factors for FY 2012 using an unweighted regression analysis. However, after carefully considering all of the comments that we received on the proposed FY 2012 updates to the facility-level adjustment factors, we decided to hold the facility-level adjustment factors at FY 2011 levels for FY 2012 to conduct further research on the underlying data and the best methodology for calculating the facility-level adjustment factors. We based this decision, in part, on comments we received about the financial hardships that the proposed updates would create for facilities with teaching programs and a higher disproportionate share of low-income patients.

B. Freezing the Facility-Level Adjustment Factors at FY 2014 Levels

Since the FY 2012 final rule (76 FR 47836), we have conducted further research into the best methodology to use to estimate the IRF facility-level

adjustment factors, to ensure that the adjustment factors reflect as accurately as possible the costs of providing IRF care across the full spectrum of IRF providers. Our recent research efforts reflect the significant differences that exist between the cost structures of freestanding IRFs and the cost structures of IRF units of acute care hospitals (and critical access hospitals, otherwise known as "CAHs"). We have found that these cost structure differences substantially influence the estimates of the adjustment factors. Therefore, we believe that it is important to control for these cost structure differences between hospital-based and freestanding IRFs in our regression analysis, so that these differences do not inappropriately influence the adjustment factor estimates. In Medicare's payment system for the treatment of end-stage renal disease (ESRD), we already control for the cost structure differences between hospital-based and freestanding facilities in the regression analyses that are used to set payment rates. Also, we received comments from an IRF industry association on the FY 2012 IRF PPS proposed rule suggesting that the addition of this particular control variable to the model could improve the methodology for estimating the IRF facility-level adjustment factors.

Thus, in the FY 2014 IRF PPS proposed rule, we proposed to add an indicator variable to our 3-year moving average methodology for updating the IRF facility-level adjustments that would have an assigned value of "1" if the facility is a freestanding IRF hospital or would have an assigned value of "0" if the facility is an IRF unit of an acute care hospital (or CAH). Adding this variable to the regression analysis enables us to control for the differences in costs that are primarily due to the differences in cost structures between freestanding and hospital-based IRFs, so that those differences do not become inappropriately intertwined with our estimates of the differences in costs between rural and urban facilities, high-LIP percentage and low-LIP percentage facilities, and teaching and non-teaching facilities. Further, by including this variable in the regression analysis, we greatly improve our ability to predict an IRF's average cost per case (that is, the R-squared of the regression model increases from about 11 percent to about 41 percent). In this way, it enhances the precision with which we can estimate the IRF facility-level adjustments.

In the FY 2014 IRF PPS final rule (78 FR 47860), we finalized our decision to add an indicator variable for a facility's freestanding/hospital-based status to the payment regression, and, with that

change, to update the IRF facility-level adjustment factors for FY 2014 using the same methodology, with the exception of adding the indicator variable, that we used in updating the FY 2010 IRF facility-level adjustment factors, including the 3-year moving average approach. Thus, in the FY 2014 IRF PPS final rule, we finalized a rural adjustment of 14.9 percent, a LIP adjustment factor of 0.3177, and a teaching status adjustment factor of 1.0163 for FY 2014.

Based on the substantive changes to the facility-level adjustment factors that were adopted in the FY 2014 final rule, we are freezing the facility-level adjustment factors for FY 2015 and all subsequent years at the FY 2014 levels while we continue to monitor the most current IRF claims data available and evaluate the effects of the FY 2014 changes. Additionally, we want to allow providers time to acclimate to the FY 2014 changes. At such future time as our data analysis may indicate the need for further updates to the facility-level adjustment factors, we would propose to update the adjustment factors through notice and comment rulemaking.

We received 4 comments on our proposal to freeze the facility-level adjustment factors at FY 2014 levels for FY 2015 and all subsequent years (unless and until we propose to update them again through future notice and comment rulemaking), which are summarized below.

Comment: The majority of commenters support our proposal to freeze the facility-level adjustment factors. However, those same commenters encourage CMS to continue to analyze changes to the facility-level adjustments and adjust all three factors at a minimum of every three years. Additionally, commenters recommended that CMS make the methodology and findings available to the public.

Response: We appreciate the commenters' support with our decision to freeze the facility-level adjustment factors. As discussed in the proposed rule, we believe that it is appropriate to freeze the facility-level adjustment factors at FY 2014 levels while we continue to monitor the most current IRF claims data available and evaluate the effects of the FY 2014 changes. Additionally, this will allow providers time to acclimate to the FY 2014 changes that were implemented. We will continue to monitor the data and periodically update the adjustment factors, as needed, to ensure the accuracy of IRF PPS payment rates. Rather than specify an exact period, such as every 3 years, for updating the

adjustment factors, we believe that it is better for the overall efficiency of the IRF PPS payment system to update the adjustment factors whenever it appears that the benefits of updating (in terms of improved accuracy of payment rates) outweigh the costs (in terms of less stability in the annual payment rates). At such time as we determine that the data support updating the adjustment factors or changes in the methodology, we will make our findings available through the rulemaking process.

Comment: One commenter suggested that CMS be more transparent about the criteria the agency is using to determine when changes to the facility-level adjustments occur. For example, the commenter suggested CMS adopt a minimum threshold of annual change for the adjustment factors, such as 5 to 10 percent and examine unfreezing the adjustment factors and issuing an update if analysis finds that any of the factors meet or exceed the suggested threshold.

Response: While we agree with transparency during this process, we do not believe that setting a minimum threshold of annual change would be beneficial to the industry or to the Medicare program. As stated in our previous response, we believe that monitoring the data and making periodic changes when the benefits of such changes outweigh the costs is the most appropriate way to enhance both the accuracy and the stability of the IRF PPS payment system. In addition, we disagree with the suggestion that we should publicize the interim results that we use in making these determinations each time. We believe that this would only serve to confuse the industry, as the adjustment factors tend to fluctuate significantly from one period to the next and providers would potentially be confused about which adjustment factors were being proposed for implementation and which ones were not.

Comment: One commenter suggested that depending on the magnitude of any change in facility level adjustments, CMS should also propose a transition to phase in the implementation.

Response: Thank you for your comment. We will certainly take this recommendation into consideration for the future.

Final Decision: After careful consideration of the public comments, we are finalizing our proposal to freeze the facility-level adjustment factors for FY 2015 and all subsequent years (unless and until we propose to update them again through future notice and comment rulemaking).

VI. FY 2015 IRF PPS Federal Prospective Payment Rates

A. Market Basket Increase Factor, Productivity Adjustment, and Other Adjustment for FY 2015

Section 1886(j)(3)(C) of the Act requires the Secretary to establish an increase factor that reflects changes over time in the prices of an appropriate mix of goods and services included in the covered IRF services, which is referred to as a market basket index. According to section 1886(j)(3)(A)(i) of the Act, the increase factor shall be used to update the IRF federal prospective payment rates for each FY. Sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(iv) of the Act required the application of a 0.2 percentage point reduction to the market basket increase factor for FY 2015. In addition, section 1886(j)(3)(C)(ii)(I) of the Act requires the application of a productivity adjustment, as described below. Thus, in the FY 2015 IRF PPS proposed rule, we proposed to update the IRF PPS payments for FY 2015 by a market basket increase factor based upon the most current data available, with a productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act, as described below and a 0.2 percentage point reduction as required by sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(iv) of the Act.

For this final rule, we use the same methodology described in the FY 2012 IRF PPS final rule (76 FR 47836 at 47848 through 47863) to compute the FY 2015 market basket increase factor and labor-related share. In that final rule, we described the market basket (referred to as the RPL market basket) as reflecting a FY 2008 base year. Based on IHS Global Insight's second quarter 2014 forecast, the most recent estimate of the 2008-based RPL market basket increase factor for FY 2015 is 2.9 percent. IHS Global Insight (IGI) is an economic and financial forecasting firm that contracts with CMS to forecast the components of providers' market baskets.

In accordance with section 1886(j)(3)(C)(ii)(I) of the Act, and using the methodology described in the FY 2012 IRF PPS final rule (76 FR 47836, 47858 through 47859), we apply a productivity adjustment to the FY 2015 RPL market basket increase factor. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable FY cost reporting period, or other

annual period) (the “MFP adjustment”). The Bureau of Labor Statistics (BLS) is the agency that publishes the official measure of private nonfarm business MFP. We refer readers to the BLS Web site at <http://www.bls.gov/mfp> to obtain the historical BLS-published MFP data. The projection of MFP is currently produced by IGI, using the methodology described in the FY 2012 IRF PPS final rule (76 FR 47836, 47859). The most recent estimate of the MFP adjustment for FY 2015 (the 10-year moving average of MFP for the period ending FY 2015) is 0.5 percent, which was calculated using the methodology described in the FY 2012 IRF PPS final rule (76 FR 47836, 47858 through 47859) and is based on IGI’s second quarter 2014 forecast.

Thus, in accordance with section 1886(j)(3)(C) of the Act, we base the FY 2015 market basket update, which is used to determine the applicable percentage increase for the IRF payments, on the most recent estimate of the FY 2008-based RPL market basket (currently estimated to be 2.9 percent based on IGI’s second quarter 2014 forecast). We then reduce this percentage increase by the current estimate of the MFP adjustment for FY 2015 of 0.5 percentage point (the 10-year moving average of MFP for the period ending FY 2015 based on IGI’s second quarter 2014 forecast), which was calculated as described in the FY 2012 IRF PPS final rule (76 FR 47836, 47859). Following application of the MFP, we further reduce the applicable percentage increase by 0.2 percentage point, as required by sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(iv) of the Act. Therefore, the current estimate of the FY 2015 IRF update is 2.2 percent (2.9 percent market basket update, less 0.5 percentage point MFP adjustment, less 0.2 percentage point legislative adjustment).

We received 5 comments on the proposed market basket increase factor, which are summarized below.

Comment: While several commenters supported the update to IRF payment rates for FY 2015, one commenter stated that the update to the IRF payment rates is not warranted based on the review of many factors—including indicators of beneficiary access to rehabilitative services, the supply of providers, and Medicare margins. The commenter said that Medicare’s current payment rates for IRFs appear to be adequate and, therefore, recommended no update to IRF payment rates for FY 2015.

Response: We are finalizing the IRF PPS payment update for FY 2015 of 2.2 percent (2.9 percent market basket update, less 0.5 percentage point MFP

adjustment, less 0.2 percentage point legislative adjustment), as section 1886(j)(3)(C) of the Act does not provide the Secretary with the authority to apply a different update factor to IRF PPS payment rates for FY 2015.

Comment: Several commenters expressed concern about the applicability of the productivity adjustment to the IRF setting. One commenter suggested that we take into consideration the unique needs of rehabilitation patients and the highly skilled professional teams who provide their care. This commenter also stated that CMS should be mindful that increasing reimbursement financial pressures without allowing IRFs to improve their efficiency in ways that best serve patients may result in barriers to access for the most complex and needy Medicare beneficiaries. Another commenter noted that while CMS is bound by the Affordable Care Act to apply specific market basket reductions to the full market basket update in FY 2015 and subsequent years, they believe it is unlikely that productivity improvements will be generated by rehabilitation hospitals at a pace matching the productivity of the economy at large on an ongoing, consistent basis. The commenter also noted that services provided in rehabilitation hospitals are very labor intensive through the provision of hands-on care by physical therapists, occupational therapists, speech therapists and rehabilitation nursing staff, and that many of the treatment plans do not lend themselves to continual productivity improvements. The commenter said that we should carefully monitor the impact that the productivity adjustments have on IRFs and provide feedback to Congress as appropriate.

Response: Section 1886(j)(3)(C)(ii)(I) of the Act requires the application of a productivity adjustment that must be applied to the IRF PPS market basket update. We will continue to monitor the impact of the payment updates, including the effects of the productivity adjustment, on IRF provider margins as well as beneficiary access to care.

Final Decision: Based on careful consideration of the comments, we are finalizing the FY 2015 market basket update for IRF payments of 2.2 percent, which is the most recent estimate of the FY 2008-based RPL market basket adjusted for productivity and the FY15 legislative reduction. Therefore, the current estimate of the FY 2015 IRF update is 2.2 percent (2.9 percent market basket update, less 0.5 percentage point MFP adjustment, less

0.2 percentage point legislative adjustment).

B. Development of an IRF-Specific Market Basket

In the FY 2010 IRF PPS proposed rule (74 FR 21062), we expressed our interest in exploring the possibility of creating a stand-alone, or IRF-specific, market basket that reflects the cost structures of only IRF providers. We noted that, of the available options, one would be to join the Medicare cost report data from freestanding IRF providers with data from hospital-based IRF providers. We indicated that an examination of the Medicare cost report data comparing freestanding and hospital-based IRFs revealed considerable differences between the two for cost levels and cost structures. At that time, we stated that we were unable to fully explain the differences in costs between freestanding and hospital-based IRFs and solicited comments regarding our findings. We summarized and responded to several public comments we received on the potential creation of a stand-alone IRF market basket in the FY 2010 IRF final rule (74 FR 39776 through 39778). At that time, we stated the need for further research regarding the differences in cost levels and cost structures between freestanding IRFs and hospital-based IRFs.

Since the FY 2010 IRF PPS final rule was published, we have made significant progress on the development of a stand-alone, or IRF-specific, market basket. Our research has focused on addressing several concerns regarding the use of the hospital-based IRF Medicare cost report data in the calculation of the major market basket cost weights. As discussed above, one concern is the cost level differences for hospital-based IRFs relative to freestanding IRFs that were not readily explained by the specific characteristics of the individual providers and the patients that they serve (for example, characteristics related to case mix, urban/rural status, teaching status). Furthermore, we are concerned about the variability in the cost report data among these hospital-based IRF providers and the potential impact on the market basket cost weights. These concerns led us to consider whether it is appropriate to use the universe of IRF providers to derive an IRF-specific market basket.

Recently, we have investigated the use of regression analysis to evaluate the effect of including hospital-based IRF Medicare cost report data in the calculation of cost distributions. We created preliminary regression models to try to explain variations in costs per

discharge across both freestanding and hospital-based IRFs. These models were intended to capture the effects of facility-level and patient-level characteristics (for example, wage index, urban/rural status, ownership status, length-of-stay, occupancy rate, case mix, and Medicare utilization) on IRF costs per discharge. Using the results from the preliminary regression analyses, we identified smaller subsets of hospital-based and freestanding IRF providers where the predicted costs per discharge using the regression model closely matched the actual costs per discharge for each IRF. We then derived different sets of cost distributions using (1) these subsets of IRF providers and (2) the entire universe of freestanding and hospital-based IRF providers (including those IRFs for which the variability in cost levels remains unexplained). After comparing these sets of cost distributions, the differences were not substantial enough for us to conclude that the inclusion of those IRF providers with unexplained variability in costs in the calculation of the cost distributions is a major cause of concern.

Another concern with incorporating the hospital-based IRF data in the derivation of an IRF-specific market basket is the complexity of the Medicare cost report data for these providers. The freestanding IRFs independently submit a Medicare cost report for their facilities, making it relatively straightforward to obtain the cost categories necessary to determine the major market basket cost weights. However, cost report data submitted for a hospital-based IRF are embedded in the Medicare cost report submitted for the entire hospital facility in which the IRF is located. Therefore, adjustments would have to be made to obtain cost weights that represent just the hospital-based IRF (as opposed to the hospital as a whole). For example, ancillary costs for services such as therapy, radiology, and laboratory services for the entire hospital would need to be appropriately converted to a value that only represents the hospital-based IRF unit's costs. The preliminary method we have developed to allocate these costs is complex and still needs to be fully evaluated before we are ready to propose an IRF-specific market basket that would reflect both hospital-based and freestanding IRF data.

In our ongoing research, we are also evaluating the differences in salary costs as a percent of total costs for both hospital-based and freestanding IRFs. Salary costs are historically the largest component of the market baskets. Based on our review of the data reported on

the applicable Medicare cost reports, our initial findings (using the preliminary allocation method as discussed above) have shown that the hospital-based IRF salary costs as a percent of total costs tend to be lower than those of freestanding IRFs. We are still evaluating the method for deriving salary costs as a percent of total costs, and one of the main issues is to further investigate the percentage of ancillary costs that should be appropriately allocated to the IRF salary costs for the hospital-based IRF, as discussed above.

Also, as stated in the FY 2012 IRF PPS final rule (76 FR 47836, 47851), effective for cost reports beginning on or after May 1, 2010, we finalized a revised Hospital and Hospital Health Care Complex Cost Report, Form CMS 2552–10 (74 FR 31738). The report is available for download from the CMS Web site at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/Cost-Reports/Hospital-2010-form.html>. The revised Hospital and Hospital Health Care Complex Cost Report includes a new worksheet (Worksheet S–3, part V) that identifies the contract labor costs and benefit costs for the hospital/hospital care complex, is applicable to sub-providers and units. As we gain access to the data reported by IRFs on this new form, we plan to evaluate the appropriateness of using these data to derive benefits and contract labor cost weights for the market basket instead of the data and methods currently used for the RPL market basket. This includes comparing these data with costs submitted on the other forms composing the Medicare cost report.

For the reasons discussed above, while we believe we have made significant progress on the development of an IRF-specific market basket, we believe that further research is required at this time. As a result, we did not propose an IRF-specific market basket for FY 2015. We plan to complete our research during the remainder of this year and, provided that we are prepared to draw conclusions from our research, may propose an IRF-specific market basket for the FY 2016 rulemaking cycle.

We received 4 comments on the development of an IRF-specific market basket, which are summarized below.

Comment: One commenter agreed with the continued use of the RPL market basket instead of changing to a rehabilitation-specific market basket. The commenter noted that CMS has utilized the RPL Market Basket for several years and that CMS has not been able to reconcile the cost structure issues between freestanding and hospital-based rehabilitation facilities.

The commenter stated that CMS's description of attempts to adjust and convert costs and data from the hospital cost report for the hospital-based rehabilitation units will not ultimately reflect the true cost of that hospital-based unit, as it will be artificially derived based on assumptions and comparisons to freestanding rehabilitation facilities. Further, the commenter stated, the hospital-based rehabilitation unit is part of a higher cost structure facility, and any future rehabilitation market basket should reflect that.

Response: We have made significant progress in addressing our initial concerns of the research that showed substantial cost differences between hospital-based and freestanding IRF providers. Nonetheless, we concur with the commenter's concerns about the difficulty of disentangling cost of hospital-based IRFs from the overall hospital. We note that our regression analysis, detailed above, provides a start at addressing these issues. However, we disagree with the commenter's claim that data from hospital-based providers will not reflect the true cost of the hospital-based unit. We believe that the approach described above, while more complicated than only using freestanding facility cost report data, would directly reflect the costs of the hospital-based unit and be a technical improvement. As noted above, we will continue to research and analyze the development of an IRF-specific market basket that uses the most appropriate and reliable data sources and methods and provide detailed explanations of the proposed methodology most likely in the FY 2016 proposed rule.

Comment: Several commenters supported the proposal to have a stand-alone IRF market basket, but urged CMS to share findings and materials in a transparent manner in order to allow the IRF community to validate and analyze these research activities.

Response: As the commenters suggested, we will continue to research and analyze the development of an IRF-specific market basket that uses the most appropriate and reliable data sources and methods. We anticipate proposing to use an IRF-specific market basket in the FY 2016 IRF proposed rule, and the public will have the opportunity to comment on our market basket methodology and data sources during the 60-day comment period following the publication of the proposed rule.

Final Decision: After careful consideration of the comments, we will continue to research the possibility of creating and proposing an IRF-specific

market basket based on data from both freestanding and hospital-based IRF facilities in the future.

C. Secretary's Final Recommendation

For FY 2015, the Medicare Payment Advisory Commission (MedPAC) recommends that a 0.0 percent update be applied to IRF PPS payment rates. As discussed above, and in accordance with sections 1886(j)(3)(C) and 1886(j)(3)(D) of the Act, the Secretary proposes to update IRF PPS payment rates for FY 2015 by an adjusted market basket increase factor of 2.2 percent, as section 1886(j)(3)(C) of the Act does not provide the Secretary with the authority to apply a different update factor to IRF PPS payment rates for FY 2015.

We did not receive any public comments on the Secretary's recommendation.

D. Labor-Related Share for FY 2015

The labor-related share for FY 2015 is updated using the methodology described in the FY 2012 IRF PPS final rule (76 FR 47836, 47860 through 47863). Using this method and IGI's second quarter 2014 forecast of the 2008-based RPL market basket, the proposed IRF labor-related share for FY 2015 is the sum of the FY 2015 relative importance of each labor-related cost category. This figure reflects the different rates of price change for these cost categories between the base year (FY 2008) and FY 2015. As shown in Table 3, the FY 2015 labor-related share is 69.294 percent.

TABLE 3—FY 2015 IRF RPL LABOR-RELATED SHARE RELATIVE IMPORTANCE

	FY 2015 Relative importance labor- related share
Wages and Salaries	48.271
Employee Benefits	12.963
Professional Fees: Labor- Related	2.058
Administrative and Business Support Services	0.415
All Other: Labor-Related Services	2.061
Subtotal	65.741
Labor-Related Portion of Capital Costs (.46)	3.553
Total Labor-Related Share	69.294

Source: IHS Global Insight, Inc. Second quarter 2014 forecast; Historical Data through 1st quarter 2014.

We received one comment on the proposed IRF labor-related share for FY 2015, which is summarized below.

Comment: One commenter supported using the latest available data to update the IRF PPS and noted that the current methodology relies upon acute care hospital data for certain items (that is, employee benefits, contract labor) that were not collected in RPL settings. The commenter also noted that changes to the Medicare cost report (Form 2552–10) were implemented to gather additional information on labor costs. The commenter requested that CMS continue to review the available data and, if appropriate, implement changes to allow the use of IRF-specific data for all cost categories, weights and price proxies.

Response: We appreciate the commenter's concerns with respect to the data for the benefits and contract labor categories. We have been monitoring and analyzing the data that is being reported based on the revised cost report and instructions. We hope to use this data in the future if it is statistically representative and we have a reliable response rate for these data.

Final Decision: After careful consideration of the comments, we are finalizing the FY 2015 labor-related share of 69.294 percent.

E. Wage Adjustment

Section 1886(j)(6) of the Act requires the Secretary to adjust the proportion of rehabilitation facilities' costs attributable to wages and wage-related costs (as estimated by the Secretary from time to time) by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the rehabilitation facility compared to the national average wage level for those facilities. The Secretary is required to update the IRF PPS wage index on the basis of information available to the Secretary on the wages and wage-related costs to furnish rehabilitation services. Any adjustment or updates made under section 1886(j)(6) of the Act for a FY are made in a budget-neutral manner.

For FY 2015, we are maintaining the policies and methodologies described in the FY 2012 IRF PPS final rule (76 FR 47836, at 47863 through 47865) related to the labor market area definitions and the wage index methodology for areas with wage data. Thus, we are using the CBSA labor market area definitions and the FY 2014 pre-reclassification and pre-floor hospital wage index data. In accordance with section 1886(d)(3)(E) of the Act, the FY 2014 pre-reclassification and pre-floor hospital wage index is based on data submitted for hospital cost reporting periods beginning on or after October 1, 2009, and before

October 1, 2010 (that is, FY 2010 cost report data).

The labor market designations made by the OMB include some geographic areas where there are no hospitals and, thus, no hospital wage index data on which to base the calculation of the IRF PPS wage index. We will continue to use the same methodology discussed in the FY 2008 IRF PPS final rule (72 FR 44299) to address those geographic areas where there are no hospitals and, thus, no hospital wage index data on which to base the calculation for the FY 2015 IRF PPS wage index.

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 data used to determine the IRF PPS wage index. The OMB bulletins are available at <http://www.whitehouse.gov/omb/bulletins/index.html>.

In keeping with the established IRF PPS wage index policy; we will use the prior year's (FY 2014) pre-floor, pre-reclassified hospital wage index data to derive the FY 2015 applicable IRF PPS wage index. We anticipate using the FY 2014 pre-floor, pre-reclassified hospital wage index data to derive the applicable IRF PPS wage index for FY 2015. We note, however, that the FY 2014 pre-floor, pre-reclassified hospital wage index does not use OMB's new 2010 Census-based area delineations, which were outlined in the February 28, 2013, OMB Bulletin 13–01, as we did not receive these changes in time to incorporate them into the FY 2014 hospital wage index. We therefore intend to consider the incorporation of these CBSA changes during the development of the FY 2015 hospital wage index. Assuming that we would continue to follow our established methodology for the IRF PPS wage index, this means that the 2010 Census-based CBSA changes would not be considered for inclusion in the IRF PPS wage index until FY 2016.

To calculate the wage-adjusted facility payment for the payment rates set forth in this final rule, we multiply the unadjusted Federal payment rate for IRFs by the FY 2015 labor-related share based on the FY 2008-based RPL market basket (69.294 percent) to determine the labor-related portion of the standard payment amount. We then multiply the labor-related portion by the applicable IRF wage index from the tables in the addendum to this final rule. These tables are available through the Internet on the CMS Web site at <http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/>. Table A is for

urban areas, and Table B is for rural areas.

Adjustments or updates to the IRF wage index made under section 1886(j)(6) of the Act must be made in a budget-neutral manner. We calculate a budget-neutral wage adjustment factor as established in the FY 2004 IRF PPS final rule (68 FR 45689), codified at § 412.624(e)(1), as described in the steps below. We use the listed steps to ensure that the FY 2015 IRF standard payment conversion factor reflects the update to the wage indexes (based on the FY 2010 hospital cost report data) and the labor-related share in a budget-neutral manner:

Step 1. Determine the total amount of the estimated FY 2014 IRF PPS rates, using the FY 2014 standard payment conversion factor and the labor-related share and the wage indexes from FY 2014 (as published in the FY 2014 IRF PPS final rule (78 FR 47860)).

Step 2. Calculate the total amount of estimated IRF PPS payments using the FY 2015 standard payment conversion factor and the FY 2015 labor-related share and CBSA urban and rural wage indexes.

Step 3. Divide the amount calculated in step 1 by the amount calculated in step 2. The resulting quotient is the FY 2015 budget-neutral wage adjustment factor of 1.0017.

Step 4. Apply the FY 2015 budget-neutral wage adjustment factor from step 3 to the FY 2014 IRF PPS standard payment conversion factor after the application of the adjusted market basket update to determine the FY 2015 standard payment conversion factor.

We discuss the calculation of the standard payment conversion factor for FY 2015 in section VI.F. of this final rule.

We received 4 comments on the proposed IRF wage adjustment for FY 2015, which are summarized below.

Comment: Several commenters expressed concern regarding the possible incorporation of the 2010 Census-based CBSA changes in the calculation of the wage index and the time frame over which the changes would be implemented. More specifically, these commenters urged CMS to establish a two-year or four-year phase-in for the wage index changes, particularly for providers most adversely affected by the new CBSA delineations.

Response: We appreciate all of the comments on this topic and support for the proposed FY 2015 wage index methodology. We will take these comments into consideration during the development of the FY 2016 IRF PPS wage index.

Comment: Commenters recommended that we develop a new methodology for area wage adjustment that eliminates hospital wage index reclassifications for all hospitals and reduces the problems associated with annual fluctuations in wage indices and across geographic boundaries. These commenters also recommended that we consider wage index policies under the current IPPS because IRFs compete in a similar labor pool as acute care hospitals. The commenters suggested that the IPPS wage index policies would allow IRFs to benefit from the IPPS reclassification and/or floor policies. One commenter further recommended that until a new wage index system is implemented, we institute a “smoothing” variable to the current process to reduce the fluctuations IRFs annually experience.

Response: Consistent with our previous responses to these comments (most recently published in our FY 2014 IRF PPS final rule (78 FR 47874)), we note that the IRF PPS does not account for geographic reclassification under sections 1886(d)(8) and (d)(10) of the Act, and does not apply the “rural floor” under section 4410 of the BBA. Furthermore, as we do not have an IRF-specific wage index, we are unable to determine at this time the degree, if any, to which a geographic reclassification adjustment or a “rural floor” policy under the IRF PPS would be appropriate. The rationale for our current wage index policies is fully described in the FY 2006 IRF PPS final rule (70 FR 47880, 47926 through 47928).

Additionally, while some commenters recommended that we adopt IPPS reclassification and/or floor policies, we note the Medicare Payment Advisory Commission (MedPAC’s) June 2007 report to the Congress, titled “Report to Congress: Promoting Greater Efficiency in Medicare,” (available at http://www.medpac.gov/documents/Jun07_EntireReport.pdf) recommends that Congress “repeal the existing hospital wage index statute, including reclassification and exceptions, and give the Secretary authority to establish new wage index systems.” We continue to believe it would not be prudent at this time to adopt the IPPS wage index policies, such as reclassification and/or floor policies, and will, therefore, continue to use the CBSA labor market area definitions and the pre-reclassification and pre-floor hospital wage index data based on 2010 cost report data in this final rule.

With regard to issues mentioned about ensuring that the wage index minimizes fluctuations, matches the costs of labor in the market, and

provides for a single wage index policy, section 3137(b) of the Affordable Care Act required us to submit a report to the Congress by December 31, 2011 that includes a plan to reform the hospital wage index system. The report that we submitted is available online at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Reform.html>.

However, we will continue to monitor the IPPS wage index to identify any policy changes that may be appropriate for IRFs. This is consistent with our previous responses to these recurring comments.

Final Decision: After careful consideration of the comments, we are finalizing use of the FY 2014 pre-floor, pre-reclassified hospital wage index data to derive the applicable IRF PPS wage index for FY 2015.

F. Description of the IRF Standard Conversion Factor and Payment Rates for FY 2015

To calculate the standard payment conversion factor for FY 2015, as illustrated in Table 4, we begin by applying the adjusted market basket increase factor for FY 2015 that was adjusted in accordance with sections 1886(j)(3)(C) and (D) of the Act, to the standard payment conversion factor for FY 2014 (\$14,846). Applying the 2.2 percent adjusted market basket increase factor for FY 2015 to the standard payment conversion factor for FY 2014 of \$14,846 yields a standard payment amount of \$15,173. Then, we apply the budget neutrality factor for the FY 2015 wage index and labor-related share of 1.0017, which results in a standard payment amount of \$15,198. We next apply the budget neutrality factors for the revised CMG relative weights of 1.0000, which results in the proposed standard payment conversion factor of \$15,198 for FY 2015.

TABLE 4—CALCULATIONS TO DETERMINE THE FY 2015 STANDARD PAYMENT CONVERSION FACTOR

Explanation for adjustment	Calculations
Standard Payment Conversion Factor for FY 2014	\$14,846
Market Basket Increase Factor for FY 2015 (2.9 percent), reduced by a 0.5 percentage point reduction for the productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act, and reduced by 0.2 percentage points in accordance with paragraphs 1886(j)(3)(C) and (D) of the Act	× 1.0220

TABLE 4—CALCULATIONS TO DETERMINE THE FY 2015 STANDARD PAYMENT CONVERSION FACTOR—Continued

Explanation for adjustment	Calculations
Budget Neutrality Factor for the Wage Index and Labor-Related Share	× 1.0017
Budget Neutrality Factor for the Revisions to the CMG Relative Weights	× 1.0000

TABLE 4—CALCULATIONS TO DETERMINE THE FY 2015 STANDARD PAYMENT CONVERSION FACTOR—Continued

Explanation for adjustment	Calculations
FY 2015 Standard Payment Conversion Factor	= \$15,198
We did not receive any comments on the proposed FY 2015 standard payment conversion factor.	

Final Decision: As we did not receive any comments on the proposed FY 2015 standard payment conversion factor, we are finalizing the IRF standard payment conversion factor at \$15,198 for FY 2015.

After the application of the CMG relative weights described in section IV of this final rule, to the FY 2015 standard payment conversion factor (\$15,198), the resulting unadjusted IRF prospective payment rates for FY 2015 are shown in Table 5.

TABLE 5—FY 2015 PAYMENT RATES

CMG	Payment rate Tier 1	Payment rate Tier 2	Payment rate Tier 3	Payment rate no comorbidity
0101	\$11,934.99	\$10,866.57	\$9,896.94	\$9,495.71
0102	14,948.75	13,609.81	12,393.97	11,893.95
0103	17,684.39	16,100.76	14,663.03	14,070.31
0104	18,421.50	16,772.51	15,273.99	14,656.95
0105	21,512.77	19,587.18	17,837.89	17,115.99
0106	24,521.97	22,327.38	20,333.40	19,511.19
0107	27,395.91	24,942.96	22,714.93	21,796.97
0108	34,145.35	31,089.03	28,312.35	27,167.94
0109	31,262.29	28,462.81	25,920.19	24,873.05
0110	40,925.17	37,262.46	33,934.09	32,561.72
0201	12,378.77	10,085.39	9,048.89	8,632.46
0202	16,096.20	13,114.35	11,764.77	11,223.72
0203	18,483.81	15,059.70	13,511.02	12,889.42
0204	20,360.76	16,588.62	14,883.40	14,197.97
0205	24,201.30	19,717.89	17,690.47	16,875.86
0206	29,373.17	23,932.29	21,470.21	20,482.34
0207	38,967.67	31,748.62	28,482.57	27,174.02
0301	16,751.24	14,170.62	12,846.87	11,851.40
0302	20,971.72	17,740.63	16,082.52	14,836.29
0303	24,880.65	21,047.71	19,081.09	17,603.84
0304	32,738.01	27,693.80	25,107.10	23,161.75
0401	15,599.23	13,359.04	12,357.49	11,020.07
0402	21,441.34	18,360.70	16,985.28	15,146.33
0403	35,045.07	30,011.49	27,763.71	24,756.02
0404	62,056.47	53,142.85	49,162.49	43,838.63
0405	50,692.93	43,411.57	40,160.72	35,811.05
0501	12,793.68	10,340.72	9,478.99	8,576.23
0502	17,599.28	14,223.81	13,038.36	11,798.21
0503	21,844.09	17,654.00	16,182.83	14,643.27
0504	25,737.81	20,801.50	19,067.41	17,252.77
0505	29,430.93	23,786.39	21,803.05	19,728.52
0506	41,134.91	33,245.63	30,475.03	27,575.25
0601	15,643.30	12,384.85	11,438.01	10,428.87
0602	20,187.50	15,982.22	14,761.82	13,459.35
0603	25,421.69	20,126.71	18,588.67	16,948.81
0604	33,295.78	26,360.93	24,347.20	22,199.72
0701	14,742.06	12,249.59	11,743.49	10,693.31
0702	18,889.59	15,694.97	15,047.54	13,702.52
0703	22,882.11	19,014.22	18,228.48	16,599.26
0704	29,421.81	24,447.50	23,436.84	21,344.07
0801	11,249.56	9,222.15	8,523.04	7,860.41
0802	15,032.34	12,324.06	11,390.90	10,504.86
0803	20,325.81	16,661.57	15,400.13	14,202.53
0804	17,965.56	14,726.86	13,611.33	12,553.55
0805	22,344.10	18,318.15	16,930.57	15,614.43
0806	26,844.23	22,005.18	20,339.48	18,757.37
0901	14,264.84	11,521.60	10,743.47	9,714.56
0902	18,818.16	15,198.00	14,172.14	12,814.95
0903	23,635.93	19,090.21	17,801.42	16,096.20
0904	30,049.49	24,268.17	22,629.82	20,462.59
1001	15,538.44	14,134.14	12,241.99	11,193.33
1002	20,012.73	18,204.16	15,766.41	14,415.30
1003	28,538.80	25,959.70	22,483.92	20,558.33
1101	19,214.83	15,415.33	15,273.99	13,023.17
1102	28,778.93	23,088.80	22,876.03	19,506.63
1201	15,249.67	14,471.54	13,497.34	12,547.47

TABLE 5—FY 2015 PAYMENT RATES—Continued

CMG	Payment rate Tier 1	Payment rate Tier 2	Payment rate Tier 3	Payment rate no comorbidity
1202	18,109.94	17,185.90	16,029.33	14,901.64
1203	22,999.13	21,824.33	20,354.68	18,924.55
1301	18,571.96	15,026.26	13,187.30	12,433.48
1302	24,184.58	19,565.91	17,172.22	16,190.43
1303	30,854.98	24,962.72	21,909.44	20,655.60
1401	13,726.83	11,131.02	10,138.59	9,196.31
1402	18,157.05	14,725.34	13,412.24	12,164.48
1403	22,339.54	18,116.02	16,500.47	14,965.47
1404	28,105.66	22,793.96	20,760.47	18,830.32
1501	15,194.96	12,386.37	11,454.73	11,068.70
1502	19,736.12	16,088.60	14,880.36	14,378.83
1503	24,192.18	19,720.92	18,239.12	17,625.12
1504	29,921.82	24,391.27	22,558.39	21,798.49
1601	14,354.51	13,318.01	12,287.58	11,580.88
1602	19,011.18	17,638.80	16,274.02	15,337.82
1603	24,081.23	22,345.62	20,616.09	19,429.12
1701	15,854.55	14,118.94	13,018.61	11,977.54
1702	19,923.06	17,742.15	16,359.13	15,050.58
1703	23,371.48	20,812.14	19,190.51	17,655.52
1704	30,177.15	26,873.10	24,777.30	22,797.00
1801	16,204.11	14,342.35	12,283.02	10,989.67
1802	25,660.30	22,713.41	19,450.40	17,403.23
1803	42,701.82	37,795.91	32,367.18	28,959.79
1901	15,837.84	14,196.45	14,077.91	13,430.47
1902	28,506.89	25,553.92	25,338.11	24,172.42
1903	51,296.29	45,981.55	45,594.00	43,496.68
2001	13,415.27	11,018.55	10,153.78	9,267.74
2002	18,043.07	14,819.57	13,656.92	12,463.88
2003	22,889.71	18,799.93	17,325.72	15,813.52
2004	29,646.74	24,348.72	22,439.85	20,479.31
2101	27,971.92	25,480.97	23,629.85	20,568.97
5001	2,354.17
5101	10,320.96
5102	23,616.17
5103	11,055.03
5104	29,601.14

G. Example of the Methodology for Adjusting the Federal Prospective Payment Rates

Table 6 illustrates the methodology for adjusting the federal prospective payments (as described in sections VI.A. through VI.F. of this final rule). The following examples are based on two hypothetical Medicare beneficiaries, both classified into CMG 0110 (without comorbidities). The unadjusted federal prospective payment rate for CMG 0110 (without comorbidities) appears in Table 6.

Example: One beneficiary is in Facility A, an IRF located in rural Spencer County, Indiana, and another beneficiary is in Facility B, an IRF located in urban Harrison County, Indiana. Facility A, a rural non-teaching hospital has a Disproportionate Share Hospital (DSH) percentage of 5 percent (which would result in a LIP adjustment of 1.0156), a wage index of 0.8513, and a rural adjustment of 14.9 percent. Facility B, an urban teaching hospital,

has a DSH percentage of 15 percent (which would result in a LIP adjustment of 1.0454 percent), a wage index of 0.8852, and a teaching status adjustment of 0.0784.

To calculate each IRF's labor and non-labor portion of the Federal prospective payment, we begin by taking the unadjusted Federal prospective payment rate for CMG 0110 (without comorbidities) from Table 5. Then, we multiply the labor-related share for FY 2015 (69.294 percent) described in section VI.D. of this final rule by the unadjusted federal prospective payment rate. To determine the non-labor portion of the federal prospective payment rate, we subtract the labor portion of the federal payment from the unadjusted federal prospective payment.

To compute the wage-adjusted federal prospective payment, we multiply the labor portion of the federal payment by the appropriate wage index found in tables A and B. These tables are available through the Internet on the CMS Web site at <http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/Inpatient-RehabFacPPS/>. The resulting figure is the wage-adjusted labor amount. Next, we compute the wage-adjusted federal payment by adding the wage-adjusted labor amount to the non-labor portion.

Adjusting the wage-adjusted federal payment by the facility-level adjustments involves several steps. First, we take the wage-adjusted Federal prospective payment and multiply it by the appropriate rural and LIP adjustments (if applicable). Second, to determine the appropriate amount of additional payment for the teaching status adjustment (if applicable), we multiply the teaching status adjustment (0.0784, in this example) by the wage-adjusted and rural-adjusted amount (if applicable). Finally, we add the additional teaching status payments (if applicable) to the wage, rural, and LIP-adjusted federal prospective payment rates. Table 6 illustrates the components of the adjusted payment calculation.

TABLE 6—EXAMPLE OF COMPUTING THE IRF FY 2015 FEDERAL PROSPECTIVE PAYMENT

Steps			Rural Facility A (Spencer Co., IN)		Urban Facility B (Harrison Co., IN)
1	Unadjusted Federal Prospective Payment		\$32,561.72		\$32,561.72
2	Labor Share	×	0.69294	×	0.69294
3	Labor Portion of Federal Payment	=	\$22,563.32	=	\$22,563.32
4	CBSA-Based Wage Index (shown in the Addendum, Tables 1 and 2)	×	0.8513	×	0.8852
5	Wage-Adjusted Amount	=	\$19,208.15	=	\$19,973.05
6	Non-Labor Amount	+	\$9,998.40	+	\$9,998.40
7	Wage-Adjusted Federal Payment	=	\$29,206.55	=	\$29,971.45
8	Rural Adjustment	×	1.149	×	1.000
9	Wage- and Rural-Adjusted Federal Payment	=	\$33,558.33	=	\$29,971.45
10	LIP Adjustment	×	1.0156	×	1.0454
11	FY 2015 Wage-, Rural- and LIP-Adjusted Federal Prospective Payment Rate	=	\$34,081.84	=	\$31,332.15
12	FY 2015 Wage- and Rural-Adjusted Federal Prospective Payment		\$33,558.33		\$29,971.45
13	Teaching Status Adjustment	×	0	×	0.0784
14	Teaching Status Adjustment Amount	=	\$0.00	=	\$2,349.76
15	FY 2015 Wage-, Rural-, and LIP-Adjusted Federal Prospective Payment Rate	+	\$34,081.84	+	\$31,332.15
16	Total FY 2015 Adjusted Federal Prospective Payment	=	\$34,081.84	=	\$33,691.92

Thus, the adjusted payment for Facility A would be \$34,081.84, and the adjusted payment for Facility B would be \$33,681.92.

VII. Update to Payments for High-Cost Outliers Under the IRF PPS

A. Update to the Outlier Threshold Amount for FY 2015

Section 1886(j)(4) of the Act provides the Secretary with the authority to make payments in addition to the basic IRF prospective payments for cases incurring extraordinarily high costs. A case qualifies for an outlier payment if the estimated cost of the case exceeds the adjusted outlier threshold. We calculate the adjusted outlier threshold by adding the IRF PPS payment for the case (that is, the CMG payment adjusted by all of the relevant facility-level adjustments) and the adjusted threshold amount (also adjusted by all of the relevant facility-level adjustments). Then, we calculate the estimated cost of a case by multiplying the IRF's overall CCR by the Medicare allowable covered charge. If the estimated cost of the case is higher than the adjusted outlier threshold, we make an outlier payment for the case equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold.

In the FY 2002 IRF PPS final rule (66 FR 41362 through 41363), we discussed our rationale for setting the outlier threshold amount for the IRF PPS so that estimated outlier payments would equal 3 percent of total estimated payments. For the 2002 IRF PPS final rule, we analyzed various outlier policies using 3, 4, and 5 percent of the total estimated payments, and we concluded that an outlier policy set at 3 percent of total estimated payments would optimize the extent to which we could reduce the financial risk to IRFs

of caring for high-cost patients, while still providing for adequate payments for all other (non-high cost outlier) cases.

Subsequently, we updated the IRF outlier threshold amount in the FYs 2006 through 2014 IRF PPS final rules and the FY 2011 and FY 2013 notices (70 FR 47880, 71 FR 48354, 72 FR 44284, 73 FR 46370, 74 FR 39762, 75 FR 42836, 76 FR 47836, 76 FR 59256, and 77 FR 44618, 78 FR 47860, respectively) to maintain estimated outlier payments at 3 percent of total estimated payments. We also stated in the FY 2009 final rule (73 FR 46370 at 46385) that we would continue to analyze the estimated outlier payments for subsequent years and adjust the outlier threshold amount as appropriate to maintain the 3 percent target.

To update the IRF outlier threshold amount for FY 2015, we proposed to use FY 2013 claims data and the same methodology that we used to set the initial outlier threshold amount in the FY 2002 IRF PPS final rule (66 FR 41316 and 41362 through 41363), which is also the same methodology that we used to update the outlier threshold amounts for FYs 2006 through 2014. Based on an analysis of this updated data, we estimate that IRF outlier payments as a percentage of total estimated payments are approximately 2.8 percent in FY 2014. Therefore, we update the outlier threshold amount to \$8,848 to maintain estimated outlier payments at approximately 3 percent of total estimated aggregate IRF payments for FY 2015.

We received 3 comments on the proposed update to the FY 2015 outlier threshold amount to maintain estimated outlier payments at approximately 3 percent of total estimated IRF payments, which are summarized below.

Comment: Several commenters expressed support for the proposed update to the outlier threshold amount to maintain estimated IRF outlier payments for FY 2015 at 3 percent of total IRF PPS payments. However, some commenters expressed concerns that actual IRF outlier payments in recent years have tended to fall below 3 percent of total IRF PPS payments. These commenters requested that we revise the methodology used to set the outlier threshold amount to ensure that we pay out the full 3 percent in outlier payments or incorporate any unused outlier payments from years in which aggregate outlier payments are below the 3 percent target back into the IRF PPS base payments for subsequent years.

Response: We will continue to monitor our IRF outlier policies to ensure that they continue to compensate IRFs for treating unusually high-cost patients and, thereby, promote access to care for patients who are likely to require unusually high-cost care. Although actual outlier payments in the most recent 4-year period have tended to be just slightly below the 3 percent target, actual outlier payments ranged at or above 3 percent for the 4-year period from FY 2007 through FY 2010. In fact, actual outlier payments in FY 2008 were 4.2 percent of total IRF PPS payments.

As we have indicated in previous IRF PPS final rules, we do not make adjustments to IRF PPS payment rates for the sole purpose of accounting for differences between projected and actual outlier payments. We use the best available data at the time to establish an outlier threshold for IRF PPS payments prior to the beginning of each fiscal year so that estimated outlier payments for that fiscal year will equal 3 percent of total estimated IRF PPS payments. We

evaluate the status of our outlier expenditures annually, and if there is a difference from our projection, that information is used to make a prospective adjustment to lower or raise the outlier threshold for the upcoming fiscal year. We believe a retrospective adjustment would not be appropriate. This includes instances where we have overestimated, as well as underestimated, outlier payments. If outlier payments for a given year turn out to be greater than projected, we do not recoup money from hospitals; if outlier payments for a given year are lower than projected, we do not make an adjustment to account for the difference. Payments for a given discharge in a given fiscal year are generally intended to reflect or address the average costs of that discharge in that year; that goal would be undermined if we adjusted IRF PPS payments to account for “underpayments” or “overpayments” in IRF outliers in previous years.

Final Decision: Having carefully considered the public comments received and also taking into account the most recent available data, we are finalizing the outlier threshold amount of \$8,848 to maintain estimated outlier payments at approximately 3 percent of total estimated aggregate IRF payments for FY 2015. This update is effective October 1, 2014. We will continue to monitor trends in IRF outlier payments to ensure that they are working as intended to compensate IRFs for treating exceptionally high-cost IRF patients.

B. Update to the IRF Cost-to-Charge Ratio Ceiling and Urban/Rural Averages

In accordance with the methodology stated in the FY 2004 IRF PPS final rule (68 FR 45674, 45692 through 45694), we apply a ceiling to IRFs' CCRs. Using the methodology described in that final rule, we update the national urban and rural CCRs for IRFs, as well as the national CCR ceiling for FY 2015, based on analysis of the most recent data that is available. We apply the national urban and rural CCRs in the following situations:

- New IRFs that have not yet submitted their first Medicare cost report.
- IRFs whose overall CCR is in excess of the national CCR ceiling for FY 2015, as discussed below.
- Other IRFs for which accurate data to calculate an overall CCR are not available.

Specifically, for FY 2015, we estimate a national average CCR of 0.569 for rural IRFs, which we calculated by taking an average of the CCRs for all rural IRFs using their most recently submitted cost

report data. Similarly, we estimate a national average CCR of 0.443 for urban IRFs, which we calculated by taking an average of the CCRs for all urban IRFs using their most recently submitted cost report data. We apply weights to both of these averages using the IRFs' estimated costs, meaning that the CCRs of IRFs with higher costs factor more heavily into the averages than the CCRs of IRFs with lower costs. For this final rule, we have used the most recent available cost report data (FY 2012). This includes all IRFs whose cost reporting periods begin on or after October 1, 2011, and before October 1, 2012. If, for any IRF, the FY 2012 cost report was missing or had an “as submitted” status, we used data from a previous fiscal year's (that is, FY 2004 through FY 2011) settled cost report for that IRF. We do not use cost report data from before FY 2004 for any IRF because changes in IRF utilization since FY 2004 resulting from the 60 percent rule and IRF medical review activities suggest that these older data do not adequately reflect the current cost of care.

In accordance with past practice, we will set the national CCR ceiling at 3 standard deviations above the mean CCR. Using this method, the national CCR ceiling would be 1.37 for FY 2015. This means that, if an individual IRF's CCR exceeds this proposed ceiling of 1.37 for FY 2015, we would replace the IRF's CCR with the appropriate national average CCR (either rural or urban, depending on the geographic location of the IRF). We calculated the national CCR ceiling by:

Step 1. Taking the national average CCR (weighted by each IRF's total costs, as discussed above) of all IRFs for which we have sufficient cost report data (both rural and urban IRFs combined).

Step 2. Estimating the standard deviation of the national average CCR computed in step 1.

Step 3. Multiplying the standard deviation of the national average CCR computed in step 2 by a factor of 3 to compute a statistically significant reliable ceiling.

Step 4. Adding the result from step 3 to the national average CCR of all IRFs for which we have sufficient cost report data, from step 1.

We did not receive any comments on the proposed updates to the IRF CCR ceilings and urban/rural averages.

Final Decision: As we did not receive any comments on the proposed updates to the IRF CCR ceiling and the urban/rural averages for FY 2015, we are finalizing the national average urban CCR at 0.443, the national average rural CCR at 0.569, and the national CCR ceiling at 1.37 percent for FY 2015.

These updates are effective October 1, 2014.

VIII. Refinements to the Presumptive Compliance Methodology

A. Background on the Compliance Percentage

The compliance percentage has been part of the criteria for defining IRFs since implementation of the Inpatient Prospective Payment System (IPPS) in 1983. In the September 1, 1983, interim final rule with comment period (48 FR 39752), which allowed IRFs to be paid separately from the IPPS, the initial compliance percentage was set at 75 percent. The 1983 interim rule stipulated that in accordance with sections 1886(d)(1)(B) and 1886(d)(1)(B)(ii) of the Act, a rehabilitation hospital and a rehabilitation unit were excluded from the IPPS. Sections 1886(d)(1)(B) and 1886(d)(1)(B)(ii) of the Act also give the Secretary the discretion to define a rehabilitation hospital and unit.

A hospital or unit deemed excluded from the IPPS and paid under the IRF PPS must meet the general requirements in subpart B and subpart P of part 412. Subject to the special payment provisions of § 412.22(c), a hospital or unit must meet the general criteria set forth in § 412.22 and in the regulations at § 412.23(b), § 412.25, and § 412.29 that specify the criteria for a provider to be classified as a rehabilitation hospital or unit. Hospitals and units meeting these criteria are eligible to be paid on a prospective payment basis as an IRF under the IRF PPS.

The 1983 interim final rule stipulated that one of the criteria for being classified as an IRF was that, during the facility's most recently completed 12-month cost reporting period, the hospital must be primarily engaged in furnishing intensive rehabilitation services, as demonstrated by patient medical records, indicating that at least 75 percent of the IRF's patient population were treated for one or more of the 10 medical conditions specified in the regulation that typically required the intensive inpatient rehabilitation treatment provided in an IRF. These criteria, along with other related criteria, distinguished an inpatient rehabilitation hospital or unit from a hospital that furnished general medical or surgical services, as well as rehabilitation services. We believed then, as we do now, that by examining the types of conditions for which a hospital's inpatients are treated, and the proportion of patients treated for conditions that typically require intensive inpatient rehabilitation, we

would be able to distinguish those hospitals in which the provision of rehabilitation services was primary rather than secondary. Thus, Medicare pays for rehabilitation services at IRFs at a higher rate than other hospitals because IRFs are designed to offer specialized inpatient rehabilitation care to patients with intensive needs.

The original medical conditions specified under the compliance percentage, or “75 percent rule,” were stroke, spinal cord injury, congenital deformity, amputation, major multiple trauma, fracture of femur (hip fracture), brain injury, and polyarthritis (including rheumatoid arthritis). In the January 3, 1984, final rule (49 FR 234), we expanded the list of eligible medical conditions to include neurological disorders (including multiple sclerosis, motor neuron diseases, polyneuropathy, muscular dystrophy, and Parkinson’s disease) and burns. In the May 7, 2004 final rule (69 FR 25752), we modified and expanded the list of eligible medical conditions by removing polyarthritis and substituting three more clearly defined arthritis-related conditions. The three conditions that replaced polyarthritis included the following:

- Active, polyarticular rheumatoid arthritis, psoriatic arthritis, and seronegative arthropathies resulting in significant functional impairment of ambulation and other activities of daily living, which has not improved after an appropriate, aggressive, and sustained course of outpatient therapy services or services in other less intensive rehabilitation settings immediately preceding the inpatient rehabilitation admission, or which results from a systemic disease activation immediately before admission, but has the potential to improve with more intensive rehabilitation.

- Systemic vasculitides with joint inflammation, resulting in significant functional impairment of ambulation and other activities of daily living, which has not improved after an appropriate, aggressive, and sustained course of outpatient therapy services or services in other less intensive rehabilitation settings immediately preceding the inpatient rehabilitation admission, or which results from a systemic disease activation immediately before admission, but has the potential to improve with more intensive rehabilitation.

- Severe or advanced osteoarthritis (osteoarthrosis or degenerative joint disease) involving three or more major joints (elbow, shoulders, hips, or knees) with joint deformity and substantial loss of range of motion, atrophy, significant

functional impairment of ambulation and other activities of daily living, which has not improved after an appropriate, aggressive, and sustained course of outpatient therapy services or services in other less intensive rehabilitation settings immediately preceding the inpatient rehabilitation admission, but has the potential to improve with more intensive rehabilitation. (A joint replaced by a prosthesis is no longer considered to have osteoarthritis, or other arthritis, even though this condition was the reason for the joint replacement.)

In the May 7, 2004 final rule (69 FR 25752), a 13th condition was also added to include patients who undergo knee and/or hip joint replacement during an acute hospitalization immediately preceding the inpatient rehabilitation stay and also meet at least one of the following specific criteria:

- Underwent bilateral knee or hip joint replacement surgery during the acute hospitalization immediately preceding the IRF admission.
- Are extremely obese patients as measured by the patient’s Body Mass Index (BMI) of at least 50, at the time of admission to the IRF.
- Are patients considered to be “frail elderly,” as determined by a patient’s age of 85 or older, at the time of admission to the IRF (the provision currently states only that the patients be age 85 or older at the time of admission to the IRF).

In 2002, we surveyed Medicare fiscal intermediaries to determine how they were enforcing the 75 percent rule. Although the 75 percent rule was one of the criteria that were used to distinguish an IRF from an acute care hospital from 1983 to 2004, we found evidence that different fiscal intermediaries were enforcing the rule differently. We found fiscal intermediaries were using inconsistent methods to determine whether IRFs were in compliance with the regulation, and that some IRFs were not being reviewed for compliance at all. This led to concerns that some IRFs might have been out of compliance with the regulation and inappropriately classified as IRFs, while other IRFs may have been held to overly high standards. Because of these concerns we sought to establish a more uniform enforcement of the 75 percent rule.

In the May 16, 2003, IRF PPS proposed rule (68 FR 26786), we solicited comments on the regulatory requirements of the 75 percent rule. Though we did not, at that time, propose amending the regulatory requirements for the 75 percent rule located in then § 412.23(b)(2), we did propose to amend these requirements in

the September 9, 2003, proposed rule titled, “Medicare Program; Changes to the Criteria for Being Classified as an Inpatient Rehabilitation Facility” (68 FR 53266). In that rule, we proposed some revisions to the 75 percent rule, including lowering the compliance percentage to 65 percent during a 3-year transition period for cost reporting periods between January 1, 2004, and January 1, 2007. Also, in response to comments on the September 9, 2003, proposed rule and as stated above, the May 7, 2004, final rule (69 FR 25752) expanded the number of medical conditions that would meet the compliance percentage from 10 to 13 and provided that patient comorbidities may also be included in determining an IRF’s compliance with the requirements during the transition period.

In the September 9, 2003, proposed rule, we defined “comorbidity” as a specific patient condition that is secondary to the patient’s principal diagnosis or impairment that is the primary reason for the inpatient rehabilitation stay. In the May 7, 2004, rule, we adopted the provision to use a patient with a comorbidity counting towards the compliance threshold during the transition period. In the determination of the compliance percentage, a patient comorbidity counts toward the percentage if the comorbidity falls in one of the conditions specified at § 412.29(b)(2) and has caused significant decline in functional ability in the individual that even in the absence of the admitting condition, the individual would require the intensive rehabilitation treatment that is unique to IRFs.

Anticipating that IRFs needed some time to adjust and adapt their processes to the changes in the enforcement of the 75 percent rule, in the May 7, 2004 final rule, we provided IRFs with a 3-year phase-in period (cost reporting periods beginning on or after July 1, 2004, through July 1, 2007) to establish the compliance threshold of 75 percent of the IRF’s total patient population. The 3-year phase-in period was intended to begin with cost reporting periods on or after July 1, 2004, with the threshold at 50 percent of the IRF’s population and gradually increase to 60 percent, then to 65 percent, and then to expire with cost reporting periods beginning on or after July 1, 2007, when the compliance percentage would once again be at 75 percent.

Section 5005 of the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171, enacted February 8, 2006) and section 1886(d)(1)(B) of the Act modified the provisions of the 75 percent rule originally specified in the May 7, 2004,

final rule. To reflect these statutory changes, in the August 7, 2007, final rule (72 FR 44284), we revised the regulations to prolong the overall duration of the phased transition to the full 75 percent threshold by stipulating that an IRF must meet the full 75 percent compliance threshold as of its first cost reporting period that starts on or after July 1, 2008. We also extended the policy of using a patient's comorbidities to the extent they met the conditions as outlined in the regulations to determine compliance with the classification criteria at then § 412.23(b)(2)(1) to the first cost reporting period that starts on or after July 1, 2008.

Subsequently, section 115 of the MMSEA amended section 5005 of the DRA to revise elements of the 75 percent rule that are used to classify IRFs. In accordance with the statute, in the August 8, 2008, final rule (73 FR 46370), we revised the compliance rate that IRFs must meet to be excluded from the IPPS and be paid under the IRF PPS to 60 percent for cost reporting periods beginning in or after July 1, 2006. Also, in accordance with the statute, we required that patient comorbidities that satisfy the criteria as specified at then § 412.23(b)(2)(i) [now located at § 412.29(b)(1) and § 412.29(b)(2)] be included in calculations used to determine whether an IRF meets the 60 percent compliance percentage for cost reporting periods beginning on or after July 1, 2007. As a result of these changes, the requirements started being referred to as the "60 percent rule," instead of the "75 percent rule." The regulations finalized in the FY 2009 IRF PPS final rule (73 FR 46370) continue to be in effect.

Though an IRF must serve an inpatient population of whom at least 60 percent meet the compliance percentage criteria specified at § 412.29(b), the existing regulation allows for 40 percent of reasonable and necessary admissions to an IRF to fall outside of the 13 qualifying medical conditions. Still, the 60 percent rule is one of the primary ways we distinguish an IRF from an acute care hospital. As Medicare payments for IRF services are generally significantly higher than Medicare payments for similar services provided in acute care hospital settings, we believe that it is important to maintain and enforce the criteria for medical conditions that may be counted toward an IRF's compliance calculation for the 60 percent rule to ensure that the higher Medicare payments are appropriately allocated to those providers that are providing IRF-level services.

B. Changes to the Diagnosis Codes That Are Used to Determine Presumptive Compliance

In the FY 2014 IRF PPS final rule (78 FR 47860, 47881 through 47895), we revised the list of ICD-9-CM diagnosis codes that are used to determine presumptive compliance, effective for compliance review periods beginning on or after October 1, 2014. These revisions were based on an analysis of the ICD-9-CM code list that determined the clinical appropriateness of each individual ICD-9-CM code's inclusion on the list. As a result of this analysis, we also intended to remove all of the status post-amputation diagnoses codes, but these codes were inadvertently omitted from the FY 2014 IRF PPS proposed and final rules. These codes, listed in Table 7, are used to indicate that a patient has the sequela or residual effect of a condition.

As we stated in the FY 2014 IRF PPS final rule (78 FR 47860, 47881), the ICD-9-CM diagnosis codes included on the "ICD-9-CM Codes That Meet Presumptive Compliance Criteria" list are ones that demonstrate that the patient meets criteria for the medical conditions that may be counted toward an IRF's compliance percentage under the presumptive compliance methodology. Further, we stated that the underlying premise of the presumptive compliance methodology list is that it represents particular diagnosis codes that, if applicable to a given patient, would more than likely mean that the patient required intensive rehabilitation services in an IRF for treatment of one or more of the conditions specified at § 412.29(b)(2) or that they had a comorbidity that caused significant decline in functional ability such that, even in the absence of the admitting condition, the patient would require the intensive rehabilitation treatment that is unique to IRFs and cannot be appropriately treated in another care setting. For the reasons described below, we do not believe that the ICD-9-CM diagnosis codes listed in Table 7 meet either of these criteria. We believe it is impossible to determine, from the presence of such diagnosis codes alone, whether a patient with an amputation status or prosthetic fitting and adjustment needs has a condition for which he or she would qualify for treatment in an IRF. Some patients with an amputation status or prosthetic fitting and adjustment needs will not require close medical supervision by a physician or weekly interdisciplinary team conferences to achieve their goals, while others may require these services. We believe that rehabilitation associated

with an amputation status or prosthetic fitting and adjustment needs does not necessarily need to be accompanied by the close medical management provided in IRFs, as long as the patient does not have any additional comorbidities that have caused significant decline in his or her functional ability that, in the absence of an amputation status or prosthetic fitting and adjustment needs, would necessitate treatment in an IRF. That is to say, a patient's need for intensive rehabilitation services provided in an IRF may depend on other conditions which cannot be solely identified through the presence of an amputation status or prosthetic fitting and adjustment diagnosis code. If a patient with one of the diagnosis codes listed in Table 7 has additional comorbidities that would necessitate treatment in an IRF, then those additional comorbidities would qualify the patient for inclusion in the calculation of the IRF's compliance percentage under the presumptive compliance methodology. Thus, we are removing the status post-amputation diagnosis codes listed in Table 7 from the list of "ICD-9-CM Codes That Meet Presumptive Compliance Criteria." The removal of these codes will be effective for compliance review periods beginning on or after October 1, 2015, and the changes will be incorporated into the ICD-10 lists (discussed below) when ICD-10-CM becomes the required medical data code set for use on Medicare claims and IRF-PAI submissions.

TABLE 7—ICD-9-CM CODES REMOVED FROM "ICD-9-CM CODES THAT MEET PRESUMPTIVE COMPLIANCE CRITERIA"

ICD-9-CM Code	Diagnosis
V49.65	Below elbow amputation status.
V49.66	Above elbow amputation status.
V49.67	Shoulder amputation status.
V49.73	Foot amputation status.
V49.74	Ankle amputation status.
V49.75	Below knee amputation status.
V49.76	Above knee amputation status.
V49.77	Hip amputation status.
V52.0	Fitting and adjustment of artificial arm (complete) (partial).
V52.1	Fitting and adjustment of artificial leg (complete) (partial).

We received 44 comments on the proposed changes to the diagnosis codes that are used to determine presumptive

compliance, which are summarized below.

Comment: Citing studies, several commenters emphasized that research indicates that amputees receive substantial benefits from care in the IRF setting compared to other post-acute care settings. Another commenter stated that proper fitting and training for the use of a prosthesis is a complex clinical exercise that requires the intensive multidisciplinary services provided in IRFs.

Response: We agree that some patients that present with an amputation status or prosthetic fitting or adjustment may require the close medical supervision by a rehabilitation physician and weekly interdisciplinary team conferences uniquely provided in IRFs to achieve their therapeutic goals. However, we believe that it cannot be determined from the amputation status or prosthetic fitting or adjustment diagnosis codes alone whether a patient presents with the clinical complexity that would require an IRF level of care. Indeed, we believe that many patients who are appropriately coded with these diagnosis codes can be effectively cared for in other care settings. As we stated in the FY 2015 IRF PPS proposed rule (79 FR 26308, 26327) and the FY 2014 IRF PPS final rule (78 FR 47860, 47881), the underlying premise of the presumptive compliance methodology list is that it represents particular diagnosis codes that, if applicable to a given patient, would more than likely mean that the patient required intensive rehabilitation services in an IRF for treatment of one or more of the conditions specified at § 412.29(b)(2) or that they had a comorbidity that caused significant decline in functional ability such that, even in the absence of the admitting condition, the patient would require the intensive rehabilitation treatment that is unique to IRFs and cannot be appropriately treated in another care setting. Therefore, we believe that the mere presence of an amputation status or prosthetic fitting or adjustment code alone does not provide us with enough information to determine whether the patient meets all of the requirements necessary to count for the 60 percent rule in § 412.29(b)(2).

Comment: One commenter suggested that the rationale provided by CMS for the removal of the amputation status codes confuses the concepts of medical necessity with IRF classification. The commenter stated that an amputee would only be admitted to a rehabilitation hospital by a rehabilitation physician if he or she needed intensive rehabilitation services. The commenter further stated that even

though many amputees may not need intensive inpatient rehabilitation services, the mere referral and subsequent admission to an IRF would mean that the patient needs the intensive services provided by the IRF.

Response: We disagree with this comment. The regulatory requirements at § 412.29(b) specify that at least 60 percent of an IRF's patient population must require intensive rehabilitation services in an IRF for treatment of one or more of the conditions specified at § 412.29(b)(2) or that they have a comorbidity that caused significant decline in functional ability such that, even in the absence of the admitting condition, the patient would require the intensive rehabilitation treatment that is unique to IRFs and cannot be appropriately treated in another care setting. For a patient to require intensive rehabilitation services in an IRF for treatment of a particular condition, that patient must require the close medical supervision and interdisciplinary approach to care that are unique to care in an IRF. This is not based on the IRF coverage requirements, but rather it is based directly on the regulatory language in § 412.29(b) that details the requirements that IRFs must meet to adhere to the 60 percent rule and thereby be classified for payment under the IRF PPS.

Comment: Several commenters stated that the proposed removal of the status post amputation diagnoses codes from "ICD-9-CM Codes That Meet Presumptive Compliance Criteria" list would limit access to patients that would meet admission criteria as specified in § 412.29(b)(2). One commenter stated that the effect of the proposed removal of the amputation status post diagnosis codes would be to cause more IRFs to have to undergo medical review, and the IRFs would respond by restricting admission for certain types of patients in order to avoid having to go through medical review.

Response: We do not believe that the proposed removal of these diagnosis codes will have a significant effect on access to care for these patients, as we estimate that only about 2 percent of all IRF patients are currently coded with these diagnoses, and these diagnosis codes are only used to meet the 60 percent rule requirements 0.3 percent of the time. In addition, the proposed removal of these codes from the presumptive compliance method does not necessarily mean that a patient with one of these diagnosis codes cannot be included in the IRF's population that meets the 60 percent rule. As we described in the FY 2014 IRF PPS final

rule, we use a bifurcated sub-regulatory approach to determining compliance with the rule, in which an IRF's data is first evaluated to determine whether or not the IRF is presumptively compliant with the 60 percent rule requirements. If so, then the IRF is presumed to meet the regulatory requirements. If not, then the IRF is evaluated using the more intensive medical review compliance method. If a patient with one of these diagnosis codes presents with the clinical complexity that would require an IRF level of care, then this information can be determined by the medical review, and the patient can then be included in the IRF's patient population that meets the 60 percent rule requirements. We will closely monitor the data to ensure that there are no unintended consequences of these policies on access to care.

Comment: One commenter stated that amputations in older adult populations are often the byproduct of multiple comorbid conditions (for example, diabetes or peripheral vascular disease) that make this population more at risk for post-surgical complications, such as risk of non-healing surgical incision.

Response: We agree that a patient with multiple comorbid conditions, such as diabetes or peripheral vascular disease affecting the surgical stump incision, may present with a need for intensive rehabilitation services provided in an IRF that could not be solely identified through the presence of an amputation status or prosthetic fitting or adjustment diagnosis code. These patients may meet the 60 percent rule requirements based on the presence of one of their other comorbid conditions, or the patients' clinical complexity may be determined on medical review, and the patient can then be included in the IRF's patient population that meets the 60 percent rule requirements.

Comment: One commenter requested that we apply any changes to the presumptive compliance methodology to an IRF's full 12-month compliance review period, instead of applying them to only part of an IRF's compliance review period.

Response: As the commenter suggested, all of the proposed changes to the presumptive compliance methodology are being applied effective for full 12-month compliance review periods, and will not be applied to only part of an IRF's compliance review period.

Comment: Several commenters suggested that we delay implementation of the proposed removal of the amputation status diagnosis codes and the other changes to the presumptive

compliance methodology. For example, one commenter specifically recommended that we delay implementation of changes to the presumptive compliance methodology until changes to the IRF-PAI and the associated limited medical review process are implemented. Another commenter recommended that we delay implementation of any further changes to the presumptive compliance method until at least October 1, 2015, and one commenter recommended that we delay implementation of any changes to the “non-specific ICD codes,” which we finalized in the FY 2014 IRF PPS final rule (78 FR 47884 through 47887), for at least one year following the implementation of the ICD-10-CM medical code data set, to give providers more time to adapt to the added specificity of the coding provided for under ICD-10-CM. Another commenter suggested that we delay implementation of the changes to the presumptive compliance method to give us more time to thoroughly evaluate the policies, since the changes to the presumptive compliance method that we finalized in the FY 2014 IRF PPS final rule and the changes to the presumptive compliance method that we proposed in the FY 2015 IRF PPS proposed rule, taken together, would cause as many as 15 percent of IRF Medicare cases to fail the presumptive compliance method. Finally, several commenters recommended that we keep the ICD-9-CM codes used in the presumptive compliance method as they are now—as of the date of this final rule, neither the changes finalized in the FY 2014 IRF PPS nor the changes proposed in the FY 2015 IRF PPS proposed rule have taken effect—or delay implementation of additional IGC exclusions until we transition to ICD-10-CM.

Response: We agree with these commenters that delaying the effective date of the changes to the presumptive compliance method would give CMS more time to put processes in place to mitigate some of the additional burden of increased medical reviews, and would allow providers more time to adapt to these changes. Though several of the commenters explicitly recommended that we delay the changes to the presumptive compliance method that were proposed in the FY 2015 IRF PPS proposed rule, none of the commenters explicitly stated that we should delay implementation of the changes to the presumptive compliance method that we finalized in the FY 2014 IRF PPS final rule. However, we interpret several of the comments to mean that we should delay both sets of

changes, so as to effectuate all of the related policies at the same time. For example, several of the commenters suggested delaying implementation of the “presumptive compliance” changes, without distinguishing between the changes that we finalized in the FY 2014 IRF PPS final rule and the changes that we proposed in the FY 2015 IRF PPS proposed rule. In addition, one commenter referred specifically to the impetus for recommending a delay being the significant impact that the changes would have on “15 percent” of IRF cases that would no longer meet the presumptive compliance criteria. Other commenters referenced this “15 percent” figure as the percentage of IRF cases that would be affected if we were to change from using the current presumptive compliance method to using the revised presumptive compliance method that would result from both the changes that we finalized in the FY 2014 IRF PPS final rule and the changes that were proposed in the FY 2015 IRF PPS proposed rule. Thus, we believe that the commenter was recommending a delay of both sets of presumptive compliance method changes, so as to effectuate all of the related policies at the same time.

Therefore, based on our review of these comments, and to allow for the revisions to the IRF-PAI and the associated limited medical review process discussed in section X. of this final rule to take effect prior to implementation of the changes to the presumptive compliance method, we are implementing all of the changes to the presumptive compliance method for compliance review periods beginning on or after October 1, 2015. That is, we are delaying the effective date of the changes to the presumptive compliance method that we finalized in the FY 2014 IRF PPS final rule until compliance review periods beginning on or after October 1, 2015, and we are also delaying the changes to the presumptive compliance method that we are finalizing in this final rule so that they also take effect for compliance review periods beginning on or after October 1, 2015. This represents a one-year delayed effective date for all of these changes. We believe that it will be much less confusing for providers to have all of the changes to the presumptive compliance method take effect at the same time.

We do not believe that it is necessary to delay implementation of these changes for an additional year after ICD-10-CM becomes the required medical code data set for use on IRF claims and on the IRF-PAI. Given that the effective date of the use of ICD-10-

CM has been delayed twice, and given that the ICD-10-CM code lists, which will be used when ICD-10-CM becomes the required medical code data set with respect to IRF claims and the IRF-PAI, are available for download on the CMS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Data-Files.html> in conjunction with the publication of this final rule, we believe that IRFs will have sufficient opportunity to become familiar with the added specificity of the coding offered in ICD-10-CM.

Comment: Several commenters suggested that CMS continue to count amputation status codes toward an IRF’s compliance percentage, but do so in conjunction with other related information provided in the IRF-PAI. The commenters stated that the amputation status codes could be used in combination with the Etiologic Diagnosis, which would reflect recent injury. One commenter suggested that an indicator could be added that could be “paired up” with the codes in order to maintain automation and avoid the burden of increased medical review. Another commenter stated that comorbid conditions listed on the IRF-PAI could also provide an appropriate clinical picture that would “presumptively” indicate that the patient meets conditions outlined at § 412.29(b)(2). Moreover, one commenter suggested that the added specificity of coding provided for in the ICD-10-CM coding may supply additional information that may help support the amputation status diagnosis as a “presumptively” qualifying condition.

Response: We thank the commenters for their suggestions. However, we continue to believe that it cannot be determined from the amputation status or prosthetic fitting or adjustment diagnosis codes alone whether a patient presents with the clinical complexity that would require an IRF level of care, and, for this reason, we do not believe that it is appropriate to continue to include these codes on the “ICD-9-CM Codes That Meet Presumptive Compliance” list. However, as we indicated above, these patients can continue to be counted under the medical review methodology if their clinical complexity is shown in the medical record to require an IRF level of care. In fact, as the one commenter mentioned, the patient’s comorbid conditions as listed on the IRF-PAI and described in the patient’s medical record do contribute to an overall “picture” of the patient’s condition, but at this time, this information cannot be

determined using a computer program and can only be determined through a medical review of the patient's clinical record.

While we agree that ICD-10-CM coding will likely provide more specificity and more information, we continue to believe that these amputation status or prosthetic fitting or adjustment diagnosis codes, even under ICD-10-CM, do not provide enough information about the clinical complexity of the case to warrant continued inclusion on the list of diagnosis codes that meets the presumptive compliance criteria. We will consider the commenters' suggestions for future refinements to the IRF-PAI and to the presumptive compliance methodology.

Comment: One commenter recommended that CMS ensure that MACs understand the importance of IRF care to patients with amputations (especially those with other comorbidities) since there could be an increase in medical review for amputation cases.

Response: We appreciate the commenter's suggestion, and we plan to carry out training and outreach with MACs to review policy changes to the presumptive compliance methodology.

Final Decision: After carefully considering the comments that we received on the proposed removal of the status post-amputation diagnoses codes from the "ICD-9-CM Codes That Meet Presumptive Compliance Criteria" list, we are finalizing these proposed changes to the list. The changes to the list of diagnosis codes that are used to determine presumptive compliance under the 60 percent rule are effective for compliance review periods beginning on or after October 1, 2015.

C. Changes to the Impairment Group Codes That Meet Presumptive Compliance Criteria

An "impairment group code" is not an ICD diagnosis code, but part of a separate unique set of codes specifically developed for the IRF PPS for assigning the primary reason for admission to an IRF. These codes are listed in the IRF-PAI Training Manual (*see* section II, item #21, and Appendix A). The IRF-PAI Training Manual is available through the Internet on the CMS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/IRFPAI.html>.

If an IRF is eligible to use the presumptive methodology to evaluate its compliance with the 60 percent rule, all of its IRF-PAI assessments from the most recently completed 12-month compliance review period are examined

(with the use of a computer program) to determine whether they contain any of the codes listed on the presumptive methodology lists (that is, "ICD-9-CM Codes That Meet Presumptive Compliance Criteria" and "Impairment Groups That Meet Presumptive Compliance Criteria"). Each selected assessment is presumptively categorized as either meeting or not meeting the IRF 60 percent rule requirements based upon the primary reason for the patient to be treated in the IRF (the impairment group) and the ICD diagnosis codes listed as either the etiologic diagnosis (the etiologic problem that led to the condition for which the patient is receiving rehabilitation) or one of 25 comorbidities on the assessment.

Not all impairment group codes (IGCs) meet the presumptive compliance criteria. The underlying premise of the list of eligible IGCs that are used to determine presumptive compliance (similar to the diagnosis codes listed in "ICD-9-CM Codes That Meet Presumptive Compliance Criteria") includes particular IGCs that, if applicable to a given patient, would more than likely mean that the patient required intensive rehabilitation services for treatment of one or more of the conditions specified at § 412.29(b)(2). The current list of eligible IGCs that meet presumptive compliance criteria, Appendix B: Impairment Group Codes That Meet Presumptive Compliance Criteria, can be downloaded from the October 1, 2007, IRF Compliance Rule Specification Files on the Medicare IRF PPS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Criteria.html>. Again, this list contains only those IGCs that meet the presumptive compliance criteria.

1. Removal of IGCs for Unilateral Upper Extremity Amputations and Arthritis From Appendix B: Impairment Group Codes That Meet Presumptive Compliance Criteria

In the FY 2014 IRF PPS final rule (78 FR 47889 through 47895), we finalized (applicable for compliance review periods beginning on or after October 1, 2014) the removal of certain ICD-9-CM codes for unilateral upper extremity amputations from the list of "ICD-9-CM Codes That Meet Presumptive Compliance Criteria" because we believed that it is impossible to determine, from the presence of such ICD-9-CM codes alone, whether a patient with such a unilateral upper extremity amputation has a condition for which he or she would need intensive rehabilitation services for

treatment of one or more of the conditions specified in § 412.29(b)(2). Further, we stated that a patient's need for intensive inpatient rehabilitative services for the treatment of one or more of these conditions would depend on the presence of additional comorbidities that caused significant decline in his or her functional ability to an extent that would necessitate treatment in an IRF. If the patient has one or more of the comorbidities on the list of "ICD-9-CM Codes That Meet Presumptive Compliance Criteria," then the patient would already qualify as meeting the presumptive compliance criteria. We concluded that if the diagnosis codes for such a patient's comorbidities do not appear on the list of "ICD-9-CM Codes That Meet Presumptive Compliance Criteria," then the patient could still be considered for inclusion in the IRF's compliance percentage following medical review and confirmation that the case meets the criteria for one or more of the medical conditions in the regulations.

In the FY 2014 IRF PPS final rule (78 FR 47887 through 47895), we also finalized (applicable for compliance review periods beginning on or after October 1, 2014) the removal of ICD-9-CM diagnosis codes for arthritis conditions from the list of "ICD-9-CM Codes That Meet Presumptive Compliance Criteria" because the inclusion of patients with these medical conditions in the presumptive compliance calculation of the IRF's compliance percentage is conditioned on those patients meeting the described severity and prior treatment requirements. However, the ICD-9-CM diagnosis codes that reflect these arthritis and arthropathy conditions do not provide any information about the severity of the condition or whether the prior treatment requirements were met. Therefore, we stated in the FY 2014 IRF PPS final rule that we believe that additional information beyond the presence of the code is necessary to determine if the medical record would support inclusion of individuals with the arthritis and arthropathy conditions outlined in our regulations under § 412.29(b)(2)(x) through § 412.29(b)(2)(xii) in the presumptive compliance calculation of the facility's compliance percentage. For this reason, we finalized the removal of the ICD-9-CM diagnosis codes associated with the medical conditions outlined in our regulations under § 412.29(b)(2)(x) through § 412.29(b)(2)(xii) from the list of "ICD-9-CM Codes That Meet Presumptive Compliance Criteria." However, we also stated that we expect

that the MACs will be able, upon medical review, to include those patients in a facility's compliance percentage upon confirmation that the severity and prior treatment requirements were met.

Consistent with our rationale in the FY 2014 IRF PPS final rule for removing the ICD-9-CM diagnoses codes for unilateral upper extremity amputations and the arthritis and arthropathy conditions, we are making conforming changes to the IGCs in this final rule by removing four IGCs from Appendix B: Impairment Group Codes That Meet Presumptive Compliance Criteria. Thus, we will remove the following codes from Appendix B: Impairment Group Codes That Meet Presumptive Compliance Criteria:

- IGC 0005.1—Unilateral Upper Limb Above the Elbow (AE),
- IGC 0005.2—Unilateral Upper Limb Below the Elbow (BE),
- IGC 0006.1—Rheumatoid Arthritis, and
- IGC 0006.9—Other Arthritis.

2. Other Changes to Appendix B: Impairment Group Codes That Meet Presumptive Compliance Criteria

We will revise Appendix B: Impairment Group Codes That Meet Presumptive Compliance Criteria by revising the diagnosis codes listed as exclusions on the table and by revising the title of the table.

In the FY 2014 IRF PPS final rule (78 FR 47860, 47881 through 47895), we finalized (applicable for compliance review periods beginning on or after October 1, 2014) the removal of certain ICD-9-CM codes from the list of "ICD-9-CM Codes That Meet Presumptive Compliance Criteria." Accordingly, we exclude these diagnosis codes from counting if they are the patient's Etiologic Diagnosis (that is, the etiologic problem that led to the condition for which the patient is receiving rehabilitation). That is, a given IGC that would otherwise meet the presumptive compliance criteria will not meet such criteria if the patient has one of the "excluded" Etiologic Diagnoses for that IGC.

In addition, in the FY 2014 IRF PPS final rule (78 FR 47860, 47883), we implemented a change in the titles of some tables used in the presumptive compliance methodology to no longer use alphabet characters or the "Appendix" labels to identify these tables. Consistent with the intent to reduce confusion among tables, and effective October 1, 2014, we will identify Appendix B: Impairment Group Codes That Meet Presumptive Compliance Criteria as "Impairment

Group Codes That Meet Presumptive Compliance Criteria."

In addition, we provided an additional new table, "Impairment Group Codes That Meet Presumptive Compliance Criteria," that lists Etiologic Diagnosis codes that are excluded from counting under related IGCs in ICD-10-CM code format. For example, ICD-10-CM code G72.3, "Periodic Paralysis" is an excluded Etiologic Diagnosis code under IGC 0003.8, "Neuromuscular Disorders." Further, to accommodate the Etiologic Diagnosis code exclusions, we have reformatted this table. A revised table containing the "Impairment Group Codes That Meet Presumptive Compliance Criteria," with the ICD-10-CM Etiologic Diagnosis exclusions, can be viewed on the Medicare IRF PPS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Data-Files.html>. The changes to the table, "Impairment Group Codes That Meet Presumptive Compliance Criteria," will be effective for compliance review periods beginning on or after October 1, 2015.

We received 49 comments on the proposed changes to the impairment group codes that meet presumptive compliance criteria, which are summarized below.

Comment: Several commenters expressed concerns that a potential unintended consequence of excluding the proposed arthritis diagnosis codes under IGCs 0008.51, 0008.52, 0008.61, 0008.62, 0008.71, and 0008.72 would be that most lower extremity joint replacement cases that currently satisfy the 60 percent rule, that is, bilateral joint replacement cases and unilateral joint replacement cases involving patients 85 years of age or older and/or who have a BMI of 50 or greater, would no longer be included in an IRF's presumptive compliance percentage.

Response: We appreciate the commenters' careful review of the proposed Etiologic Diagnosis exclusions for IGCs 0008.51, 0008.52, 0008.61, 0008.62, 0008.71, and 0008.72, and we agree with these commenters that there would have been unintended consequences of excluding the proposed arthritis diagnosis codes from these IGCs. As we intend to continue to count bilateral lower-extremity joint replacement cases and unilateral lower-extremity joint replacement cases involving patients 85 years of age or older and/or who have a BMI of 50 or greater as meeting the 60 percent rule criteria under the presumptive compliance method, we will remove the proposed Etiologic Diagnosis exclusions

from IGCs 0008.51, 0008.52, 0008.61, 0008.62, 0008.71, and 0008.72.

Comment: Several commenters expressed concern that the impact of the proposed changes to the presumptive compliance criteria, the changes proposed in the FY 2015 proposed rule and the changes finalized in the FY 2014, will be to increase the number of IRFs that will fail to meet presumptive compliance.

Response: We agree with commenters that one of the likely consequences of the changes to the presumptive compliance method will be an increase in the number of IRFs that will fail the presumptive compliance method and will have to be evaluated using the medical review method. However, we believe that the proposed changes to the IGCs That Meet Presumptive Compliance Criteria are necessary to continue appropriate enforcement of the regulations in § 412.29(b). We believe that it is impossible to determine from the presence of one of the IGCs or Etiologic Diagnoses alone whether the patient's clinical complexity requires an IRF level of care, or, in the case of an arthritis code, whether the patient meets the severity and prior treatment requirements in regulation at § 412.29(b)(2). This information can only be obtained through a review of the patient's medical record.

However, to mitigate some of the added burden on providers of the additional medical reviews, we discuss a new policy in section X of this final rule that will allow some arthritis cases to count toward the presumptive compliance method based on a limited medical review of these cases. We believe that this new policy will alleviate some of the burden associated with additional medical reviews.

Comment: One commenter expressed concern about the removal of IGC 0005.1—Unilateral upper limb above the elbow (AE) and IGC 0005.2—Unilateral upper limb below the elbow (BE), as the commenter said that these patients have impairments related to the ability to conduct activities of daily living that are most appropriately treated using the intensive rehabilitation therapy provided in an IRF.

Response: As we indicated in the FY 2014 IRF PPS final rule (78 FR 47860, at 47890), we believe that some patients with upper extremity amputations might require treatment in an IRF, depending on the clinical complexity of the particular case or the presence of any other complicating factors or comorbidities. However, we expect that many patients with these upper extremity amputations will not require close medical supervision by a

physician or weekly interdisciplinary team conferences to achieve their goals, and can be treated effectively in other care settings. If the patient has additional comorbidities causing significant decline in his or her functional ability which, in the absence of the unilateral upper extremity amputation, would require treatment in an IRF, then the patient will still be able to be counted towards meeting the 60 percent rule criteria. Additionally, the patient can still be counted towards meeting the 60 percent rule criteria on medical review, if appropriate.

However, we continue to believe that a patient's need for the intensive rehabilitation services provided in an IRF depends on other factors which cannot be adequately determined through the mere presence of IGC 0005.1—Unilateral upper limb above the elbow (AE) and IGC 0005.2—Unilateral upper limb below the elbow (BE). Thus, we are removing these IGCs from the IGCs That Meet the Presumptive Compliance Criteria.

Comment: One commenter expressed concern about the proposed addition of non-specific diagnosis codes to the Etiologic Diagnosis exclusions for some of the IGCs because this commenter said that it is often “administratively unrealistic” to obtain detailed medical information from a transferring facility, especially in cases where the IRF admission is not directly from an acute care hospital. The commenter said that non-specific codes should not be viewed as reflecting poor documentation or poor coding.

Response: As we stated in the FY 2014 IRF PPS final rule (78 FR 47860, 47884), we believe that highly descriptive coding provides the best and clearest way to document the appropriateness of a given patient's admission, and would improve our ability to use the presumptive compliance method of calculating a facility's 60 percent rule compliance percentage. Therefore, whenever possible, we believe that the most specific code that describes a medical disease, condition, or injury should be used to document diagnoses on the IRF-PAI. We also stated in the FY 2014 IRF PPS final rule (78 FR 47860, 47884) that we believe imprecise codes would inappropriately categorize an overly broad segment of the patient population as having the conditions required for inclusion in a facility's presumptive compliance calculation, which would result in an inflated compliance percentage. In the FY 2014 IRF PPS final rule (78 FR 47860, 47885), we also stated that if the IRF does not have enough information about the patient's

condition to code the more specific codes on the IRF-PAI, we would expect the IRF to seek out additional information from the patient's acute care hospital medical record to determine the appropriate, more specific code to use. The ICD-9-CM diagnosis codes that are listed as exclusions on “Impairment Group Codes That Meet Presumptive Compliance Criteria” are consistent with the list of diagnosis codes we removed from “ICD-9-CM Codes That Meet Presumptive Compliance Criteria.”

Comment: Several commenters expressed concerns about possible inconsistencies in the specific IGC exclusions that we proposed in the FY 2015 IRF PPS proposed rule. For example, one commenter pointed out that we were proposing to exclude the Etiologic Diagnosis of ICD-9-CM code 850.5—Concussion with loss of consciousness of unspecified duration for IGC 0002.22—Brain dysfunction, Traumatic, Closed Injury. However, we were not proposing to exclude, ICD-9-CM code 850.0—Concussion with no loss of consciousness from this same IGC.

Response: We thank the commenter for their careful review and analysis of the IGCs That Meet Presumptive Compliance Criteria. We have reviewed the IGCs That Meet Presumptive Compliance Criteria in light of these comments, and we agree with the commenter's suggestion that this represents an inadvertent inconsistency. Thus, we are adding ICD-9-CM code 850.0—Concussion with no loss of consciousness as an Etiologic Diagnosis exclusion to the list of Etiologic Diagnosis exclusions under IGC 0002.22—Brain dysfunction, Traumatic, Closed Injury.

Comment: One commenter stated that we excluded ICD-9-CM diagnosis code 438.20—Late effects of cerebrovascular disease, hemiplegia affecting unspecified side from IGC 0001.9—Other Stroke, but did not list this diagnosis code as an exclusion for other stroke IGCs.

Response: ICD-9-CM diagnosis code 438.20 is not listed as an exclusion for the other stroke IGCs because the other stroke IGCs either specify side of body involvement or no paresis.

Comment: One commenter suggested that as many as 10 percent of IRF cases will no longer qualify toward an IRF's presumptive compliance percentage should the proposed removal of IGC 0005.1, IGC 0005.2, IGC 0006.1, and IGC 0006.9 and the exclusion of Rheumatoid and Osteoarthritis diagnosis codes from hip and knee joint replacement be finalized.

Response: As discussed above, the commenters led us to discover that there would have been unintended consequences of excluding the proposed arthritis Etiologic Diagnosis codes from IGCs 0008.51, 0008.52, 0008.61, 0008.62, 0008.71, and 0008.72. As we intend to continue to count bilateral lower-extremity joint replacement cases and unilateral lower-extremity joint replacement cases involving patients 85 years of age or older and/or who have a BMI of 50 or greater as meeting the 60 percent rule criteria under the presumptive compliance method, we are removing the proposed Etiologic Diagnosis exclusions from these IGCs. We believe that this change substantially reduces the estimated percentage of IRF cases that will no longer qualify toward an IRF's presumptive compliance percentage. However, with respect to the remaining IRF cases that will no longer qualify toward an IRF's presumptive compliance percentage, we continue to believe that this is appropriate because the case's compliance with the 60 percent rule criteria cannot be adequately determined through the mere presence of the IGC or ICD-9-CM diagnosis code alone.

Comment: Several commenters indicated that the proposed changes to “Impairment Group Codes That Meet Presumptive Compliance Criteria” (and the above discussed removal of the amputation status diagnosis codes) would likely lead to reduced access to IRF care. The commenters noted that for certain types of patients, IRFs would be in the position of choosing between admitting these patients and facing “additional risk” associated with medical reviews, or not admitting these types of patients. Many of these commenters said that such changes are unnecessary in light of past regulatory actions, such as the regulatory refinements of the 60 percent rule that were implemented in 2004 and the more stringent IRF coverage requirements that were implemented in 2010, that have already reduced the number of IRF admissions and increased the average IRF case mix.

Response: We acknowledge that some IRFs may seek to avoid the possibility of medical review by limiting admission of patients with certain conditions, such as arthritis or unilateral upper-extremity amputations. However, this is not our intent in implementing this policy. The intent of these changes to the presumptive compliance method is to obtain enough information to ensure that patients who are counted as meeting the 60 percent rule in § 412.29(b) are appropriately meeting

the regulatory requirements. Although previous regulatory refinements have improved the IRF payment system, we believe that the proposed updates to the presumptive compliance method serve to further enhance the accuracy and appropriateness of the payment system. As discussed in section X. of this final rule, we are concurrently implementing policies designed to minimize the burden created by the operational aspects of this policy.

Comment: One commenter suggested that the removal of IGC 0006.1—Rheumatoid Arthritis and IGC 0006.9—Other Arthritis should coincide with the implementation of the proposed new IRF–PAI item, so that these IGCs could still be used to presumptively determine an IRF’s compliance with the 60 percent rule. The commenter also suggested that the new IRF–PAI item and associated limited medical review should replace the current policy of requiring a full medical review if an IRF fails the presumptive compliance method.

Response: We agree with the commenter’s suggestion that the effective date of the removal of IGC 0006.1—Rheumatoid Arthritis and IGC 0006.9—Other Arthritis should coincide with the implementation of the new proposed IRF–PAI item. Additionally, we believe that it makes the most sense to implement the changes to the presumptive methodology, both those that were finalized in the FY 2014 IRF PPS final rule and those that we are finalizing in this section of this final rule, for compliance review periods beginning on or after October 1, 2015, to aid in mitigating the potential burden for additional medical review as a result of the finalized policy changes. As discussed in more detail in section X. of this final rule, the new IRF–PAI item for arthritis conditions will allow IRFs to indicate whether there are any arthritis codes (either IGC or ICD–9–CM diagnosis codes) on a patient’s IRF–PAI that meet all of the regulatory requirements specified in § 412.29(b)(2)(x), (xi), or (xii). If so, then we will perform a limited medical review on these cases to ensure that the requirements are met. If we find that all of the requirements are met, those arthritis cases will be allowed to count toward the IRF’s presumptive compliance percentage. As the new IRF–PAI item is being added for IRF discharges occurring on or after October 1, 2015, we believe it makes sense to delay the effective dates of the changes to the presumptive methodology finalized in the FY 2014 IRF PPS final rule and those changes to the presumptive methodology being finalized in this section of this final

rule. Therefore, we are delaying the effective date of the presumptive methodology changes finalized in the FY 2014 IRF PPS final rule and the additional presumptive methodology changes that we are finalizing in this section of this final rule, so that they will become effective for compliance review periods beginning on or after October 1, 2015.

However, we do not agree with the suggestion that the limited medical review should replace the full medical review entirely. The medical review method has been the more detailed and comprehensive method for enforcing the 60 percent rule since the rule was first implemented in the mid-1980s, and continues to be an important way of accurately determining whether IRFs meet the criteria in § 412.29(b) to be excluded from the IPPS and be paid instead under the IRF PPS.

Comment: One commenter expressed concern that the changes to the presumptive compliance methodology finalized in the FY 2014 IRF PPS final rule and the changes proposed in the FY 2015 IRF PPS proposed rule constitute an “end run” around the statutory limit on the compliance threshold of 60 percent established by Congress.

Response: We disagree with the commenter’s assertion that we are changing the 60 percent compliance threshold. We do not believe that the changes finalized in the FY 2014 IRF PPS final rule or the changes proposed in the FY 2015 IRF PPS proposed rule erode the underlying principle of the 60 percent rule that requires an IRF to demonstrate that it “served an inpatient population of whom at least 60 percent required intensive rehabilitation services for treatment of one or more of the conditions specified at paragraph (b)(2).” We are not revising the criteria that govern the 13 medical conditions that may be counted toward an IRF’s 60 percent rule compliance percentage. As we have stated in the FY 2014 IRF PPS final rule and the FY 2015 IRF PPS proposed rule, we are refining the lists used for the presumptive compliance methodology because we believe that certain ICD diagnosis codes on the lists do not necessarily demonstrate a patient’s meeting the medical condition (including severity and prior treatment) requirements for inclusion in a facility’s 60 percent compliance calculation under the presumptive methodology method. Thus, we are removing these codes so that the presumptive methodology lists better reflect the regulations. Furthermore, the criteria under which a case may count under medical review have not changed.

Comment: Several commenters stated that ICD–9–CM codes 820.8—Closed fracture of unspecified part of neck of femur and 820.9—Open fracture of unspecified part of neck of femur should not be exclusions under IGC 0008.11—Status Post Unilateral Hip Fracture and IGC 0008.12—Status Post Bilateral Hip Fractures. The commenters said that the ICD–9–CM codes 820.8 and 820.9 are often used as Etiologic Diagnoses in combination with IGCs 0008.11 and 0008.12. One commenter said that the diagnosis codes 820.8 and 820.9 still represent a hip fracture and that the more specific information regarding where on the neck of the femur the fracture occurred would not be readily available to the IRF and would in any case not meaningfully impact care.

Response: The use of an ICD–9–CM code beginning with 820, by definition, indicates that the patient has experienced a fracture of the neck of the femur. However, this code requires that decimal points be used following the number to ensure specificity. Diagnosis codes 820.00 through 820.32, by differentiating between an intracapsular and an extracapsular fracture of the proximal femur, provide a degree of specificity not offered by diagnosis codes 820.8 and 820.9. Therefore, as we proposed, we will exclude ICD–9–CM codes 820.8 and 820.9 as Etiologic Diagnosis codes under IGC 0008.11—Status Post Unilateral Hip Fracture and IGC 0008.12—Status Post Bilateral Hip Fractures. IGC 0008.11 and IGC 0008.12 will continue to count toward 60 percent compliance under the presumptive compliance method if coded with Etiologic Diagnosis codes 820.00 through 820.32.

Final Decision: After carefully considering the comments that we received on the proposed changes to the IGCs That Meet Presumptive Compliance Criteria, we are revising the list of excluded ICD–9–CM diagnosis codes for some IGCs from “Impairment Group Codes That Meet Presumptive Compliance Criteria” as follows: We are removing the ICD–9–CM diagnosis code exclusions under IGC 0008.51 through IGC 0008.72. We are also excluding ICD–9–CM diagnosis code 850.0 under IGC 0002.22. The final “Impairment Group Codes That Meet Presumptive Compliance Criteria” list that reflects specific changes to the proposed policies listed above, is available for download from the CMS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Data-Files.html>. The presumptive methodology changes that we had finalized in the FY 2014 IRF

PPS final rule and the additional presumptive methodology changes that we are finalizing in this section of this final rule will become effective for compliance review periods beginning on or after October 1, 2015.

IX. Data Collection of the Amount and Mode (Individual, Concurrent, Group, and Co-Treatment) of Therapy Provided in IRFs According to Occupational, Speech, and Physical Therapy Disciplines

Prior to the implementation of the IRF PPS in January 2002, Medicare payment for IRF services under section 101(a) of the Tax Equity and Fiscal Responsibility Act of 1982 (Pub. L. 97–248, enacted September 3, 1982) was based on the reasonable costs incurred in furnishing services to Medicare beneficiaries, subject to a limit on allowable costs per discharge. Thus, for therapy services, Medicare reimbursed IRFs based on the reasonable costs incurred in furnishing appropriate levels of Individual Therapy or Group Therapy, which meant that IRFs had limited financial incentives to provide more of one mode of therapy than another. We presumed that decisions about the mode of therapy delivery were likely to be based on the needs of the patient and on the best way to assist patients in meeting their individualized rehabilitation goals. With the advent of the IRF PPS beginning in January 2002, Medicare began reimbursing IRFs using a set prospective payment amount that was intended to cover the costs of all treatment and services, including therapy services, provided to patients in the IRF. This increased the financial incentives for IRFs to give patients more Group Therapy and less Individual Therapy, because Individual Therapy is more costly to provide. Although we know that the financial incentives for the provision of Individual Therapy and Group Therapy changed, we do not know whether IRFs provided different modes of therapy in response to the new incentives or how much Individual Therapy and Group Therapy IRFs currently provide. Medicare does not currently collect data from IRFs on the amount of Individual, Concurrent, Group, and Co-Treatment Therapies provided by therapy discipline. We believe that it is important to begin collecting these data to determine what services Medicare is paying for under the IRF prospective payment system, which would allow us to analyze whether we are paying appropriately for services currently rendered by IRFs. Medicare administrative data (such as the IRF claims data) do not currently provide the level of detailed information

about the mode and type of therapy provided to IRF patients that we need to perform these analyses. Thus, this proposed new data collection will assist us in the development of appropriate coverage and payment criteria for the provision of Group Therapy in the IRF setting. We believe that these coverage and payment criteria are important to balance the beneficial aspects of Group Therapy for certain patients in certain instances with the IRF requirements for an intensive rehabilitation therapy program.

In the FY 2010 IRF PPS proposed rule (74 FR 21070, 21071), in which we proposed a revised set of Medicare coverage requirements for IRF services, we discussed the relative value of Individual Therapy versus Group Therapy in the IRF setting. To improve our understanding of when Group Therapy is most appropriate in IRFs, we solicited comments in that proposed rule on the types of patients for whom Group Therapy is appropriate, and the specific amount of Group Therapy that may be beneficial for these types of patients. Subsequently, we discussed the comments in the FY 2010 IRF PPS final rule (74 FR 39796, 39797).

Although the comments on the FY 2010 IRF PPS proposed rule did not offer any clinical study results or any data that would be helpful to us in developing coverage and payment criteria for the provision of Group Therapy in IRFs, the comments did suggest an important role for Group Therapy in the provision of therapies in IRFs. However, the majority of commenters remarked that Group Therapy should be limited in some way. Many commenters agreed that Group Therapy is a good adjunct to Individual Therapy, but should not be the primary source of therapy services provided in IRFs. Several commenters recommended that we limit the amount of Group Therapies provided in IRFs, and that we also limit the number of patients who can participate in a Group Therapy session. Commenters also suggested that Group Therapy sessions should be comprised of patients with similar diagnoses. We agreed with the commenters that Group Therapy should not be the primary source of therapy given to patients in IRFs. Group Therapy should be used in IRFs primarily as an adjunct to Individual Therapy services, which is the standard of care in IRFs, as Group Therapy may not uniformly represent the level of intensive rehabilitation therapy required and paid for in the IRF setting. In the final rule, we also stated that we would consider adopting specific coverage and payment criteria for Group Therapy

practice in IRFs through future rulemaking.

When an authorized clinician deems it to be necessary, we continue to believe that Group Therapy can serve as an appropriate mode of therapy delivery that can be beneficial to the particular needs of IRF patients as an adjunct to Individual Therapy. Anecdotally, we understand that Group Therapy remains a widely used mode of therapy in the IRF setting. But as we stated in the FY 2010 IRF PPS final rule, we believe that it would be inappropriate for IRFs to provide essentially all therapy in the form of Group Therapy because we do not believe that this is in the best interest of the patients, or that it reflects the services for which the IRF prospective payment system was established to pay. Therefore, to better understand the ways in which therapy services are currently being provided in IRFs, we are adding a new Therapy Information Section to the IRF-PAI to record the amount and mode of therapy (that is, Individual, Concurrent, Group, and Co-Treatment) patients receive in each therapy discipline (that is, physical therapy, occupational therapy, and speech-language pathology).

For purposes of recording therapy services in IRFs, we proposed to define Individual Therapy as the provision of therapy services by one licensed or certified therapist (or licensed therapy assistant, under the appropriate direction of a licensed or certified therapist) to one patient at a time (this is sometimes referred to as “one-on-one” therapy). In the proposed rule, we defined Group Therapy as the provision of therapy services by one licensed or certified therapist (or licensed therapy assistant, under the appropriate direction of a licensed or certified therapist) to between 2 and 6 IRF patients at one time, regardless of whether those 2 to 6 IRF patients are performing the same activity or different activities. As discussed in our responses to comments below, we will instead define Group Therapy as one licensed or certified therapist (or licensed therapy assistant, under the appropriate direction of a licensed therapist) treating 2 to 6 patients at the same time who are performing the same or similar activities. We proposed to define Co-Treatment as the provision of therapy services by more than one licensed or certified therapist (or licensed therapy assistant, under the appropriate direction of a licensed therapist) from different therapy disciplines to one patient at the same time. For example, Co-Treatment could involve one physical therapist and one occupational therapist working with one patient at

the same time to achieve the patient's goals. Because Co-Treatment is appropriate for specific clinical circumstances and is not suitable for all patients, its use should be limited. As discussed in our responses to comments below, we will define Concurrent Therapy as one licensed or certified therapist treating 2 patients at the same time who are performing different activities.

We will collect this information in a new Therapy Information Section on the IRF-PAI, which will be effective for IRF discharges beginning on or after October 1, 2015. The new Therapy Information section will be completed as part of the patient's discharge assessment. In this new section, the IRF will record how many minutes of Individual, Concurrent, Group, and Co-Treatment Therapies the patient received, according to each therapy discipline (that is, physical therapy, occupational therapy, and speech-language pathology), during the first week (7 calendar day period) of the IRF stay; how many minutes of Individual, Concurrent, Group, and Co-Treatment Therapies the patient received, according to each therapy discipline, during the second week (7 calendar day period) of the IRF stay. In the proposed rule, we proposed that IRFs would also collect the average number of minutes of Individual, Group, and Co-Treatment therapies the patient received, according to each therapy discipline, during all subsequent weeks (7 calendar day periods) of the IRF stay, beginning with the third week. For Co-Treatment, each therapist will record the amount of time spent with the patient. That is, if a physical therapist and an occupational therapist both worked with the patient from 9:00 a.m. to 9:30 a.m., then each therapist would record 30 minutes with the patient in the Co-Treatment section of the IRF-PAI. The draft of the IRF-PAI for FY 2016 that includes this new Therapy Information section is available for download from the IRF PPS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/IRFPAL.html> in conjunction with the publication of this final rule. We will use these data for the following purposes:

- To analyze the types of therapy services Medicare is currently paying for under the IRF prospective payment system; and
- To monitor the amount of therapy given and the use of different therapy modes in IRFs to support future rulemaking in this area.

For example, we are considering using these data to propose limits on the amount of Group Therapy that may be

provided in IRFs through future rulemaking. One such limit that we are currently considering is that an IRF patient may receive no more than 25 percent of his or her total therapy treatment time in Group Therapy, similar to the limit that currently exists in the skilled nursing facility (SNF) setting, as discussed in the FY 2000 SNF PPS and Consolidated Billing final rule (64 FR 41644, 41662). We specifically solicited public comment on all of these proposals, including whether 25 percent is the most appropriate limit to establish for the IRF setting.

We received 43 comments on the data collection regarding the amount and mode (Individual, Concurrent, Group, and Co-Treatment) of therapy provided in IRFs according to Occupational, Speech, and Physical Therapy Disciplines, which are summarized below.

Comment: Overall, several commenters supported CMS's proposed therapy collection item on the IRF-PAI, with one commenter indicating that collection of these data could lead to significant improvements in quality of care and accuracy of payments in the IRF PPS.

Response: We appreciate the support from the commenters regarding the new therapy item on the IRF-PAI. To date, we have been unable to track changes in the provision of therapy to patients because Medicare does not collect data on therapy modalities (Individual, Concurrent, Group, and Co-Treatment) by each therapy discipline (that is, physical therapy, occupational therapy, and speech-language pathology). We believe that by adding this item to the IRF-PAI, we will be able to determine the current services for which Medicare is paying and whether limits on the amount of group therapy that may be provided to IRF patients are needed.

Comment: Several commenters expressed concern that the proposed collection method changes the collection criteria for the weeks subsequent to the second week. Commenters suggested that this change introduces the potential for confusion and error because facilities will have to monitor every patient on the unit to determine when the third week of the stay will begin. Additionally, these commenters suggested that we should collect data on the total number of minutes of therapy provided to patients, by mode and type of therapy, only once at discharge based on the total number of minutes provided to the patient throughout the IRF stay, as it would lessen the burden of the data collection.

Response: After careful consideration of these comments, we agree that

collecting average number of minutes of therapy, by mode and type of therapy, for weeks 3 and beyond may have the potential to create confusion for providers. For this reason and in order to minimize provider burden, we are choosing not to finalize this proposal, and will instead only collect total number of minutes of therapy by mode and discipline for weeks 1 and 2. We believe that it would greatly improve our understanding of the provision of therapy in IRFs to collect data on the amount of therapy provided, by mode and type of therapy, for week 1 of the IRF stay (that is, the first 7 consecutive calendar days starting with the day of admission) and for week 2 of the IRF stay (that is, the second 7 consecutive calendar days of the IRF stay). Since the average length of stay in an IRF is 13 days, and to minimize the burden of this data collection effort, we will not require data to be reported beyond week 2 of the IRF stay. We believe that collecting total number of minutes of therapy, by mode and type of therapy, only for weeks 1 and 2 of the IRF stay is sufficient to help us to be able to develop future policy and improve the quality of care and accuracy of payments in the IRF PPS. Additionally, since our intent is to collect the most specific information regarding therapy data that we can, we recognize that collecting the average amount of therapy for weeks 3 and on, will perhaps not provide us with the specificity that we are seeking at this time. However, we may propose to require data collection on weeks 3 and beyond of the IRF stay through future notice and comment rulemaking if we later determine that such data is needed to better inform future policymaking.

While we recognize that the commenters believe that collecting the number of minutes of therapy, by mode and type of therapy, for the whole IRF stay only at the time of the patient's discharge from the IRF would lessen the burden of this data collection, we do not believe that this would provide us with level of detail that we believe we would need to develop future policy in this area or to understand what services we are paying for with the IRF benefit.

Comment: Several commenters suggested that CMS should seek to achieve its objective of better understanding therapy usage and outcomes within IRFs, by funding a study on the utilization of various therapy modes in IRFs.

Response: Unfortunately, we are not able to fund a study of therapy usage and outcomes, but we would welcome learning from such studies conducted by others. Clinical evidence linking

therapy usage with patient outcomes would greatly improve our understanding of these issues, and would not only enhance future policymaking in this area, but we believe would also inform and enhance the quality of care provided in IRFs and other post-acute care settings.

Comment: Several commenters expressed concern regarding CMS's definition of each therapy mode, most specifically, Group Therapy. One commenter suggested that we should be more consistent in our definitions of the different modes of therapy across Medicare payment settings. Many of the commenters indicated that studies regarding the benefits of one mode of therapy over another are very limited, and wanted to know what clinical basis we used when deciding that a group should be comprised of 2–6 patients. Other commenters urged CMS to recognize Concurrent Therapy as a distinct mode of therapy and not include it in the Group Therapy definition.

Response: After carefully reviewing the comments regarding the definitions of the different modes of therapy, we agree with commenters that Concurrent Therapy should be removed from the definition of Group Therapy and recognized as a distinct mode of therapy. We initially included Concurrent Therapy with Group Therapy because we wanted to lessen the burden on providers. However, we understand from the comments that separating out Concurrent Therapy from Group Therapy may actually make it easier for providers to report the data, as they already record data separately according to Concurrent Therapy and Group Therapy in the medical record. We also understand from the comments that it would make it easier for providers if we were to use the same definitions for the different modes of therapy, to the extent feasible, across Medicare's post-acute care settings. We believe that such consistency across settings will serve to improve the accuracy and reliability of the data we receive. As we also believe that it would be useful for us to better understand the provision of Concurrent Therapy in IRFs, separate from the provision of Group Therapy, we are revising our proposal, and will collect data instead on Individual, Concurrent, Group, and Co-Treatment Therapies.

Furthermore, in response to comments, we will generally define these terms using the same definitions for Individual, Concurrent, and Co-Treatment, that we currently use in the SNF PPS (see Chapter 3 Sec. O of the Minimum Data Set (MDS) Manual,

version 3.0 located at, <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/MDS30RAIManual.html>). We generally concur that, when appropriate, it is important to apply definitions consistently across Medicare's post-acute care settings. Thus, we are defining Individual Therapy as the provision of therapy services by one licensed or certified therapist (or licensed therapy assistant, under the appropriate direction of a licensed or certified therapist) to one patient at a time (this is sometimes referred to as "one-on-one" therapy), Co-Treatment as the provision of therapy services by more than one licensed or certified therapist (or licensed therapy assistant, under the appropriate direction of a licensed therapist) from different therapy disciplines to 1 patient at the same time, and Concurrent Therapy as one licensed or certified therapist treating 2 patients at the same time who are performing different activities. However, we have decided not to use the exact SNF definition for Group Therapy in IRFs. Based on our review of the public comments, we believe it is appropriate to broaden the SNF definition for the purposes of this IRF data collection effort. We may still consider changes to the definition of Group Therapy for the IRF setting in the future, based on our review of the data we receive and based on any additional feedback from providers. In the SNF setting, the data collection regarding Group Therapy is used to allocate a therapist's time for the purpose of classifying a particular patient into the appropriate case-mix group for payment. Since the purpose of the data collection in the IRF setting differs, we believe that the same interpretation is not needed. Additionally, since we have decided to separate Concurrent Therapy from the definition of Group Therapy, we have changed the definition of Group Therapy to ensure patients are performing the same or similar activities. Two patients performing different activities would now be defined as Concurrent Therapy. We will define Group Therapy as the provision of therapy services by one licensed or certified therapist (or licensed therapy assistant, under the appropriate direction of a licensed or certified therapist) treating 2 to 6 patients at the same time who are performing the same or similar activities.

We plan to update the IRF-PAI Training Manual to inform providers, in more detail, regarding completion of the Therapy Data Collection Section.

We agree with many of the commenters that evidence regarding the clinical efficacy of the various modes of therapy for different patient populations is lacking. In the FY 2010 IRF PPS proposed rule (74 FR 21052, 21070), we specifically asked for this type of information, and the commenters told us that such information is largely unavailable. We would welcome any information that might be available to better understand this issue. However, we believe that the absence of such clinical evidence makes it all the more imperative that we start by collecting data on the amounts, types, and modes of therapy provided in IRFs to inform future policymaking.

We do not specifically know of the existence of any clinical evidence on the optimal number of patients for Group Therapy. We would be interested in any studies that developed such clinical evidence. In the absence of such evidence and solely for the purposes of collecting the data, we proposed to define Group Therapy as one therapist working with 2 to 6 patients at the same time. We proposed 6 patients as the upper limit for group therapy in IRFs because we believe that more than 6 patients in a group would likely make the group more difficult for a therapist to supervise and manage, and might decrease the benefits to patients of the group interaction. We did not receive any comments suggesting that a Group Therapy session in an IRF should include more than 6 patients, and in fact received several comments in support of using 6 as an upper limit on the number of patients. Thus, we will use the definition of Group Therapy as one therapist working with 2 to 6 patients who are all performing the same or similar activities solely for the purposes of this data collection effort. We may consider revising this definition for the IRF setting through future rulemaking based on the availability of new evidence or further feedback on this issue.

Comment: While a few commenters were supportive of our consideration of 25 percent as the most appropriate limit to establish for the provision of Group Therapy in the IRF setting, the majority of commenters urged CMS not to by impose a 25 percent threshold limiting the amount of Group Therapy an IRF patient can receive. Many commenters said that a potential cap on the provision of Group Therapy in IRFs was premature in the absence of data and studies to support an appropriate limit. These commenters also indicated that such a limit would not sufficiently recognize the professional judgment of the treating clinicians who, they believe,

are best equipped to determine the modality and duration of therapy a patient needs. Additionally, several commenters suggested that IRF patients should not be held to the same therapy standards and assignment of minutes as SNF patients since the two populations are very different.

Response: While we appreciate the positive feedback from the commenters who supported the idea of a potential threshold, after careful review of the comments, the majority of commenters suggested placing a cap on the amount of Group Therapy that IRF patients should receive would be premature at this time. We appreciate the concerns raised by these commenters and believe that it would be prudent to give more consideration to setting a cap, and the appropriate threshold for such a cap, regarding the provision of Group Therapy. We believe that collecting and analyzing the current delivery of therapy services will help inform any future policymaking. At such time that we believe a threshold is needed on the amount of Group Therapy provided, we will consider policy development through notice and comment rulemaking.

If, through future rulemaking, we do decide to impose a Group Therapy threshold, we do not believe that this would limit the professional judgment of the treating clinicians. We know that clinicians are best equipped to determine the modality and duration of therapy that any particular patient needs. With that being said, we believe that the preponderance of therapy given in an IRF should be Individual, since that is the only way that we believe that an IRF patient is truly receiving the intensive rehabilitation therapy program typically provided in an IRF, and we want to be sure that continues to be the standard. A potential threshold for the provision of group therapy in IRFs would serve to further clarify what we mean by “preponderance.”

Comment: One commenter expressed concern that we might believe that all IRF patients should receive 100 percent individual therapy. Another commenter suggested that we explicitly recognize the clinical value that Group Therapy provides over other therapy modes for certain patients.

Response: We do not believe that all IRF patients should only receive individualized therapy. We understand that different types of patients need different motivation and various forms of therapy in order to achieve their therapy goals. As we indicated in the proposed rule (79 FR 26329), when an authorized clinician deems it to be necessary, we continue to believe that

Group Therapy can serve as an appropriate mode of therapy delivery that can be beneficial to the particular needs of IRF patients as an adjunct to Individual Therapy. An important goal of rehabilitation is community reintegration and groups are important to that process. The interaction with other patients provides tremendous psychosocial benefits, providing encouragement and confidence in skills learned. However, we believe that the preponderance of therapy provided to patients in IRFs should be individual therapy in order to reflect the intensity of therapy provided in IRFs.

Comment: Several commenters suggested that we provide additional information about how IRFs should allocate or attribute minutes among patients participating in a Concurrent Therapy or Group Therapy session on the IRF-PAI.

Response: We will include more detailed information regarding completion of the Therapy Data Collection Section of the IRF-PAI in an update to the IRF-PAI Training Manual that we will post on the IRF PPS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS> prior to October 1, 2015.

Final Decision: After careful consideration of the comments we received on the proposed therapy data collection on the IRF-PAI, we are finalizing our collection of data on the amount and mode (that is, Individual, Concurrent, Group, and Co-Treatment) of therapy provided in the IRF setting according to therapy discipline (that is, physical therapy, occupational therapy, and speech-language pathology). These data will be collected on a revised IRF-PAI form which is available for download from the CMS Web site [<http://cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/index.html>] in conjunction with this final rule. This requirement will become effective for IRF discharges occurring on or after October 1, 2015.

X. Revision to the IRF-PAI for Arthritis Conditions

In the FY 2014 IRF PPS final rule (78 FR 47860, 47881 through 47895), we revised the list of ICD-9-CM diagnosis codes used to determine presumptive compliance, effective for compliance review periods beginning on or after October 1, 2014. As part of these revisions, we removed all of the ICD-9-CM codes for arthritis conditions because we found that such codes did not provide any information as to whether the patients met the severity and prior treatment requirement

portions of the criteria for the medical conditions that may be counted toward an IRF's compliance percentage under the presumptive compliance method. As we said in the FY 2014 IRF PPS final rule, we did not adopt any and all arthritis conditions in the May 7, 2004, final rule (69 FR 25752). Rather, we only included certain kinds of arthritic conditions which met defined severity and prior treatment requirements. We anticipated that less severe arthritic conditions could be satisfactorily managed outside of IRFs, as these cases would not require the intensive therapy provided in the inpatient rehabilitation setting.

We received a number of comments on the FY 2014 IRF PPS proposed rule (78 FR 26880) regarding the proposed removal of the ICD-9-CM codes for arthritis. The majority of commenters suggested that removing ICD-9-CM codes for arthritis would increase the use of the medical review method, which is more burdensome for both CMS and for IRFs. Several commenters suggested that IRFs should not be required to undergo a “full medical review” if they fail to meet the required compliance percentage using the presumptive compliance method. Instead, commenters suggested use of a “limited medical review” in which only arthritis and systemic vasculidities cases would be reviewed. We said in the FY 2014 IRF PPS final rule (78 FR 47860 at 47888 through 47889) that we would use the time afforded by the 1-year delayed implementation to consider the feasibility of minimizing any burdens created by the operational aspects of this policy.

In keeping with what we stated in the FY 2014 IRF PPS final rule, in the FY 2015 IRF PPS proposed rule (79 FR 26308 at 26330 through 26331), we proposed to add an item to the IRF-PAI form for an IRF to record the specific arthritis diagnosis code(s) for each patient that meets the severity and prior treatment requirements outlined in the regulation. By coding arthritis diagnosis codes in this section, the IRF would indicate that the patient's arthritis conditions met all of the severity and prior treatment requirements (as outlined in regulation at § 412.29(b)(2)(x) through § 412.29(b)(2)(xii)) to be counted toward an IRF's compliance percentage under the presumptive compliance method.

The purpose of the proposed new item is to provide us with the additional severity and prior treatment information necessary for us to identify the arthritis diagnoses that are appropriate to count toward an IRF's compliance percentage under the presumptive compliance

method, thus reducing the medical review burden. If an IRF's presumptive compliance percentage is below the compliance threshold (currently, 60 percent), but inclusion of the arthritis codes reported in the new proposed data item would result in the IRF's presumptive compliance percentage meeting or exceeding the compliance threshold, then we proposed to perform a "limited" medical review on a statistically valid random sample of the cases documented under this new proposed item to ensure that the severity and prior treatment requirements were actually met. The number of cases from the statistically valid random sample found to meet the severity and prior treatment requirements would be extrapolated to the total number of cases documented under the new proposed item (that is, if 70 percent of the cases in the statistically valid random sample meet the severity and prior treatment requirements, we would presume that 70 percent of all of the cases documented in the new proposed item met the severity and prior treatment requirements). If the IRF's presumptive compliance percentage meets or exceeds the compliance threshold (currently, 60 percent) with the addition of the compliant cases documented under the new proposed item, then the IRF will be presumed to meet the 60 percent rule requirements using the presumptive compliance method. However, if the number of compliant cases documented under the new proposed item does not result in the IRF's presumptive compliance percentage meeting or exceeding the compliance threshold (currently 60 percent), then the normal medical review procedures for IRFs not meeting the compliance threshold (currently 60 percent) under the presumptive compliance method would apply. A draft of the proposed new IRF-PAI for FY 2016, with the new proposed item, was made available for download on the IRF PPS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/IRFPAI.html> in conjunction with the release of the proposed rule.

The purpose of the proposal is to reduce the medical review burden associated with the removal of the ICD-9-CM codes for arthritis conditions from the presumptive methodology, while still allowing us to ensure that the arthritis diagnosis codes included in the calculation of an IRF's compliance percentage under the presumptive compliance method meet the severity

and prior treatment regulatory requirements.

We received 21 comments on our proposed revision to the IRF-PAI to add a data item for arthritis conditions, which are summarized below.

Comment: Several commenters supported the proposed revision to the IRF-PAI to allow providers to indicate whether the case coded with the arthritis condition met the prior treatment and severity requirements. Commenters especially supported the associated limited medical review process as described in the proposed rule. However, many commenters said that asking IRFs to code the arthritis diagnosis codes twice would create confusion, increase provider burden, and possibly lead to duplicative coding. Several commenters suggested that we instead provide for a simplified yes/no field on the IRF-PAI to indicate whether the case meets the prior treatment and severity regulatory requirements.

Response: We appreciate the commenters' suggestions. Based on our review of the suggestions offered by the commenters, we believe that a much simpler approach than what we had proposed would be to provide an item on the IRF-PAI allowing the IRF to indicate whether or not the IRF-PAI contains any arthritis codes which meet the severity and prior treatment regulatory requirements at § 412.29(b)(2)(x) through § 412.29(b)(2)(xii). This approach would also be easier to administer. Thus, we are adopting this change to item #24A of the IRF-PAI form, instead of the additional IRF-PAI item that had been proposed for that item. The new item #24A would instead ask the IRF to mark the box if there are any arthritis codes listed in items #21, 22, or 24 that meet the severity and prior treatment regulatory requirements at § 412.29(b)(2)(x) through § 412.29(b)(2)(xii).

Comment: Several commenters indicated that IRFs are sometimes unable to obtain the necessary information about a patient's course of treatment prior to the IRF admission. These commenters suggested that the prior treatment requirements should be removed from the regulation.

Response: The requirement that patients with arthritis conditions admitted to IRFs must not have shown adequate improvement following an appropriate, aggressive, and sustained course of outpatient therapy services or services in other less intensive rehabilitation settings has been in regulation since this requirement was finalized in the May 7, 2004 final rule (69 FR 25752). As stated in that final

rule, the rehabilitation prescriptions for many types of arthritis conditions, especially osteoarthritis, typically involve outpatient therapy several times a week for 4 weeks or more. Although we recognized in that final rule that some very unusual cases may require intensive therapies and the interdisciplinary approach to care typically provided in IRFs, we believe that patients should have participated in a required course of appropriate, sustained, and aggressive outpatient treatment (or treatment in a less-intensive setting) which failed to improve the patient's condition in order to demonstrate that the IRF admission is reasonable and necessary. This requirement allows us to be able to count toward the 60 percent rule those "exceptional" cases that the IRF is able to demonstrate truly require the intensive and interdisciplinary level of care provided in an IRF, without counting the majority of cases we believe do not represent the type of patient requiring intensive rehabilitation in an IRF.

These requirements have been in regulation for almost a decade. Until now, IRFs have not expressed any concerns to us regarding their inability to obtain the required prior treatment information, and many IRFs treat a significant number of these patients. We do not believe difficulties obtaining prior treatment information are a widespread problem among IRFs. Further, we believe that a patient's prior course of treatment is useful and important clinical information for the treating physicians and therapists in the IRF to design the most effective treatment plan for the patient. Thus, we believe that the prior treatment information is necessary and important information for the IRF to obtain, both to meet the regulatory requirements and to provide the most effective care to the patient, and we disagree with the commenter's suggestion that this requirement should be removed from the regulation.

Final Decision: After carefully considering the comments we received on the proposed new item on the IRF-PAI to indicate the arthritis codes that meet the prior treatment and severity regulatory requirements, we are modifying our proposal, based on the commenters' suggestions, to simplify it. Instead of the new item we had proposed for item #24A on the IRF-PAI, we will instead ask IRFs to mark the box in item #24A if there are any arthritis codes listed in items #21, 22, or 24 that meet the severity and prior treatment regulatory requirements at § 412.29(b)(2)(x) through

§ 412.29(b)(2)(xii). If an IRF's presumptive compliance percentage is below the compliance threshold (currently, 60 percent), but inclusion of the cases that have been marked in the affirmative in the new item #24A in the IRF's presumptive compliance percentage would cause the IRF's presumptive compliance percentage to exceed 60 percent, then we will perform a "limited" medical review on a statistically valid random sample of such cases. The number of cases from the statistically valid random sample that are found to meet the severity and prior treatment requirements would be extrapolated to the total number of cases that have been marked in the affirmative by the IRF in the new item #24A. For example, if 70 percent of the IRF's cases in the statistically valid random sample are found to meet the severity and prior treatment requirements, we would presume that 70 percent of all of the IRF's cases marked in the affirmative by the IRF in the new item #24A met the severity and prior treatment requirements. If the IRF's presumptive compliance percentage meets or exceeds the compliance threshold (currently, 60 percent) with the addition of the compliant cases that are found to meet the severity and prior treatment requirements by this method, then the IRF will be presumed to meet the 60 percent rule requirements using the presumptive compliance method. However, if the number of compliant cases that are found to meet the severity and prior treatment requirements by this method do not result in the IRF's presumptive compliance percentage meeting or exceeding the compliance threshold (currently 60 percent), medical review procedures for IRFs not meeting the compliance threshold (currently 60 percent) under the presumptive compliance method would apply. A draft of the proposed new IRF-PAI for FY 2016, with the simpler item #24A, is available for download on the IRF PPS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/IRFPAL.html> in conjunction with this final rule.

Because item #24A is specifically intended to mitigate some of the burden of additional medical reviews that would be required as a result of the refinements to the presumptive compliance method that are finalized in section VIII of this final rule, we believe that this change to the IRF-PAI should have an effective date that is as close as possible to the effective date of the refinements to the presumptive compliance method. However, as noted

in section VIII of this final rule, the refinements to the presumptive compliance method are effective for compliance review periods beginning on or after October 1, 2015, but changes to the IRF-PAI must instead be implemented for all IRF discharges occurring on or after a specific date and cannot be done on a compliance review period basis. Thus, an effective date for new IRF-PAI item #24A of October 1, 2015, will enable this change to take effect on or before any IRFs are subject to the new presumptive compliance method. This change to the IRF-PAI is effective for IRF discharges on or after October 1, 2015.

XI. International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM), Conversion

A. Background on the Use of Diagnosis Information in the IRF PPS

As described in section I.C. of this final rule, IRFs are required to complete the appropriate sections of a PAI, designated as the IRF-PAI, upon the admission and discharge of a Medicare Part A Fee-for-Service patient. In addition, beginning with IRF discharges occurring on or after October 1, 2009, the IRF is also required to complete the appropriate sections of the IRF-PAI upon the admission and discharge of each Medicare Part C (Medicare Advantage) patient, as described in the FY 2010 IRF PPS final rule (74 FR 39762, 39798 through 39800). Several sections of the IRF-PAI (currently, items #22, 24, 46, and 47) require IRFs to report diagnosis information for patients. Until ICD-10-CM becomes the required medical data code set for use on Medicare claims and IRF-PAI submissions, we will continue to use the ICD-9-CM medical data code set. Medicare uses the diagnosis information recorded on the IRF-PAI for the following purposes:

(1) To case-mix adjust the IRF PPS payment for a patient by assigning the patient to an appropriate payment tier based on the patient's comorbidities.

(2) To determine, using the presumptive compliance method, whether an IRF presumptively meets the 60 percent rule requirements in § 412.29(b).

As described in more detail in the FY 2002 IRF PPS final rule (66 FR 41316), we developed a list of diagnosis codes (previously, ICD-9-CM codes) that, if coded as a comorbidity in item #22 on a patient's IRF-PAI, would result in that patient being assigned to one of three higher-paying payment tiers under the IRF PPS. In the FY 2006 IRF PPS final rule (70 FR 57166), we updated and

revised the list of diagnosis codes (at that time, ICD-9-CM codes). We refer to the current list of diagnosis codes that, if present on a patient's IRF-PAI, result in the patient being assigned to a higher-paying tier as the "List of Comorbidities" in this final rule.

In addition to determining the appropriate tier assignment for case-mix adjusting IRF PPS payments, the diagnosis coding on the IRF-PAI is also used within the presumptive compliance method that typically serves as the first step in determining an IRF's compliance with the 60 percent rule. As discussed in more detail in section VII. of this final rule, the presumptive compliance method is one of two ways that MACs may evaluate an IRF's compliance with the 60 percent rule (the other method being the medical review method). The diagnosis coding on the IRF-PAI assessments from an IRF's most recently completed 12-month compliance review period are examined (with the use of a computer program) to determine whether they contain any of the diagnosis codes that are listed in the "ICD-9-CM Codes That Meet Presumptive Compliance Criteria" (which is also known as the presumptive methodology list).

Additionally, the computer program examines the impairment group codes, which are not ICD-9-CM or ICD-10-CM codes, but are instead part of a separate unique set of codes specifically developed for the IRF PPS for assigning the primary reason for admission to an IRF. The computer program compares the impairment group codes listed in item #21 to the list of "Impairment Group Codes That Meet Presumptive Compliance Criteria" to determine whether the patient's impairment group code presumptively meets the 60 percent rule requirements. In certain cases, the list of "Impairment Group Codes That Meet Presumptive Compliance Criteria" contains Etiologic Diagnosis exclusions. For example, impairment group code 0005.4, which represents a unilateral lower limb amputation below the knee is included on the list of "Impairment Group Codes that Meet Presumptive Compliance Criteria," unless the associated Etiologic Diagnosis recorded on the patient's IRF-PAI in item #22 is 895.0 (under ICD-9-CM), which indicates a traumatic amputation of the toe or toes. Therefore, the list of "Impairment Group Codes That Meet Presumptive Compliance Criteria" contains diagnosis code information (currently ICD-9-CM codes) in addition to impairment group codes.

These lists contain diagnosis code information (currently in the form of

ICD-9-CM diagnosis codes) which is used to case-mix adjust payments, determine an IRF's presumptive compliance with the 60 percent rule, and to assist IRFs in accurately completing the impairment group code information on the IRF-PAI. As such, these lists must all be converted to ICD-10-CM for the IRF PPS to assign payments and classify IRF facilities appropriately when ICD-10-CM becomes the required medical data code set for use on Medicare claims and IRF-PAI submissions.

B. Conversion of Diagnosis Information From ICD-9-CM to ICD-10-CM for the IRF PPS

In the September 5, 2012, final rule, "Administrative Simplification: Adoption of a Standard for a Unique Health Plan Identifier; Addition to the National Provider Identifier Requirements; and a Change to the Compliance Date for the International Classification of Diseases, 10th Edition (ICD-10-CM and ICD-10-PCS) Medical Data Code Sets" (77 FR 54664), the Department of Health and Human Services announced a delay in the implementation of the ICD-10-CM and ICD-10-PCS code sets from October 1, 2013, to October 1, 2014. The transition to the ICD-10 code sets is required for entities covered by the Health Insurance Portability and Accountability Act of 1996 (HIPAA). On April 1, 2014, the Protecting Access to Medicare Act of 2014 (Pub. L. No. 113-93) (PAMA) was enacted. Section 212 of PAMA, titled "Delay in Transition from ICD-9 to ICD-10 Code Sets," provides that "[t]he Secretary of Health and Human Services may not, prior to October 1, 2015, adopt ICD-10 code sets as the standard for code sets under section 1173(c) of the Social Security Act (42 U.S.C. 1320d-2(c)) and section 162.1002 of title 45, Code of Federal Regulations." As of now, the Secretary has not implemented this provision under HIPAA.

We are addressing the conversion of ICD-9-CM to ICD-10-CM codes for the IRF PPS in this final rule, but in light of PAMA, the effective date of those changes would be the date when ICD-10-CM becomes the required medical data code set for use on Medicare claims and IRF-PAI submissions. Until that time, we will continue to require use of the ICD-9-CM codes for the IRF PPS.

CMS, along with our support contractor 3M, has spent several years implementing a process for the transition from the use of ICD-9-CM diagnosis codes to ICD-10-CM codes within both the IRF PPS Grouper and the software for evaluating IRFs' compliance with the 60 percent rule. As

this will be the first time that ICD-10-CM codes have been used for the IRF PPS, we invited public comment in the proposed rule on our translation of the diagnosis code lists into ICD-10-CM.

To ensure a smooth transition from the use of ICD-9-CM diagnosis codes to ICD-10-CM codes for the IRF PPS and to allow for public comment on these lists, we proposed ICD-10-CM lists that were available for download from the CMS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Data-Files.html>. The proposed ICD-10-CM code lists were intended to be used when ICD-10-CM becomes the required medical data code set for use on Medicare claims and IRF-PAI submissions. To convert these lists from ICD-9-CM to ICD-10-CM, we used the General Equivalence Mappings (GEMs) that were developed as a tool to assist in converting ICD-9-CM-based applications to ICD-10-CM. The GEMs tool is a comprehensive translation dictionary that was developed over a 3-year period by CMS and the Centers for Disease Control and Prevention (CDC), with input from both the American Hospital Association and the American Health Information Management Association (AHIMA). They can be used to translate any ICD-9-CM-based data into ICD-10-CM. For more information on GEMs, please refer to the General Equivalence Mappings Frequently Asked Questions Booklet, which is available for download from the CMS Web site at <http://www.cms.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html>. Like a translation dictionary, the GEMs tool is based on the complete meaning of a given code, where "meaning" refers to the correspondence between the official documents (tabular and index) that define each code set. The GEMs tool contains a complete and comprehensive bidirectional set of mappings between ICD-9-CM and ICD-10-CM.

Our intention in converting the ICD-9-CM diagnosis codes to ICD-10-CM diagnosis codes within the IRF PPS was for the converted codes to reflect the same "meaning" as the original codes. That is, except for the specific changes to the "Impairment Group Codes That Meet Presumptive Compliance Criteria" list and to the "ICD-9-CM Codes That Meet Presumptive Compliance Criteria" list described in section VIII of this final rule, we did not intend to add conditions to, or delete conditions from, the ICD-9-CM codes used in the IRF PPS. Thus, for all IRF lists containing an ICD-9-CM code, we used the 2014 GEMs, which can be downloaded from the CMS Web site at <http://>

www.cms.gov/Medicare/Coding/ICD10/2014-ICD-10-CM-and-GEMs.html to create a translation list, and then we reviewed and revised that translation list to ensure that all of the codes on the new ICD-10-CM list reflect as closely as possible the same "meaning" as the codes that were present on the old ICD-9-CM list.

The majority of ICD-9-CM codes have straightforward translation alternative(s) in ICD-10-CM, where the diagnoses classified to a given ICD-9-CM code are replaced by one or more ICD-10-CM codes. Wherever possible, we erred on the side of including a given ICD-10-CM code if we believed that a patient coded with that ICD-10-CM code would have been correctly coded with the associated ICD-9-CM prior to the transition from ICD-9-CM to ICD-10-CM. Our intent is that the meaning of the diagnosis codes is thereby unchanged because all of the patient records that would have been correctly coded using the ICD-9-CM codes are correctly coded using one or more of the specific ICD-10-CM codes. For example, the ICD-9-CM code 582.1, "Human herpesvirus 6 encephalitis," translates directly to the ICD-10-CM code B1001, "Human herpesvirus 6 encephalitis."

Below, we note two issues within ICD-10-CM coding that differ from ICD-9-CM coding, and therefore, require special attention to ensure correct coding of patient diagnoses under ICD-10-CM.

- *Combination Diagnosis Codes in ICD-9-CM and ICD-10-CM*—Both ICD-9-CM and ICD-10-CM contain diagnosis codes called combination codes, meaning that one code contains two or more diagnoses. Typically, one diagnosis in the combination code is a chronic disease, such as diabetes, and the other diagnosis is an associated manifestation or complication of the disease, such as diabetic nephropathy.

ICD-10-CM contains many new combination codes that are not contained in ICD-9-CM. In terms of a coded record, this means that the same diagnoses coded with one ICD-10-CM combination code may require two or more ICD-9-CM codes to capture a comparable level of detail. In addition, ICD-9-CM contains combination codes with diagnosis terminology that was revised or deleted from ICD-10-CM, with the result that the same diagnoses coded with one ICD-9-CM code may require two or more ICD-10-CM codes to capture a comparable level of detail. For example, ICD-9-CM code 115.11, "Infection by *Histoplasma duboisii*, meningitis" translates to a pair of ICD-10-CM codes, "B39.5—Histoplasmosis

duboisii” and code “G02—Meningitis in other infectious and parasitic diseases classified elsewhere.” In such instances, the intent of our policy is unchanged because the patient records that would have been correctly coded using the single ICD-9-CM code will now be correctly coded using a combination of ICD-10-CM codes. Furthermore, to maintain the same meaning and reflect the same diagnoses as the ICD-9-CM code in such instances, we require the patient’s IRF-PAI record to have all of the relevant combination of ICD-10-CM codes present to reflect the condition on the list. If only one of the ICD-10-CM codes required to reflect the condition on the list is included on the IRF-PAI, the record will not accurately reflect the same diagnoses as the ICD-9-CM code. We note that, in some cases, IRFs may need to use a combination of ICD-10-CM codes to represent an Etiologic Diagnosis on the IRF-PAI form. For this reason, we will add additional spaces to the Etiologic Diagnosis field (Item #22) on the IRF-PAI, effective October 1, 2015. The new draft IRF-PAI form for IRF discharges occurring on or after October 1, 2015, is available for download from the CMS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/IRFPAI.html>.

• **Seventh Character Extensions in ICD-10-CM**—Certain codes in ICD-10-CM require the use of a seventh character in the code, where each seventh character of the code has one of the following meanings:

++ The seventh character “A” in the code indicates that the diagnosis is an initial encounter.

++ The seventh character “D” in the code indicates that the patient is receiving aftercare for the injury or illness.

++ The seventh character “S” in the code indicates that the patient no longer requires care for any aspect of the initial injury or illness itself, but that the patient is receiving care for a late effect of the injury or illness.

In the IRF PPS context, these seventh character extensions only apply to ICD-10-CM diagnosis codes related to certain types of injuries. The corresponding ICD-9-CM diagnosis codes currently listed on the “List of Comorbidities,” “ICD-9-CM Codes That Meet Presumptive Compliance Criteria,” and “Impairment Group Codes That Meet Presumptive Compliance Criteria” only map to the seventh character extensions of “A” and “S,” but not to the seventh character extension of “D,” using the GEMs tool. Thus, including codes under ICD-10-CM with the seventh character extension of “D”

would mean adding conditions to the lists that were not included on the lists under ICD-9-CM. As we indicated previously, we did not intend to add, delete, or alter the conditions included on these lists in transitioning from ICD-9-CM to ICD-10-CM. Thus, we are not including ICD-10-CM codes with the seventh character extension of “D” on the ICD-10-CM versions of the “List of Comorbidities,” “ICD-9-CM Codes That Meet Presumptive Compliance Criteria,” or “Impairment Group Codes That Meet Presumptive Compliance Criteria.” In the IRF context, we define the patient as having a current diagnosis requiring the use of the seventh character extension of “A” if the patient requires current treatment for the injury and if the diagnosis has a direct effect on the patient’s rehabilitation therapy program in the IRF.

In addition, ICD-10-CM injury codes specify that traumatic fractures are coded using the appropriate seventh character extension for an initial encounter, where each seventh character of the code has one of the following meanings:

• The seventh character “A” in the code indicates that the diagnosis is an initial encounter for closed fracture.

• The seventh character “B” in the code indicates that the diagnosis is an initial encounter for open fracture.

• The seventh character “C” in the code indicates that the diagnosis is an initial encounter for open fracture type IIIA, IIIB, or IIIC.

We used the GEMs tool and the guiding rationales described above to translate the following lists of ICD-9-CM diagnosis codes for the IRF PPS into lists of ICD-10-CM diagnosis codes:

• **List of Comorbidities**—This file contains the list of comorbidities (ICD-9-CM codes) that are used to determine placement in tiers within the IRF Grouper software. Placement in one of the higher-paying tiers, which is triggered by the presence of one of the comorbidities on this list, results in a higher prospective payment amount for the IRF.

• **ICD-9-CM Codes That Meet Presumptive Compliance Criteria**—This file contains the list of diagnoses (ICD-9-CM codes) that are used for determining presumptive compliance with the IRF 60 percent rule.

• **Impairment Group Codes That Meet Presumptive Compliance Criteria**—This file contains the list of IGCs that meet presumptive compliance criteria for the 60 percent rule. While the IGC codes themselves are not ICD-9-CM diagnosis codes, the file contains a list of Etiologic Diagnosis codes (ICD-9-CM codes) that are excluded from particular IGCs. That

is, a given IGC that would otherwise meet the presumptive compliance criteria will not meet such criteria if the patient has one of the “excluded” Etiologic Diagnoses for that IGC.

The converted ICD-10-CM code tables associated with each of these lists are available for download from the CMS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Data-Files.html> in conjunction with this final rule.

We received 3 comments on our proposed translation of the lists into ICD-10-CM, effective when ICD-10-CM becomes the required medical data code set for use on Medicare claims and IRF-PAI submissions, which are summarized below.

Comment: One commenter expressed concern about using the GEMs tool as the only means of converting the diagnosis codes from ICD-9-CM to ICD-10-CM, as this commenter said that the GEMs tool is limited in its ability to capture all of the clinical nuances of the coding conversion. This commenter suggested some enhanced conversions related to specific codes.

Response: As we described in the proposed rule, we used the GEMs tool as our starting point in converting the ICD-9-CM codes to ICD-10-CM, but we also reviewed and revised the resulting translation list from GEMs to ensure that all of the codes on the new ICD-10-CM list reflect as closely as possible the same “meaning” as the codes that were present on the old ICD-9-CM list. Thus, we did not use the GEMs tool as the sole method of converting the codes, but instead started with the GEMs tool translation and then reviewed and revised the translated lists from a clinical perspective to ensure that we were appropriately capturing the clinical nuances of the ICD-9-CM to ICD-10-CM conversions. We appreciate the commenter’s specific suggestions regarding particular code translations, and we will carefully consider the suggestions in finalizing the ICD-10-CM lists for implementation when ICD-10-CM becomes the required medical data code set for use on Medicare claims and IRF-PAI submissions.

Comment: One commenter requested that we provide a crosswalk from ICD-9-CM to ICD-10-CM to assist IRFs in better understanding the specific diagnosis codes that will be used for the IRF PPS when ICD-10-CM becomes the required medical data code set for use on Medicare claims and IRF-PAI submissions.

Response: The GEMs tool already provides a crosswalk from ICD-9-CM to ICD-10-CM, and it is readily available

for download from the CMS Web site at <http://www.cms.gov/Medicare/Coding/ICD10/2014-ICD-10-CM-and-GEMs.html> for use by all providers. We believe that providing a crosswalk ourselves apart from the GEMs tool that already exists would potentially create added confusion.

Comment: One commenter expressed support for our proposal to use the GEMs tool to convert diagnosis codes from ICD-9-CM to ICD-10-CM, but indicated some specific ICD-10-CM codes that the commenter believed should be added to the various ICD-10-CM lists. The specific ICD-10-CM codes that this commenter suggested for inclusion on the lists are divided into 3 categories. The first category includes those ICD-10-CM codes that the commenter said they believe may represent inconsistencies between the GEMs tool conversion of ICD-9-CM codes and our proposed translation of those codes in the proposed ICD-10-CM code lists. The second and third categories contain ICD-10-CM diagnosis codes that represent clinical conditions that the commenter said they believe should be added to the ICD-10-CM Codes That Meet Presumptive Compliance Criteria and the List of Comorbidities, respectively, and that are not currently reflected on these same lists in ICD-9-CM.

Response: We appreciate the commenter's detailed analysis of the converted ICD-10-CM lists that were published on the CMS Web site in conjunction with the proposed rule, and the specific suggestions this commenter provided regarding codes that we may have inadvertently omitted from the lists. We will carefully consider all of the specific ICD-10-CM codes that the commenter noted to ensure that we do not inadvertently omit any ICD-10-CM codes that should be included based on the use of the GEMs tool and our subsequent review and revision of these ICD-10-CM codes to ensure that they reflect the same clinical meaning as the ICD-9-CM codes that are currently on the respective lists. However, as we indicated in the proposed rule, we do not intend to add conditions to, or delete conditions from, the ICD-10-CM Codes That Meet Presumptive Compliance Criteria or the List of Comorbidities in translating the codes from ICD-9-CM to ICD-10-CM. Thus, at this time, we will not add the ICD-10-CM codes that would add additional clinical conditions to the lists. However, we will take the commenter's suggestions into consideration for future rulemaking.

Final Decision: After carefully considering the comments that we

received on our proposed translation of the ICD-9-CM code lists into ICD-10-CM using the GEMs tool, we are finalizing the ICD-10-CM lists that are available for download from the CMS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Data-Files.html> for use when ICD-10-CM becomes the required medical data code set for use on Medicare claims and IRF-PAI submissions.

XII. Revisions and Updates to the Quality Reporting Program for IRFs

A. Background and Statutory Authority

Section 3004(b) of the Affordable Care Act added section 1886(j)(7) to the Act, which requires the Secretary to implement a quality reporting program (QRP) for IRFs. This program applies to freestanding IRFs, as well as IRF units that are affiliated with acute care facilities, which includes critical access hospitals (CAHs).

Beginning in FY 2014, section 1886(j)(7)(A)(i) of the Act requires the reduction of the applicable IRF PPS annual increase factor, as previously modified under section 1886(j)(3)(D) of the Act, by 2 percentage points for any IRF that fails to submit data to the Secretary in accordance with requirements established by the Secretary for that fiscal year. Section 1886(j)(7)(A)(ii) of the Act notes that this reduction may result in the increase factor being less than 0.0 for a fiscal year, and in payment rates under subsection (j) for a fiscal year being less than such payment rates for the preceding fiscal year. Any reduction based on failure to comply with the reporting requirements is, in accordance with section 1886(j)(7)(B) of the Act, limited to the particular fiscal year involved. The reductions are not to be cumulative and will not be taken into account in computing the payment amount under subsection (j) for a subsequent fiscal year.

Section 1886(j)(7)(C) of the Act requires that each IRF submit data to the Secretary for quality measures specified by the Secretary. The required quality measure data must be submitted to the Secretary in a form, manner, and time specified by the Secretary.

The Secretary is generally required to specify measures that have been endorsed by the entity with a contract under section 1890(a) of the Act. This contract is currently held by the National Quality Forum (NQF), which is a voluntary consensus standard-setting organization. The NQF was established to standardize health care quality measurement and reporting through its

consensus development process. Additional information regarding NQF and its consensus development process is available at http://www.qualityforum.org/Measuring_Performance/Measuring_Performance.aspx.

We have adopted NQF-endorsed measures in our reporting programs. However, section 1886(j)(7)(D)(ii) of the Act provides that “[i]n the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) [of the Act], the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.”

Section 1886(j)(7)(E) of the Act requires the Secretary to establish procedures for making data submitted under the IRF QRP available to the public. The Secretary must ensure that each IRF is given the opportunity to review the data that is to be made public prior to the publication or posting of this data.

We seek to promote higher quality and more efficient health care for all patients who receive care in acute and post-acute care settings. Our efforts are, in part, effectuated by quality reporting programs coupled with the public reporting of data collected under those programs. The initial framework of the IRF QRP was established in the FY 2012 IRF PPS final rule (76 FR 47873).

B. Quality Measures Previously Finalized for and Currently Used in the IRF Quality Reporting Program

1. Measures Finalized in the FY 2012 IRF PPS Final Rule

In the FY 2012 IRF PPS final rule (76 FR 47874 through 47878), we adopted applications of 2 quality measures for use in the first data reporting cycle of the IRF QRP: (1) An application of Catheter-Associated Urinary Tract Infection (CAUTI) for Intensive Care Unit Patients (NQF#0138); and (2) an application of Percent of Residents with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678). We adopted applications of these 2 measures because neither of them, at the time, was endorsed by the NQF for the IRF setting. We also discussed our plans to propose a 30-Day All-Cause Risk-Standardized Post-IRF Discharge Hospital Readmission Measure.

2. Measures Finalized in the CY 2013 OPPS/ASC Final Rule

In the CY 2013 OPPS/ASC final rule (77 FR 68500 through 68507), we adopted:

- Updates to the CAUTI measure to reflect the NQF's expansion of this quality measure to the IRF setting, replacing our previous adoption of an application of the quality measure for the IRF QRP;
- A policy that would allow any quality measure adopted for use in the IRF QRP to remain in effect until the measure was actively removed, suspended, or replaced (and specifically applied this policy to the CAUTI and Pressure Ulcer measures that had already been adopted for use in the IRF QRP); and
- A subregulatory process to incorporate NQF updates to IRF quality measure specifications that do not substantively change the nature of the measure.

At the time of the CY 2013 OPPS/ASC final rule, the NQF had endorsed the Pressure Ulcer measure for the IRF setting, and retitled it to cover both residents and patients within Long-Term Care Hospitals (LTCH) and IRF settings, in addition to the Nursing Home/Skilled Nursing Facility setting. Although the quality measure had been expanded to the IRF setting, we concluded that it was not possible to adopt the NQF-endorsed measure Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678) because it is a risk-adjusted measure, and the "Quality Indicator" section of the IRF-PAI did not contain the data elements that would be needed to calculate a risk-adjusted quality measure. As a result, we decided to: (1) Adopt an application of the Pressure Ulcer measure that was a non-risk-adjusted Pressure Ulcer measure (numerator and denominator data only); (2) collect the data required for the numerator and the denominator using the then-current version of the IRF-PAI; (3) delay public reporting of Pressure Ulcer measure results until we could amend the IRF-PAI to add the data elements necessary for risk-adjusting the Pressure Ulcer measure, and then (4) adopt the NQF-endorsed version of the measure covering the IRF setting through rulemaking (77 FR 68507).

a. National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138)

In the CY 2013 OPPS/ASC final rule, we adopted the current version of

NHSN CAUTI Outcome Measure (NQF #0138) (replacing an application of this measure that we initially adopted in the FY 2012 IRF PPS (76 FR 47874 through 47886)). The NQF-endorsed measure applies to the FY 2015 adjustments to the IRF PPS annual increase factor and all subsequent annual increase factors (77 FR 68504 through 68505).

Since the publication of the CY 2013 OPPS/ASC final rule, the NHSN CAUTI quality measure has not changed, and it remains an active part of the IRF QRP. Additional information about this measure can be found at <http://www.qualityforum.org/QPS/0138>. Our procedures for data submission for this measure have also remained the same. IRFs should continue to submit their CAUTI measure data to the Centers for Disease Control and Prevention (CDC) NHSN. Details regarding submission of IRF CAUTI data to the NHSN can be found at the NHSN Web site at <http://www.cdc.gov/nhsn/inpatient-rehab/index.html>.

b. Application of Percent of Residents or Patients With Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678)

In the CY 2013 OPPS/ASC final rule (77 FR 68500 through 68507), we adopted a non-risk-adjusted application of this measure using the 2012 version of the IRF-PAI.

3. Measures Finalized in the FY 2014 IRF/PPS Final Rule

For the FY 2016 adjustments to the IRF PPS annual increase factor, in addition to retaining the previously discussed CAUTI and Pressure Ulcer measures, we finalized the adoption of one new measure: Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) (78 FR 47902 through 47921). In addition, for the FY 2017 adjustments to the IRF PPS annual increase factor, we adopted 3 quality measures: (1) All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from Inpatient Rehabilitation Facilities; (2) Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680); and (3) the NQF-endorsed version of Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678).

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

In the FY 2014 IRF PPS final rule (78 FR 47905 through 47906), we adopted the CDC developed Influenza

Vaccination Coverage among Healthcare Personnel (NQF #0431) quality measure that is currently collected by the CDC via the NHSN. This measure reports on the percentage of IRF health care personnel (HCP) who receive the influenza vaccination.

In the FY 2014 IRF PPS final rule, we finalized that the Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) measure have its own reporting period to align with the influenza vaccination season, which is defined by the CDC as October 1 (or when the vaccine becomes available) through March 31. We further finalized that IRFs will submit their data for this measure to the NHSN (<http://www.cdc.gov/nhsn/>). The NHSN is a secure Internet-based healthcare-associated infection tracking system maintained by the CDC and can be utilized by all types of health care facilities in the United States, including IRFs. The NHSN collects data via a web-based tool hosted by the CDC. Information on the NHSN system, including protocols, report forms, and guidance documents, can be found at <http://www.cdc.gov/nhsn/>. NHSN will submit the HCP influenza vaccination adherence percentage data to CMS on behalf of the facility. We also finalized that for the FY 2016 adjustments to the IRF PPS annual increase factor, data collection will cover the period from October 1, 2014 (or when the vaccine becomes available), through March 31, 2015.

Details related to the use of the NHSN for data submission and information on definitions, numerator data, denominator data, data analyses, and measure specifications for the Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) measure can be found at <http://www.cdc.gov/nhsn/inpatient-rehab/hcp-vacc/index.html>. Because IRFs are already using the NHSN for the submission of CAUTI measure data, the additional administrative burden related to data collection and submission for this measure under the IRF QRP should be minimal.

While IRFs can enter information in NHSN at any point during the influenza vaccination season for the Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) measure, data submission is only required once per influenza vaccination season, unlike the CAUTI measure, which is the other quality measure finalized for the IRF QRP that utilizes the CDC NHSN. We finalized that the final deadline for data submission associated with this quality measure will be May 15th of each year.

Also, the data collection period for this quality measure is not 12 months, as with other measures, but is approximately 6 months (that is, October 1, or when the vaccine becomes available, through March 31 of the following year). This data collection period is applicable only to Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431), and is not applicable to any other IRF QRP measures, proposed or adopted, unless explicitly stated. The measure specifications for this measure can be found at <http://www.cdc.gov/nhsn/inpatient-rehab/hcp-vacc/index.html> and at <http://www.qualityforum.org/QPS/0431>.

b. All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge From Inpatient Rehabilitation Facilities (NQF #2502, Under Review at NQF; see http://www.qualityforum.org/All-Cause_Admissions_and_Readmissions_Measures.aspx)

In the FY 2014 IRF PPS final rule (78 FR 47906 through 47910), we adopted an All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from Inpatient Rehabilitation Facilities. This quality measure estimates the risk-standardized rate of unplanned, all-cause hospital readmissions for cases discharged from an IRF who were readmitted to a short-stay acute care hospital or LTCH, within 30 days of an IRF discharge. We noted that this is a claims-based measure that will not require reporting of new data by IRFs and thus will not be used to determine IRF reporting compliance for the IRF QRP. Please note that this measure is not NQF-endorsed, but it was submitted by CMS to the NQF for review on February 5, 2014 (http://www.qualityforum.org/All-Cause_Admissions_and_Readmissions_Measures.aspx).

c. Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680)

In the FY 2014 IRF PPS final rule (78 FR 47906 through 47911), we adopted

the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680) measure for the IRF QRP, and we will collect the data for this measure through the addition of data items to the “Quality Indicator” section of the IRF-PAI.

We also added the data elements needed for this measure, as an influenza data item set, to the “Quality Indicator” section of the IRF-PAI, and data for this measure will be collected using this revised version of the IRF-PAI. The revised IRF-PAI will become effective on October 1, 2014. These data elements are harmonized with data elements (O0250: Influenza Vaccination Status) from the Minimum Data Set (MDS) 3.0 and the LTCH CARE Data Set Version 2.01, and the specifications and data elements for this measure are available at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/IRFPAI.html>.

For purposes of this quality measure, the influenza vaccination season takes place from October 1 (or when the vaccine becomes available) through March 31 each year. The measure calculation and public reporting of this measure (once public reporting is implemented) will also be based on the influenza vaccination season, starting on October 1 (or when the vaccine becomes available) and ending on March 31 of the subsequent year.

The IRF-PAI Training Manual indicates how providers should complete these items during the time period outside of the vaccination season (that is, prior to October 1, or when the vaccine becomes available, and after March 31 of the following year). The measure specifications for this measure, Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680), can be found on the CMS Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/NHQIQualityMeasures.html>. Additional

information on this measure can also be found at <http://www.qualityforum.org/QPS/0680>.

d. Percent of Residents or Patients With Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678)—Adoption of the NQF-Endorsed Version of This Measure

In the FY 2014 IRF PPS final rule (78 FR 47911 through 47912), we adopted the NQF-endorsed version of the Percent of Residents or Patients With Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678), with data collection beginning October 1, 2014, using the revised version of the IRF-PAI, for quality reporting affecting the FY 2017 adjustments to the IRF PPS annual increase factor and subsequent year annual increase factors. We noted in the rule that, until September 30, 2014, IRFs should continue to submit pressure ulcer data using the version of the IRF-PAI released on October 1, 2012, for the purposes of data submission requirements for the FY 2015 and FY 2016 adjustments to the annual IRF PPS increase factor.

In the FY 2014 IRF PPS final rule (78 FR 47912 through 47916), we also adopted a revised version of the IRF-PAI starting October 1, 2014, for the FY 2017 adjustments to the IRF PPS annual increase factor and subsequent year annual increase factors.

We received several comments and questions related to previously finalized measures and our current policies. While we greatly appreciate the commenters' views on such previously finalized measures and policies, we did not make any proposals relating to them in the FY 2015 IRF PPS proposed rule. As such, we will not address these comments in this final rule. However, we will consider all of these comments in future rulemaking and program development.

TABLE 8—QUALITY MEASURES FINALIZED IN THE FY 2014 IRF PPS FINAL RULE AFFECTING THE FY 2016 AND 2017 ADJUSTMENTS TO THE IRF ANNUAL INCREASE FACTORS AND SUBSEQUENT YEAR INCREASE FACTORS

NQF measure ID	Measure title
NQF #0431+	Influenza Vaccination Coverage among Healthcare Personnel.
NQF #0680*	Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay).
NQF #0678*	Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay)—Adoption of the NQF-Endorsed Version of this Measure.
NQF #2502**	All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from Inpatient Rehabilitation Facilities.

+ Using the CDC NHSN.

* Using the IRF-PAI Version 1.2 that is effective on October 1, 2014; available at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Downloads/IRF-PAI-FINAL-for-Use-Oct2014-updated-v4.pdf>.

** Not NQF-endorsed, currently under review by NQF. (See http://www.qualityforum.org/All-Cause_Admissions_and_Readmissions_Measures.aspx).

C. New IRF QRP Quality Measures Affecting the FY 2017 Adjustments to the IRF PPS Annual Increase Factor and Beyond

1. General Considerations Used for Selection of Quality Measures for the IRF QRP

In the FY 2014 IRF PPS final rule (78 FR 47094), we noted that the successful development of an IRF quality reporting program that promotes the delivery of high-quality health care services in IRFs is our paramount concern. We discussed several of the factors we had taken into account in selecting measures to propose and finalize. We do wish to note here that, in our measure selection activities for the IRF QRP, we must take into consideration input we receive from a multi-stakeholder group, the Measure Applications Partnership (MAP), which is convened by the NQF as part of a pre-rulemaking process that we have established and are required to follow under section 1890A of the Act. The MAP is a public-private partnership comprised of multi-stakeholder groups convened by the NQF for the primary purpose of providing input to CMS on the selection of certain categories of quality and efficiency measures, as required by section 1890A(a)(3) of the Act. By February 1 of each year, the NQF must provide MAP input to CMS. We have taken the MAP's input into consideration in selecting measures for this rule. Input from the MAP is located at https://www.qualityforum.org/Publications/2014/01/MAP_Pre-Rulemaking_Report_2014_Recommendations_on_Measures_for_More_than_20_Federal_Programs.aspx. We also take into account national priorities, such as those established by the National Priorities Partnership (NPP) at http://www.qualityforum.org/Setting_Priorities/NPP/National_Priorities_Partnership.aspx, the HHS Strategic Plan at <http://www.hhs.gov/secretary/about/priorities/priorities.html>, the National Strategy for Quality Improvement in Health Care at <http://www.ahrq.gov/workingforquality/nqs/nqs2012annlrpt.pdf>, and the CMS Quality Strategy at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.html>.

To the extent practicable, we have sought to adopt measures that have been endorsed by a national consensus organization, recommended by multi-stakeholder organizations, and developed with the input of providers, purchasers/payers, and other stakeholders.

For the FY 2017 adjustments to the IRF PPS annual increase factor, in addition to retaining the previously discussed CAUTI (NQF #0138), Pressure Ulcer, Patient Influenza Vaccination (NQF #0680), Healthcare Personnel Influenza Vaccination (NQF #0431), and Hospital Readmission (NQF #2502) quality measures, we proposed in the FY 2015 IRF PPS proposed rule (79 FR 26336 through 26338) to adopt two new quality measures: (1) National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716), and (2) National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717). These quality measures are discussed in more detail below.

a. National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716).

In the FY 2015 IRF PPS proposed rule (79 FR 26336 through 26337), we proposed to adopt the CDC-developed National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716). The MRSA measure is a measure of hospital-onset unique blood source MRSA laboratory-identified events among all inpatients in the facility. This measure was adopted by the Hospital Inpatient Quality Reporting (IQR) Program in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51630, 51645) for the FY 2015 payment determination, with data collection beginning on January 1, 2013. It was also adopted by the LTCH Quality Reporting (LTCHQR) Program in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50712 through 50717) for the FY 2017 payment determination, with data collection beginning on January 1, 2015. This measure is NQF-endorsed. We included the MRSA measure in the December 1, 2013 Measures under Consideration (MUC) list. The MAP conditionally supported the direction of this quality measure, noting that the measure is not ready for implementation and suggesting that we harmonize this measure with other infection measures. We respectfully disagree with the position of the MAP, as the MRSA measure is fully endorsed by the NQF for various settings, including the IRF setting, which speaks to its suitability

for use in that setting. Methicillin-resistant *Staphylococcus aureus* (*S. aureus*) infections are caused by a strain of *S. aureus* bacteria that has become resistant to antibiotics commonly used to treat *S. aureus* infections. Between 2003 and 2004, an estimated 4.1 million persons in the United States had nasal colonization with MRSA.¹ In addition, in 2005 there were an estimated 94,000 invasive MRSA infections in the United States, which were associated with an estimated 18,000 deaths.² Healthcare-associated MRSA infections occur frequently in patients whose treatment involves the use of invasive devices, such as catheters or ventilators.

Currently, there are 22 States that have implemented a MRSA Prevention Collaborative, and at least 15 states that have reporting mandates for MRSA bacteremia in NHSN.³ For Medicare populations, MRSA infection is associated with increased cost, hospital length of stay, morbidity, and mortality. MRSA infections can be a consequence of poor quality of care.^{4,5} Older adults and patients in health care settings are most vulnerable to MRSA infections, as these patients may have weakened immune systems. A recent study reported that 9.2 percent of patients without a history of MRSA tested positive for MRSA at the time of the IRF admission.⁶ We also recently analyzed IRF claims submitted to Medicare during CY 2009. According to our analysis, IRFs reported a total of 3,464 cases of MRSA in 2009, including cases either present on admission or acquired during the IRF stay ("present on admission" indicators for ICD-9 codes are not available on the IRF claims).⁷

¹ Gorwitz RJ, Kruszon-Moran D, McAllister SK, et al. Changes in the prevalence of nasal colonization with *Staphylococcus aureus* in the United States, 2001–2004. *J Infect Dis* 2008; 197: 1226–34.

² Department of Health and Human Services. National Action Plan to Prevent Healthcare-Associated Infections: Roadmap to Elimination. Available at <http://www.hhs.gov/ash/initiatives/hai/infection.html>.

³ Centers for Disease Control and Prevention. State Has Implemented a MRSA Prevention Collaborative. Available at <http://www.cdc.gov/hai/stateplans/states-w-MRSA-collaborative.html>.

⁴ Centers for Disease Control and Prevention. People at Risk of Acquiring MRSA Infections. Available at <http://www.cdc.gov/mrsa/index.html>.

⁵ Centers for Disease Control and Prevention. Management of Multidrug-Resistant Organisms in Healthcare Settings, 2006. Available at <http://www.cdc.gov/hicpac/pdf/guidelines/MDROGuideline2006.pdf>.

⁶ Rabinowitz RP, Kufera JA, Makely MJ. A Hidden Reservoir of Methicillin-resistant *Staphylococcus aureus* and Vancomycin-resistant *Enterococcus* in Patients Newly Admitted to an Acute Rehabilitation Hospital. *Physical Medicine & Rehabilitation* 2012 (4):18–22.

⁷ Bernard SL, Dalton K, Lenfestey N F, Jarrett NM, Nguyen KH, Sorensen AV, Thaker S, West ND.

We believe it is important to collect data on MRSA infections acquired during the IRF stay, because MRSA infection is associated with increased cost, hospital length of stay, morbidity, and mortality.

In the FY 2015 IRF PPS proposed rule (79 FR 26336 through 26337), we proposed to use the CDC/NHSN data collection and submission framework for reporting of the MRSA measure. This is the same framework currently used for reporting the CAUTI (NQF #0138) and Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) quality measures. Details related to the procedures for using the NHSN for data submission and information on definitions, numerator data, denominator data, data analyses, and measure specifications for the MRSA measure can be found at <http://www.qualityforum.org/QPS/1716> and <http://www.cdc.gov/nhsn/inpatient-rehab/mdro-cdi/index.html>. For January 2012 through January 2013, an estimated 15 IRFs reported laboratory-identified MRSA event data into NHSN. We refer readers to section XI.B.3.a. of this final rule for more information on data collection and submission. We sought public comments on the National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716) for the FY 2017 IRF PPS annual increase factor and subsequent years. Our responses to public comments on this measure are discussed in this section of the final rule.

Comment: Several commenters expressed support of our proposal to adopt the MRSA measure, citing the importance of focusing on outcomes, such as healthcare-associated infections, because they are meaningful to patients and because of their impact on provider behavior. One commenter noted, as stated above, that the measure is NQF-endorsed for the IRF setting. A few commenters expressed support for CMS's effort to align IRF QRP quality measures with measures in other quality reporting initiatives.

Response: We appreciate the commenters' support for this outcome measure and recognition of our efforts to adopt measures for the IRF QRP that emphasize high-priority patient safety concerns and harmonize measures across settings, when applicable.

Study to support a CMS Report to Congress: Assess feasibility of extending the hospital-acquired conditions—present on admission IPPS payment policy to non-IPPS payment environments. Prepared for the Centers for Medicare & Medicaid Services (CMS Contract No. HHSM-500-T00007). 2011.

Comment: Several commenters objected to the proposed MRSA healthcare-associated infection measure due to the low prevalence of MRSA in IRFs, indicating that the measure would not be a meaningful quality measure in IRFs. Several comments noted the MRSA measure received only "conditional support" from the MAP, and several commenters noted that it would add additional data collection burden.

Response: The MRSA measure is endorsed by the National Quality Forum for use in several settings, including IRFs. Because of the scope of the patient safety problem posed by MRSA to the IRF patient population, as discussed earlier in this section of the final rule, as well as its burden on the health care system, we continue to believe it is in the best interest of patients to adopt this measure for the IRF QRP in order to promote awareness and encourage implementation of MRSA control procedures in the IRF setting. The measure is on the list of NQF-endorsed measures and can be found on the NQF Web site at <http://www.qualityforum.org/QPS/1716>. We note that we have taken the MAP's input into consideration in selecting quality measures, as we are required to do under section 1890(a)(4) of the Act. However, we are not required to follow the MAP's recommendations, but to take them into account when selecting measures for proposal. In addition to MAP input, we take a variety of other factors into account in selecting measures. In this instance, for example, the MRSA measure is NQF-endorsed for the IRF setting, an indication that it is appropriate for IRF patients. In addition, this measure is appropriate in light of the fact that MRSA infection most commonly affects older adults in hospitals or in facilities with longer lengths of stay and is associated with increased costs, hospital length of stay, morbidity, and mortality. For the reasons listed above, we continue to believe that this measure is appropriate for IRF patients.

Comment: One commenter was concerned that it may be difficult to distinguish infections present on admission from those that are healthcare-associated infections. Several commenters expressed concern that adoption of this quality measure would lead to additional and inappropriate screening for these conditions when patients are admitted to an IRF, and one commenter noted a concern about antibiotic resistance.

Response: The definition of MRSA laboratory-identified (LabID) events—used in the measure we proposed,

National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset MRSA Bacteremia Outcome Measure (NQF #1716)—is provided in the measure specifications, which are posted on the NQF Web site at <http://www.qualityforum.org/QPS/1716>, and it specifically addresses attribution through categorization of MRSA LabID events based on date admitted to the facility and date specimen collected, as well as by the current date and prior dates of specimen collection. As specified in the measure, Community-Onset (CO) is a LabID event collected as an outpatient or an inpatient less than or equal to 3 days after admission to the facility (that is, days 1, 2, or 3 of admission), while Healthcare Facility-Onset (HO) is defined as a LabID event collected from a patient greater than 3 days after admission to the facility (that is, days 4 or later of admission). Data from emergency department and outpatient observation locations (that is, outpatient encounters) are also included in this reporting of CO and HO events, in order to ensure that events are accurately categorized and identified. The CO definition accounts for infections acquired outside the IRF setting, either in the community or in other health care settings.

Regarding the commenter's concern that adoption of this quality measure would lead to additional and inappropriate screening, per NHSN protocol, LabID events are to be reported only from specimens collected for clinical decision-making and never from screening or surveillance cultures. Because these required LabID events are to be reported only from MRSA blood specimens, they represent actual and serious infections that should be treated appropriately and according to physician decision, as MRSA bacteria should never be found in blood. Therefore, this reporting should not be a driver of inappropriate antibiotic use. Additionally, we believe it is imperative that we close the gap with respect to monitoring for this serious infection within the continuum of care. Because this measure has been finalized for several other health care settings (see the FY 2012 IPPS/LTCH PPS final rule (76 FR 51630, 51645) for IQR Program; FY 2014 IPPS/LTCH PPS final rule (78 FR 50712 through 50717) for the LTCHQR Program), we believe that requiring IRFs to monitor for MRSA infections is necessary and will help further improve the quality of care provided to patients receiving services across the continuum of care.

Comment: One commenter suggested collecting MRSA data for one year in

order to determine if the measure is valuable.

Response: We believe that this is unnecessary because quality measures already undergo maintenance review at regular intervals in order to evaluate the value of ongoing use of these measures. As noted above, it is important to collect data on MRSA infections acquired during the IRF stay because MRSA infections are associated with increased cost, hospital length of stay, morbidity, and mortality.

Final Decision: Having carefully considered the comments we received on the National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset MRSA Bacteremia Outcome Measure (NQF #1716), we are finalizing the adoption of this measure as proposed for use in the IRF QRP.

b. National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717)

In the FY 2015 IRF PPS proposed rule (79 FR 26337 through 26338), we proposed to adopt the CDC-developed National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717) that is currently collected by the CDC via the NHSN. The CDI measure is a measure of hospital-onset CDI laboratory-identified events among all inpatients in the facility. This measure was adopted by the Hospital IQR Program in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51630 through 51631) for the FY 2015 payment determination, with data collection having begun on January 1, 2013. It was also adopted by the LTCHQR program in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50712 through 50717) for the FY 2017 payment determination, with data collection beginning on January 1, 2015. This measure is NQF-endorsed. We included the CDI measure in the December 1, 2013 MUC list. The MAP supported this measure.⁸ CDI can cause a range of serious symptoms, including diarrhea, serious intestinal conditions, sepsis, and death.⁹ In the United States, CDI is

responsible for an estimated 337,000 infections and 14,000 deaths annually.¹⁰ According to the HHS National Action Plan to Prevent Health Care-Associated Infections, CDI rates have increased in recent years.¹¹ The CDC estimates that CDIs cost more than \$1 billion in additional health care costs each year.¹² In recent years, CDIs have become more frequent, more severe, and more difficult to treat. Mortality rates for CDIs are highest in elderly patients.¹³ Rates of CDI among hospitalized patients aged 65 years and older increased 200 percent between 1996 and 2009, while deaths related to CDIs increased 400 percent between 2000 and 2007, partly attributed to a stronger germ strain.¹⁴ Further, the emergence and continued rise of CDI as a leading cause of gastroenteritis hospitalizations and deaths, particularly in the elderly, has been documented.¹⁶ CDI is associated with increased patient care costs, hospital lengths of stay, morbidity, and mortality. CDI can be a consequence of poor quality of care for Medicare patients.¹⁷

Illness from CDI most commonly affects older adults in hospitals or in facilities with longer lengths of stay, where germs spread more easily,

www.jstor.org/stable/pdfplus/10.1086/511798.pdf?acceptTC=true.

¹⁰ Centers for Disease Control and Prevention. *Investigating Clostridium difficile Infections Across the U.S.* Available at: <http://www.cdc.gov/hai/eip/pdf/Cdiff-factsheet.pdf>.

¹¹ Department of Health and Human Services. National Action Plan to Prevent Health Care-Associated Infections: Roadmap to Elimination. Available at <http://www.hhs.gov/ash/initiatives/hai/infection.html>.

¹² Centers for Disease Control and Prevention. Making Health Care Safer: Stopping *C. difficile* Infections. Available at: <http://www.cdc.gov/VitalSigns/HAI/index.html>.

¹³ Centers for Disease Control and Prevention. *Investigating Clostridium difficile Infections Across the U.S.* Available at: <http://www.cdc.gov/hai/eip/pdf/Cdiff-factsheet.pdf>.

¹⁴ Centers for Disease Control and Prevention. QuickStats: Rates of Clostridium difficile Infection Among Hospitalized Patients Aged ≥65 Years,* by Age Group—National Hospital Discharge Survey, United States, 1996–2009. MMWR, 60(34); 1171. Available at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6034a7.htm>.

¹⁵ Centers for Disease Control and Prevention. Making Health Care Safer: Stopping *C. difficile* Infections. Available at: <http://www.cdc.gov/VitalSigns/HAI/index.html>.

¹⁶ Aron J. Hall, Aaron T. Curns, L. Clifford McDonald, Umesh D. Parashar, and Ben A. Lopman. The Roles of Clostridium difficile and Norovirus Among Gastroenteritis-Associated Deaths in the United States, 1999–2007. *Clinical Infectious Diseases* 2012;55(2):216–23. Published by Oxford University Press on behalf of the Infectious Diseases Society of America 2012. DOI: 10.1093/cid/cis386.

¹⁷ Dubberke ER, Reske KA, Olsen MA, McDonald LC, Fraser VJ. Short- and long-term attributable costs of Clostridium difficile-associated disease in nonsurgical inpatients. *Clin Infect Dis* 2008; 46:497–504. Available at: <http://cid.oxfordjournals.org/content/46/4/497.long>.

antibiotic use is more common, and people are especially vulnerable to infection.¹⁸ Considering CDIs are increasing in all health care facilities, and the IRF population is highly vulnerable to CDI, it is important to measure these rates in IRFs.¹⁹ According to an analysis of ICD–9 codes reported on Medicare claims, IRFs reported 7,720 cases of CDI-associated disease in 2009.²⁰ Currently, the “present on admission” indicators for ICD–9 codes are not available on IRF claims. Therefore, we are unable to determine whether the 7,720 reported cases of CDI were present on admission or acquired during the IRF stay. There is evidence that CDIs are preventable, and therefore, surveillance and measuring infection rates is important to reducing infections and improving patient safety. Thirty-seven states have implemented a *C. difficile* Prevention Collaborative, and at least 15 states have reporting mandates for CDI LabID events in NHSN.²¹ The goal for the CDI measure is to collect and publicly report IRF data on CDIs so that IRFs will be better informed about the incidence of this condition and better equipped to prevent it.

In the FY 2015 IRF PPS proposed rule (79 FR 26337 through 26338), we proposed to use the CDC/NHSN data collection and submission framework for reporting of the NHSN Facility-Wide Inpatient Hospital-Onset CDI Outcome Measure (NQF #1717). This framework is currently used for reporting the CAUTI (NQF #0138) and Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) measures. Details related to the procedures for using the NHSN for data submission and information on definitions, numerator data, denominator data, data analyses, and measure specifications for the NHSN Facility-Wide Inpatient Hospital-Onset CDI Outcome Measure (NQF #1717) can be found at <http://www.qualityforum.org/QPS/1717> and

¹⁸ Centers for Disease Control and Prevention. Frequently Asked Questions about Clostridium difficile for Healthcare Providers. Available at: http://www.cdc.gov/HAI/organisms/cdiff/Cdiff_faqs_HCP.html.

¹⁹ Marciniak C, Chen D, Stein A, et al. Prevalence of Clostridium Difficile Colonization at Admission to Rehabilitation. *Archives of Physical Medicine and Rehabilitation* 2006; 87(8):1086–1090.

²⁰ Bernard SL, Dalton K, Lenfestey N F, Jarrett NM, Nguyen KH, Sorensen AV, Thaker S, West ND. Study to support a CMS Report to Congress: Assess feasibility of extending the hospital-acquired conditions—present on admission IPPS payment policy to non-IPPS payment environments. Prepared for the Centers for Medicare & Medicaid Services (CMS Contract No. HHSM–500–T00007). 2011.

²¹ Centers for Disease Control and Prevention. State Has Implemented a *C. diff* Prevention Collaborative. Available at: <http://www.cdc.gov/hai/stateplans/states-w-CDI-collaborative.html>.

⁸ National Quality Forum. *Measure Applications Partnership Pre-Rulemaking Report: 2014 Recommendations of Measures Under Consideration by HHS: February 2014*. Available at: https://www.qualityforum.org/Publications/2014/01/MAP_Pre-Rulemaking_Report_2014_Recommendations_on_Measures_for_More_than_20_Federal_Programs.aspx.

⁹ McDonald LC, Coignard B, Dubberke E, et al. Recommendations for surveillance of Clostridium difficile-associated disease. *Infect Control Hosp Epidemiol* 2007;28:140–145. Available at: <http://>

<http://www.cdc.gov/nhsn/inpatient-rehab/mdro-cdi/index.html>.

We sought public comments on the National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset CDI Outcome Measure (NQF #1717) for the FY 2017 IRF PPS annual increase factor and subsequent years. The responses to public comments on this measure are discussed below in this section of the final rule.

Comment: Several commenters supported the CMS proposal to adopt the CDI measure, citing the importance of focusing on outcomes, such as healthcare-associated infections, because they are meaningful to patients and because it can impact provider behavior. One commenter supported the measure because it encourages hospitals to focus on prevention and appropriate treatment and has important implications for patient outcomes, society, and reduced health care expenditures. One commenter noted the measure is NQF-endorsed for the IRF setting, and two commenters expressed support for CMS's effort to align IRF QRP quality measures with measures in other quality reporting initiatives. A commenter who supports the measure suggested the significance of reporting CDIs is increased due to a higher than expected number of cases.

Response: We appreciate the commenters' support and recognition of the importance of the expansion of the IRF QRP to include this measure. *C. difficile* is a pathogen of serious concern, causing morbidity and mortality throughout the continuum of care. Transmission can only be controlled and infection prevented if monitoring occurs across the health care settings.

Comment: Several commenters objected to the proposed CDI measure due to the low prevalence of CDIs in IRFs, indicating that the measure would not be a meaningful quality measure in IRFs. One commenter noted that it adds additional data collection burden.

Response: The CDI measure is endorsed by the NQF for use in several settings, including the IRF setting. As with MRSA, because of the scope of the patient safety problem posed by CDI to the very vulnerable IRF population, as well as its burden on the health care system, we believe it is in the best interest of patients to adopt this measure to promote awareness and

encourage immediate implementation of CDI control procedures within the IRF setting. The measure is on the list of NQF-endorsed measures and can be found on the NQF Web site at <http://www.qualityforum.org/QPS/1717>. In addition, the MAP supported this quality measure for the IRF setting. This measure is appropriate in light of the fact that illness from CDI most commonly affects older adults in hospitals or in facilities with longer lengths of stay and is associated with increased costs, hospital length of stay, and those who have been treated with antibiotics. *C. difficile* is a pathogen of serious concern that causes patient morbidity and mortality throughout all health care settings. Furthermore, lack of monitoring for this serious infection in the IRF setting creates a monitoring gap within the continuum of care. Because this measure has been proposed and finalized for several other hospital settings, we believe that requiring IRFs to monitor for CDI is necessary and will help further improve the quality of care provided to Medicare beneficiaries. For all of the reasons we have discussed, we continue to believe this measure is appropriate for IRF patients.

Comment: One commenter was concerned that it may be difficult to distinguish infections present on admission from those that are hospital-acquired infections. The commenter expressed concern about inappropriate screening for these conditions if the quality measure was adopted.

Response: The definition of CDI LabID events, as provided in the measure specifications, which are posted on the NQF Web site at <http://www.qualityforum.org/QPS/1717>, specifically addresses attribution through categorization of CDI LabID events based on date admitted to the facility and date specimen collected, as well as by the current date and prior dates of specimen collection. As specified in the measure, Community-Onset (CO) is a LabID event collected as an outpatient or an inpatient less than or equal to 3 days after admission to the facility (that is, days 1, 2, or 3 of admission), while Community-Onset Healthcare Facility-Associated (CO-HCFA) is defined as a CO LabID event collected from a patient who was discharged from the facility within 4 weeks prior to current date of stool specimen collection. Data from emergency department and outpatient

observation locations (that is, outpatient encounters) are also included in this reporting of CO and HO events, in order to ensure that events are accurately categorized and identified. A Healthcare Facility-Onset (HO) is a LabID event collected more than 3 days after admission to the facility (that is, on or after day 4). The CDI measure is already in use in the hospital inpatient setting, where similar concerns have been raised and successfully addressed (see the FY 2012 IPPS/LTCH PPS final rule (76 FR 51630 through 51631) for the IQR program). We also note that the definition of CDI LabID events (as required by this measure) is based on laboratory testing and admission date data, and not clinical evaluation of the patient, allowing for a much less labor-intensive method to track CDIs. This provides an infection measure of CDI health care acquisition, exposure burden, and infection burden based almost exclusively on laboratory data and limited admission date data, including patient care location. LabID events use NHSN forms to collect all required data, using the definitions of each data field. Per NHSN protocol, LabID events are to be reported only from specimens collected for clinical decision-making (that is, collected from patients with greater than or equal to 3 unformed stools within 24 hours) and never from screening or surveillance cultures.

Final Decision: Having carefully considered the comments we received on the National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717), we are finalizing the adoption of this measure as proposed for use in the IRF QRP.

D. IRF QRP Quality Measures and Concepts Under Consideration for Future Years

We are considering whether to propose one or more of the quality measures and quality measure topics listed in Table 9 for future years in the IRF QRP. We invited public comment on these quality measures and quality measure topics, specifically the clinical importance of reported measure data, the feasibility of measure data collection and implementation, current use of reported measure data, and usefulness of the reported measure data to inform quality of care delivered to IRF patients.

TABLE 9—FUTURE MEASURES AND MEASURE TOPICS UNDER CONSIDERATION FOR PROPOSAL FOR THE IRF QUALITY REPORTING PROGRAM

National Quality Strategy Priority: Patient Safety:

Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long-Stay) (NQF #0674).

National Quality Strategy Priority: Patient and Caregiver-Centered Care:

Application of Percent of Residents Who Self-Report Moderate to Severe Pain (Short-Stay) (NQF #0676).

Not Endorsed/Under Development—IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients.

Not Endorsed/Under Development—IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients.

Not Endorsed/Under Development—IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients.

Not Endorsed/Under Development—IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients.

In particular, we are considering whether to propose one or more of the following measures for future year IRP PPS increase factors: (1) IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients; (2) IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients; (3) IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients; (4) IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients; (5) Application of the Percent of Residents Experiencing One or More Falls with Major Injury (Long-Stay) (NQF #0674); and (6) Application of Percent of Residents Who Self-Report Moderate to Severe Pain (Short-Stay) (NQF #0676).

IRFs are designed to provide intensive rehabilitation services to patients. Patients seeking care in IRFs are those whose illness, injury, or condition has resulted in a loss of function, and for whom rehabilitative care is expected to help regain that function. Examples of conditions treated in IRFs include stroke, spinal cord injury, hip fracture, brain injury, neurological disorders, and other diagnoses characterized by loss of function.

Given that the primary goal of rehabilitation is improvement in functional status, IRF clinicians have traditionally assessed and documented patients' functional statuses at admission and discharge to evaluate the effectiveness of the rehabilitation care provided to individual patients, as well as the effectiveness of the rehabilitation unit or hospital overall. In addition, research results have found differences in IRF patients' functional outcomes, thus we believe there is an opportunity for improvement in this area. Differences in IRF patients' functional outcomes have been found by geographic region, insurance type, and race/ethnicity after adjusting for key patient demographic characteristics and admission clinical status. This supports the need to monitor IRF patients' functional outcomes. For example,

Reistetter²² examined discharge motor function and functional gain among IRF patients with stroke and found statistically significant differences in functional outcomes by U.S. geographic region, insurance type, and race/ethnicity group after risk adjustment. O'Brien and colleagues²³ found differences in functional outcomes across race/ethnicity groups in their analysis of Medicare assessment data for patients with stroke after risk adjustment. O'Brien and colleagues²⁴ also noted that the overall IRF length of stay decreased 1.8 days between 2002 and 2007 and that shorter IRF stays were significantly associated with lower functioning at discharge.

We are currently developing 4 functional status quality measures for the IRF setting:

(1) Quality Measure: IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients for Medical Rehabilitation Patients;

(2) Quality Measure: IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients for Medical Rehabilitation Patients;

(3) Quality Measure: IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients for Medical Rehabilitation Patients; and

(4) Quality Measure: IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients for Medical Rehabilitation Patients.

We invited public comment on our intent to propose these measures for the FY 2019 adjustments to the IRF PPS annual increase factor and subsequent

year increase factors. The draft measure specifications for these measures are posted at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Details.html>. The development of these measures is expected to be completed in 2014, at which time they will be submitted to the NQF, the entity with a contract under section 1890(a) of the Act, for review. Our responses to public comments on these quality measures are discussed in this section of the final rule.

Comment: Several comments were received about the quality measure Application of the Percent of Residents Experiencing One or More Falls with Major Injury (Long-Stay) (NQF #0674). One commenter supported this measure. Several commenters opposed the measure, citing that the measure is not appropriate for the IRF setting and that it is unclear how a major fall is defined and what tool will be used to collect this data.

Response: We thank the commenters for their input and will take these comments into consideration to inform our ongoing measure development efforts for this measure and our ongoing consideration of the potential to adopt this measure in the IRF QRP through future rulemaking. For the purpose of this measure, "major injury" is defined as including bone fractures, joint dislocations, closed head injuries with altered consciousness, or subdural hematoma. If selected for proposal, and finalized through the future rulemaking process, for data collection purposes, we would revise the IRF PAI to include the items used for this quality measure, which are found in the Minimum Data Set version 3.0. We believe that this measure is appropriate for the IRF setting. Fall-related injuries are the most common cause of accidental death in people aged 65 years and older, resulting in approximately 41 fall-related deaths per 100,000 people per

²² Reistetter TA, Karmarkar AM, Graham JE, et al. Regional variation in stroke rehabilitation outcomes. *Arch Phys Med Rehabil*. 95(1):29–38, Jan. 2014.

²³ O'Brien SR, Xue Y, Ingersoll G, et al. Shorter length of stay is associated with worse functional outcomes for medicare beneficiaries with stroke. *Physical Therapy*. 93(12):1592–1602, Dec. 2013.

²⁴ O'Brien SR, Xue Y, Ingersoll G, et al. Shorter length of stay is associated with worse functional outcomes for medicare beneficiaries with stroke. *Physical Therapy*. 93(12):1592–1602, Dec. 2013.

year.^{25 26} In 2010, the total direct medical costs of fall injuries for people aged 65 years and older was \$30 billion. The annual direct and indirect cost of fall injuries is expected to reach \$54.9 billion by 2020.²⁷ Falls thus represent a significant cost burden to the entire health care system, with injurious falls accounting for 6 percent of medical expenses among those aged 65 years and older.²⁸ This measure was developed by CMS and is currently NQF-endorsed for the Nursing Home/Skilled Nursing Facility setting. Further, we adopted this measure for the LTCH Quality Reporting Program in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50874 through 50877). We included the Falls with Major Injury quality measure in the December 1, 2013 Measures Under Consideration (MUC) list, and the MAP conditionally supported this quality measure for the IRF setting. Additional information regarding NQF #0674, on which our application of the measure will be based, if proposed and adopted through future rulemaking process, is available at <http://www.qualityforum.org/QPS/0674>.

Comment: Several comments were received about the quality measure Application of Percent of Residents Who Self-Report Moderate to Severe Pain (Short-Stay) (NQF #0676). One commenter supported this measure. Several commenters opposed the measure, indicating that it is not appropriate for the IRF setting and does not take into account pain that may be a healthy part of a treatment protocol. One commenter opposed the measure because it was unclear when the assessment would be completed, noting that patients whose pain was inadequately assessed at a previous facility would be admitted to the IRF experiencing pain, and the commenter did not want pain present at the time of admission to be attributed to the IRF. This commenter also noted that it is not addressed how the self-report of pain would be conducted for cognitively impaired patients.

²⁵ L. Currie, *Chapter 10: Fall and Injury Prevention*. In: *Patient Safety and Quality: An Evidence-Based Handbook for Nurses* (Rockville: Agency for Healthcare Research and Quality, 2008).

²⁶ U.S. Department of Health & Human Services, "Implementation Guide to Prevention of Falls with Injury," http://www.dcha.org/wp-content/uploads/falls_change-package_508.pdf.

²⁷ Centers for Disease Control and Prevention, "Costs of Falls Among Older Adults," <http://www.cdc.gov/homeandrecreationalafety/falls/fallcost.html>.

²⁸ L. Z. Rubenstein, C. M. Powers, and C. H. MacLean, "Quality indicators for the management and prevention of falls and mobility problems in vulnerable elders," *Ann Intern Med* 135, no. 8 Pt 2 (2001).

Response: We thank the commenters for their input and will take these comments into consideration to inform our ongoing measure development efforts and our ongoing consideration of including this measure in the future.

Comment: Several commenters expressed strong support for functional status quality measures because functional improvement is a key focus of IRF care. The commenters noted several issues that CMS should consider in the development of these functional status quality measures, including NQF endorsement as well as the importance of adequate risk adjustment and specified exclusion criteria. Several commenters requested that CMS consider using the FIM[®] instrument as part of the quality measure. One commenter suggested expediting the development of the functional status quality measures.

Response: We appreciate the strong support for functional status measures in the IRF setting. The functional status quality measures are in development and will be submitted to NQF for consideration of endorsement in the fall. The draft quality measure specifications (version 2), including the inclusion and exclusion criteria, the risk adjustment variables and risk adjustment approach can be found on the CMS Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/Downloads/Draft-Specifications-for-the-Functional-Status-Quality-Measures-for-Inpatient-Rehabilitation-Facilities-Version-2.pdf>. We appreciate the commenters for their input on the quality measures and will take this feedback under consideration as we finalize the development of the IRF functional status quality measures.

Comment: Several commenters questioned CMS's future proposal of the self-care and mobility functional status quality measures due to their concern that the measures are not yet fully developed nor adequately risk adjusted.

Response: The functional status quality measures have been under development for more than 3 years. The steps in measure development have included analysis, technical expert panel review, and public posting of specifications with public input. Nearing their completion, we anticipate submission of the quality measures to the NQF for its review this fall. The current specifications for the self-care quality measure lists 41 risk adjusters, and the mobility quality measure list 43 risk adjusters. The risk adjusters were selected based on our review of the literature, input from the function

expert panel and feedback from public comments.

Comment: One commenter conveyed their concern regarding the use of the Continuity Assessment Record and Evaluation Tool (CARE Tool) as currently proposed, because the CARE Tool is not appropriate for data collection for the IRF setting.

Response: We interpret the commenter's comment to mean that they were concerned that we would use the CARE Tool as the data source for the functional status quality measures. We further interpret the commenter to mean that we would use the CARE Tool in its entirety for the collection of these measures because they believe that the use of the CARE Tool in its entirety would be inappropriate in an IRF. We would like to clarify that the functional status quality measures do not require data collection of the entire CARE Tool. The functional status measures were developed using a subset of the CARE Tool items (and their response codes), not the CARE Tool in its entirety. These particular assessment items (and response codes) used for the functional status measures, were derived from a subset of items within the CARE Tool which had been tested for reliability and validity in the IRF setting as part of the Post-Acute Payment Reform Demonstration (PAC PRD). A summary of the reliability and validity results are provided in the draft measure specifications posted at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Details.html>.

Comment: Several commenters conveyed concern related to undue burden associated with "double documentation" for the functional status quality measures.

Response: We interpret the comment to refer to the collection of both existing data elements and additional similar or redundant data elements. We appreciate the concerns related to any undue burden, including collection of both existing data elements and additional similar data elements, and take such concerns under consideration.

Comment: One commenter was concerned about relying on data from a demonstration that had flaws in data collection and testing, and wondered whether these quality measures will perform as intended.

Response: We interpreted the commenter's concern to be a concern about the validity of the CARE items tested as part of the PAC PRD. We further interpret their concern being related to the measures performing "as

intended” to imply that they wonder if the measures would be able to depict quality. We have described the development and the assessment of the CARE items and examined the validity and reliability of these CARE items in reports that summarize this work and these reports are posted on the CMS Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/The-Development-and-Testing-of-the-Continuity-Assessment-Record-and-Evaluation-CARE-Item-Set-Final-Report-on-the-Development-of-the-CARE-Item-Set-and-Current-Assessment-Comparisons-Volume-3-of-3.pdf> and <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/The-Development-and-Testing-of-the-Continuity-Assessment-Record-and-Evaluation-CARE-Item-Set-Final-Report-on-the-Development-of-the-CARE-Item-Set-Volume-1-of-3.pdf>. We anticipate that the quality measures will perform as intended and that they will provide information pertaining to quality due to the rigor applied in the development of the measures, including the risk adjustment variables used in measure calculation. In addition, we intend to perform ongoing analysis of the performance of the measures as part of our obligation as a quality measure steward.

Comment: We received several comments pertaining to concerns surrounding the ability of the quality measures to capture small, but important levels of functional change, specifically concerns related to “floor and ceiling effects.”

Response: We interpret the commenter to mean that “floor and ceiling effects” pertain to the assessment items used in the measure not being able to capture change for patients who would fall at the lower or upper ends of the measurement scale. We appreciate concerns related to any instrument that would have limitations such as these floor and ceiling effects. In the development of these quality measures this major concern was taken under consideration, and there was a focus on including items that would cover a wide range of functioning, thus minimizing limitations in measuring change for patients who are low functioning and patients who are high functioning. Details about the development of the CARE items can be

found on the CMS Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/Downloads/Draft-Specifications-for-the-Functional-Status-Quality-Measures-for-Inpatient-Rehabilitation-Facilities-Version-2.pdf>.

Comment: Several commenters indicated concerns about the need for standardized training to ensure inter-rater reliability for the CARE function items and noted that this training would add additional burden to facilities.

Response: We appreciate the commenters’ concerns related to data collection and the requirements that accompany the implementation of new quality measures and have addressed this in the past with public outreach including training sessions, webinars, open door forums, and help desk support.

E. Timeline for Data Submission for New IRF QRP Quality Measures Affecting the FY 2017 Adjustments to the IRF PPS Annual Increase Factor

In the FY 2015 IRF PPS proposed rule (79 FR 26339), we proposed the following data submission timeline for the quality measures for the FY 2017 adjustments to the IRF PPS annual increase factor. We proposed that IRFs would be required to submit data on admissions and discharges occurring between January 1, 2015, and December 31, 2015 (CY 2015), for the FY 2017 adjustments to the IRF PPS annual increase factor. We proposed this time frame because we believe this will provide sufficient time for IRFs and CMS to put processes and procedures in place to meet the additional quality reporting requirements. Given these measures are collected through the CDC’s NHSN, and IRFs are already familiar with the NHSN reporting system, as they currently report the CAUTI measure, we believe this time frame will allow IRFs ample opportunity to begin reporting the MRSA and CDI measures. We also proposed the quarterly data submission deadlines for the FY 2017 adjustments to the IRF PPS annual increase factor to occur approximately 135 days after the end of each quarter, as outlined in the Table 10. Each quarterly deadline would be the date by which all data collected during the preceding quarter would be required to be submitted to us for measures using the IRF-PAI and to the CDC for measures using the NHSN. We invited public comment on these proposed timelines for data submission

for the proposed IRF QRP quality measures for the FY 2017 adjustments to the IRF PPS annual increase factor.

Comment: Several commenters recommended that CMS delay the adoption of the National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716), because it is not ready for implementation. They recommended additional education and training as well as additional testing should be conducted before implementation.

Response: As the MRSA quality measure is already NQF-endorsed for the IRF setting, we do not believe that additional testing is required before implementation. By utilizing CDC’s NHSN for MRSA reporting, we are building upon IRFs’ ongoing experience with data reporting via the NHSN. Quality measures undergo maintenance review at regular intervals in order to evaluate the value of ongoing use of these measures.

Comment: Several commenters recommended that CMS delay the adoption of the National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset Clostridium difficile Infection (CDI) Outcome Measure (NQF #1717), because it is not ready for implementation. They recommended additional testing should be conducted before implementation.

Response: As the CDI quality measure is NQF-endorsed for the IRF setting, we do not believe that additional testing is required before implementation. By utilizing CDC’s NHSN for CDI reporting, we are building upon IRFs’ ongoing experience with data reporting via the NHSN, but recognize that additional education and training would be helpful.

Final Decision: After careful consideration of the comments we received, we are finalizing our proposal to begin to submit data for the MRSA and CDI measures on admissions and discharges starting January 1, 2015, including the quarterly submission deadlines. While we have taken into consideration comments suggesting that we delay implementation of these measures, we do not believe we can delay closing the monitoring gap that would continue to exist if we delayed implementation of these important measures. Adjustments to the IRF PPS annual increase factor for the MRSA and CDI measures will begin with FY 2017.

TABLE 10—TIMELINES FOR SUBMISSION OF IRF QRP QUALITY DATA USING CDC/NHSN FOR FY 2017 ADJUSTMENTS TO THE IRF PPS ANNUAL INCREASE FACTOR: NATIONAL HEALTH SAFETY NETWORK (NHSN) FACILITY-WIDE INPATIENT HOSPITAL-ONSET METHICILLIN-RESISTANT STAPHYLOCOCCUS AUREUS (MRSA) BACTEREMIA OUTCOME MEASURE (NQF #1716) AND NATIONAL HEALTHCARE SAFETY NETWORK (NHSN) FACILITY-WIDE INPATIENT HOSPITAL-ONSET CLOSTRIDIUM DIFFICILE INFECTION (CDI) OUTCOME MEASURE (NQF #1717) *

Quarter	CDC/NHSN data collection period	CDC/NHSN data submission deadline
FY 2017 Increase Factor		
Quarter 1	January 1, 2015–March 31, 2015	August 15, 2015.
Quarter 2	April 1, 2015–June 30, 2015	November 15, 2015.
Quarter 3	July 1, 2015–September 30, 2015	February 15, 2016.
Quarter 4	October 1, 2015–December 31, 2015	May 15, 2016.

* The quarterly deadlines provided in this table apply to the CDC/NHSN data only. Timelines for submission of IRF–PAI data for the IRF PPS and Quality Indicator items are provided separately.

TABLE 11—SUMMARY OF IRF QRP MEASURES AFFECTING THE FY 2017 ADJUSTMENTS TO THE IRF PPS ANNUAL INCREASE FACTOR AND SUBSEQUENT YEAR INCREASE FACTORS

Continued IRF QRP Measure Affecting the FY 2015 Adjustments to the IRF PPS Annual Increase Factor and Subsequent Year Increase Factors:

- NQF #0138: National Health Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure.*

Continued IRF QRP Measure Affecting the FY 2016 Adjustments to the IRF PPS Annual Increase Factor and Subsequent Year Increase Factors:

- NQF #0431: Influenza Vaccination Coverage among Healthcare Personnel.*

Continued IRF QRP Measures Affecting the FY 2017 Adjustments to the IRF PPS Annual Increase Factor and Subsequent Year Increase Factors:

- NQF #2502: All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from Inpatient Rehabilitation Facilities.^**
- NQF #0680: Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay).*
- NQF #0678: Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay).*

New IRF QRP Measures Affecting the FY 2017 Adjustments to the IRF PPS Annual Increase Factor and Subsequent Year Increase Factors:

- NQF #1716: National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure.
- NQF #1717: National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset *Clostridium difficile* Infection (CDI) Outcome Measure.

+ Using CDC/NHSN.

* Using the IRF–PAI effective October 1, 2014.

^ Medicare Fee-for-Service claims data.

** This measure is under review at NQF (http://www.qualityforum.org/All-Cause_Admissions_and_Readmissions_Measures.aspx).

F. Timing for New IRFs To Begin Reporting Quality Data Under the IRF QRP Affecting the FY 2017 Adjustments to the IRF PPS Annual Increase Factor and Beyond

In the FY 2015 IRF PPS proposed rule (79 FR 26340 through 26341), we proposed that for the FY 2017 adjustments to the IRF PPS annual increase factor and subsequent year increase factors, that new IRFs be required to begin reporting quality data under the IRF QRP by no later than the first day of the calendar quarter subsequent to the quarter in which they have been designated as operating in the CASPER system. We invited public comment on this proposed timing for new IRFs to begin reporting quality data under the IRF QRP.

Comment: We did not receive any comments on the above proposal.

Final Decision: We are finalizing our policy regarding the timing for new IRFs to begin reporting quality data under the IRF QRP affecting the FY 2017

adjustments to the IRF PPS annual increase factor and beyond, as proposed.

G. IRF QRP Reconsideration and Appeals Procedures for the FY 2016 Adjustments to the IRF PPS Annual Increase Factor and Beyond

1. IRF QRP Reconsideration and Appeals for the FY 2014 and FY 2015 Adjustments to the IRF PPS Annual Increase Factor

In the FY 2014 IRF PPS final rule (78 FR 47919), we finalized a voluntary process that allowed IRF providers the opportunity to seek reconsideration of our initial noncompliance decision for the FY 2014 and FY 2015 adjustments to the IRF PPS annual increase factor. We stated that we would notify IRFs found to be noncompliant with the IRF QRP reporting requirements that they may be subject to the 2-percentage point reduction to their IRF PPS annual increase factor. The purpose of this notification is to put the IRF on notice of the following: (1) That the IRF has

been identified as being noncompliant with the IRF QRP reporting requirements for a given reporting period; (2) that the IRF will be scheduled to receive a 2-percentage point reduction to its IRF PPS annual increase factor for the applicable fiscal year; (3) that the IRF may file a request for reconsideration if it believes that the finding of noncompliance is erroneous, or that if it was noncompliant, it had a valid and justifiable excuse for this noncompliance; and (4) that, to receive reconsideration, the IRF must follow a defined process on how to file a request for reconsideration, which will be described in the notification. This defined process for filing a request for reconsideration was described on the CMS Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/Reconsideration-and-Disaster-Waiver-Requests.html>.

We further stated that upon the conclusion of our review of each request

for reconsideration, we would render a decision. We may reverse our initial finding of noncompliance if: (1) The IRF provides adequate proof of full compliance with all IRF QRP reporting requirements during the reporting period; or (2) the IRF provides adequate proof of a valid or justifiable excuse for noncompliance if the IRF was not able to comply with the requirements during the reporting period. We will uphold our initial finding of noncompliance if the IRF cannot show any justification for noncompliance.

If an IRF is dissatisfied with either our initial finding of noncompliance or a CMS decision rendered at the reconsideration level, it can appeal the decision with the Provider Reimbursement Review Board (PRRB) under 42 CFR part 405, subpart R. We recommended, however, that IRF providers submit requests for reconsideration to us before submitting appeals to the PRRB. We noted that this order of appeals has had good success under other established quality reporting programs and, from an IRF perspective, it allows for the opportunity to resolve issues earlier in the process, when we have dedicated resources to consider all reconsideration requests before payment changes are applied to the IRF's annual payment.

2. IRF QRP Program Reconsideration and Appeals Procedures for the FY 2016 Adjustments to the IRF PPS Annual Increase Factor and Beyond

In the FY 2015 IRF PPS proposed rule (79 FR 26340 through 26341), we proposed, for the FY 2016 adjustments to the IRF PPS annual increase factor and subsequent year increase factors, to adopt an updated process, as described below, that will enable an IRF to request a reconsideration of our initial noncompliance decision in the event that an IRF believes that it was incorrectly identified as being subject to the 2-percentage point reduction to its IRF PPS annual increase factor due to noncompliance with the IRF QRP reporting requirements for a given reporting period.

For the FY 2016 adjustments to the IRF PPS annual increase factor and subsequent year increase factors, we proposed that an IRF would receive a notification of noncompliance if we determine that the IRF did not submit data in accordance with section 1886(j)(7)(C) of the Act for the applicable fiscal year, and therefore, that the IRF is subject to a 2-percentage point reduction in the applicable IRF PPS annual increase factor as required by section 1886(j)(7)(A)(i) of the Act. We will only consider requests for

reconsideration once a provider has been found to be noncompliant and not before. IRFs will have 30 days from the date of the initial notification of noncompliance to review the CMS determination and submit to us a request for reconsideration. This proposed time frame allows us to balance our desire to ensure that IRFs have the opportunity to request reconsideration with our need to complete the reconsideration process and provide IRFs with our decision in a timely manner. Notifications of noncompliance and any subsequent notifications from CMS will be sent via a traceable delivery method such as certified U.S. mail or registered U.S. mail. We will not accept any requests for reconsideration that are submitted after the 30-day deadline.

We further proposed that as part of the IRF's request for reconsideration, the IRF will be required to submit all supporting documentation and evidence demonstrating (1) full compliance with all IRF QRP reporting requirements during the reporting period or (2) a valid or justifiable excuse for noncompliance if the IRF was not able to comply with the requirements during the reporting period. We will be unable to review any reconsideration request that fails to provide the necessary documentation and evidence along with the request. The documentation and evidence may include copies of any communications that demonstrate its compliance with all IRF QRP reporting requirements, as well as any other records that support the IRF's rationale for seeking reconsideration. A sample list of the proposed acceptable supporting documentation and evidence, as well as instructions for IRF providers to retrieve copies of the data submitted to CMS for the appropriate program year, can be found on the CMS Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/Reconsideration-and-Disaster-Waiver-Requests.html>.

We proposed that providers may withdraw reconsideration requests at any time and may file new requests within the proposed 30-day deadline. We also proposed that, in very limited circumstances, we may extend the proposed deadline for submitting reconsideration requests. It will be the responsibility of a provider to request an extension and demonstrate that extenuating circumstances existed that prevented the filing of the reconsideration request by the proposed deadline. We will not respond to any other types of requests, such as requests for administrative review of the

methodology and standards that determine the quality reporting requirements.

We proposed that an IRF provider wishing to request a reconsideration of our initial noncompliance determination will be required to do so by submitting an email to the following email address:

IRFQRPreconsiderations@cms.hhs.gov. Any request for reconsideration submitted to us by an IRF will be required to follow the guidelines outlined on the CMS Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/Reconsideration-and-Disaster-Waiver-Requests.html>. Following receipt of a request for reconsideration, we will provide—

- An email acknowledgment, using the contact information provided in the reconsideration request, to the CEO or CEO-designated representative that the request has been received; and

- Once we have reached a decision regarding the reconsideration request, an email to the IRF CEO or CEO-designated representative, using the contact information provided in the reconsideration request, regarding our decision.

We proposed to require any IRF that believes it was incorrectly identified as being subject to the 2-percentage point reduction to its IRF PPS annual increase factor to submit a request for reconsideration and receive a decision on that request before the IRF can file an appeal with the PRRB, as authorized by the Administrative Procedure Act. If the IRF is dissatisfied with the decision rendered at the reconsideration level, the IRF can appeal the decision with the PRRB under § 405.1835. We believe this proposed process is more efficient and less costly for us and for IRFs because it decreases the number of PRRB appeals by resolving issues earlier in the process. Additional information about the reconsideration process including requirements for submitting reconsideration request is posted on the CMS Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/Reconsideration-and-Disaster-Waiver-Requests.html>. We invited public comment on the proposed procedures for reconsideration and appeals. The responses to the public comments we received on this proposal are discussed below.

Comment: Several commenters supported the proposal to continue the reconsideration process for FY 2016.

Response: We thank the commenters for taking the time to express their support.

Comment: One commenter supported the reconsideration process, but believed that it should be expanded to include reconsideration of the results of the data validation process described in section XII.K. of this final rule. Specifically, if two clinicians do not document the patient's condition in the same way, but the rationale for the difference can be explained through the reconsideration and appeals process, then the provider should be allowed to use this process.

Response: We thank the commenter for their support of the proposed reconsideration process. We believe the current reconsideration process could be utilized for reconsideration of the results of the validation process, as long as all of the supporting documentation necessary for the request for reconsideration was previously submitted at the time of validation (that is, as long as the reconsideration request was based on the same documentation that was submitted for validation).

Final Decision: Having carefully considered the comments we received on the IRF QRP Reconsideration and Appeals procedures for the FY 2016 adjustments to the IRF PPS annual increase factor and beyond, we are finalizing this policy as proposed.

H. IRF QRP Data Submission Exception or Extension Requirements for the FY 2017 Adjustments to the IRF PPS Annual Increase Factor and Beyond

In the FY 2015 IRF PPS proposed rule (79 FR 26341 through 26342), for the IRF QRP's data submission exception or extension requirements for the FY 2017 adjustments to the IRF PPS annual increase factor and subsequent year increase factors, we proposed to continue using the IRF QRP's disaster waiver requirements that were adopted in the FY 2014 IRF PPS final rule (78 FR 47920) for the FY 2015 adjustments to the IRF PPS annual increase factor and subsequent year increase factors, which are outlined in this section, with the exception that the phrase "exception or extension" will be substituted for the word "waiver." We also proposed, for the FY 2017 adjustments to the IRF PPS annual increase factor and subsequent year increase factors, that we may grant an exception or extension to IRFs if we determine that a systemic problem with one of our data collection systems directly affected the ability of the IRF to submit data. Because we do not anticipate that these types of systemic errors will happen often, we do not anticipate granting an exception or

extension on this proposed basis frequently. We proposed that if we make the determination to grant an exception or extension, we will communicate this decision through routine communication channels to IRFs and vendors, including, but not limited to, issuing memos, emails, and notices on the CMS Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/index.html>.

In the FY 2014 IRF PPS final rule (78 FR 47920), we finalized a process for IRF providers to request and for us to grant exceptions or extensions for the quality data reporting requirements of the IRF QRP for one or more quarters, beginning with the FY 2015 adjustments to the IRF PPS annual increase factor and subsequent year increase factors, when there are extraordinary circumstances beyond the control of the provider.

In the event that an IRF seeks to request an exception or extension for quality reporting purposes, the IRF must request an exception or extension within 30 days of the occurrence of an extraordinary event by submitting a written request to CMS via email to the IRF QRP mailbox at IRFQRPReconsiderations@cms.hhs.gov. Exception or extension requests sent to us through any other channel will not be considered as a valid request for an exception or extension from the IRF QRP reporting requirements for any adjustment to the IRF PPS annual increase factor. The written request must contain all of the finalized requirements in the FY 2014 IRF PPS final rule (78 FR 47920) and on the CMS Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/Reconsideration-and-Disaster-Waiver-Requests.html>. When an exceptions or extension is granted, an IRF will not incur payment reduction penalties for failure to comply with the requirements of the IRF QRP, for the time frame specified by CMS. If an IRF is granted an exception, we will not require that the IRF submit any quality data for a given period of time. If we grant an extension to an IRF, the IRF will still remain responsible for submitting quality data collected during the time frame in question, although we will specify a revised deadline by which the IRF must submit this quality data. It is important to note that requesting an exception or extension from the requirements of the IRF QRP is separate and distinct from the purpose and requirements of § 412.614, which outline the requirements to follow if an

IRF is requesting a waiver regarding consequences of failure to submit complete and timely IRF-PAI payment data specified in that regulation. IRFs that have filed and were granted an IRF-PAI waiver in accordance with § 412.614 may so indicate when requesting an exception or extension from the IRF QRP requirements, but the submission of an IRF-PAI waiver request pursuant to § 412.614 will not be considered a valid request for an exception or extension from the IRF QRP requirements. To request an exception or extension from the IRF QRP requirements, the previously discussed process must be followed.

Additionally, in the FY 2014 IRF PPS final rule (78 FR 47920), we finalized a policy that allowed us to grant waivers (which we are now calling exceptions or extensions) to IRFs that have not requested them if we determine that an extraordinary circumstance, such as an act of nature, affects an entire region or locale. We stated that if this determination was made, we will communicate this decision through routine communication channels to IRFs and vendors, including, but not limited to, issuing memos, emails, and notices on the CMS Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/index.html>.

We invited public comment on these proposals regarding the IRF QRP's data submission exception or extension requirements for the FY 2017 adjustments to the IRF PPS annual increase factor and subsequent year increase factors. The responses to the public comments we received on this proposal are discussed below.

Comment: Several commenters supported the proposed Exception/Exemption waiver proposal.

Response: We thank the commenters for taking time to express their support.

Final Decision: Having carefully considered the comments we received on the proposed IRF QRP data submission exception or extension requirements for the FY 2017 adjustments to the IRF PPS annual increase factor and beyond, we are finalizing these requirements, as proposed.

I. Public Display of Quality Measure Data for the IRF QRP

Under section 1886(j)(7)(E) of the Act, the Secretary is required to establish procedures for making data submitted under the IRF QRP available to the public. Section 1886(j)(7)(E) of the Act also requires these procedures to ensure that each IRF provider has the

opportunity to review the data that is to be made public for its facility, prior to such data being made public. Section 1886(j)(7)(E) of the Act requires the Secretary to report quality measures that relate to services furnished in IRFs on the CMS Web site at <http://www.cms.hhs.gov/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/>.

Currently, the Agency is developing plans regarding the implementation of these provisions. We appreciate the need for transparency into the processes and procedures that will be implemented to allow for the public reporting of the IRF QRP data and to afford providers the opportunity to preview that data before it is made public. At this time, we have not established procedures or timelines for public reporting of data, but we intend to make the public aware of our strategy in the future. We invited public comments on what we should consider when developing future proposals related to public reporting. Our responses to the public comments we received on this topic are discussed below.

Comment: Several commenters encouraged CMS to report IRF quality data on Hospital Compare in the same manner that it reports data for acute care hospitals. One commenter encouraged CMS to report on IRF quality data as soon as possible.

Response: We thank the commenters for taking the time to express these views and suggestions regarding public reporting and will take them into consideration for future public reporting development.

J. IRF QRP Data Completion Thresholds for the FY 2016 Adjustments to the IRF PPS Annual Increase Factor and Beyond

Beginning in FY 2014, section 1886(j)(7)(A)(i) of the Act requires the reduction of the applicable IRF PPS annual increase factor, as previously modified under section 1886(j)(3)(D) of the Act, by 2 percentage points for any IRF that fails to submit data on quality measures specified by the Secretary in accordance with the form and manner specified by the Secretary for that fiscal year. To date, we have not established a standard for compliance other than for IRF providers to submit all applicable required data for all finalized IRF QRP quality measures, by the previously finalized quarterly deadlines. We have also specifically required monthly submission of such quality data for the healthcare-associated infection or vaccination data, which is reported to the CDC. In the FY 2015 IRF PPS proposed rule (79 FR 26342 through

26343), in reaction to the input received from our stakeholders seeking additional specificity related to required IRF QRP compliance affecting FY annual increase factor determinations and, due to the importance of ensuring the integrity of quality data submitted to CMS, we proposed to set specific IRF QRP thresholds for completeness of provider quality data beginning with data affecting the FY 2016 annual increase factor determination and beyond.

The IRF QRP, through the FY 2012 IRF PPS final rule, CY 2013 OPPTS/ASC final rule, and FY 2014 IRF PPS final rule, requires providers to submit quality data using 2 separate data collection/submission mechanisms: Measures collected using the quality indicator section of the IRF-PAI are submitted through the CMS Quality Improvement Evaluation System (QIES); and measures stewarded by the Centers for Disease Control and Prevention (CDC) (Healthcare-associated Infection (HAI) measures and vaccination measures) are submitted using the CDC's National Healthcare Safety Network (NHSN). While we have previously finalized a claims-based measure (All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from Inpatient Rehabilitation Facilities), such measures do not require IRFs to actually submit quality data to us, as they are calculated using claims data submitted to us for payment purposes. Thus, with claims-based measures, there is no quality data to which we could apply the proposed data completion thresholds. To ensure that IRF providers are meeting an acceptable standard for completeness of submitted data, we proposed that for the FY 2016 annual increase factor and beyond, IRF providers must meet or exceed two separate program thresholds: One threshold for quality measures data collected using the quality indicator section of the IRF-PAI and submitted through QIES; and a second threshold for quality measures data collected and submitted using the CDC's NHSN. We proposed that IRFs must meet or exceed both thresholds discussed below to avoid receiving a 2 percentage point reduction to their IRF PPS annual increase factor for a given FY, beginning with FY 2016, which considers quality data submitted during CY 2014. We proposed to hold IRF providers accountable for two different data completion thresholds for each of the 2 data submission mechanisms: A 95 percent data completion threshold for data collected using the quality indicator items on the IRF-PAI and

submitted through QIES; and a 100 percent threshold for data collected and submitted through the CDC's NHSN. We have chosen to hold providers to the lower threshold of 95 percent for the quality indicator items on the IRF-PAI, as there has to be some margin for error related to IRF patients that have been discharged emergently or against medical advice, as these situations make it more difficult to collect and submit the mandatory IRF-PAI quality indicator items at discharge. We do not believe the same impediments exist for the infection, vaccination, or other quality measures data that IRFs submit to the CDC's NHSN.

1. IRF QRP Completion Threshold for the Required Quality Indicator Data Items on the IRF-PAI

The quality indicator section of the IRF-PAI is composed of data collection items designed to inform quality measure calculations, including risk-adjustment calculations as well as internal consistency checks for logical inaccuracies. In the FY 2015 IRF PPS proposed rule (79 FR 26342 through 26343), we proposed that beginning with quality data affecting the FY 2016 IRF PPS annual increase factor (CY 2014 data) and beyond, IRF providers must meet or exceed a proposed IRF-PAI quality indicator data completion threshold of 95 percent. We proposed to assess the completeness of submitted data by verifying that, for all IRF-PAI Assessments submitted by any given IRF, at least 95 percent of those IRF-PAI Assessments must have 100 percent of the mandatory quality indicator data items completed where, for the purposes of this proposed rule, "completed" is defined as having provided actual patient data as opposed to a non-informative response, such as a dash (–), that indicates the IRF was unable to provide patient data. The proposed threshold of 95 percent is based on the need for complete records, which allows appropriate analysis of quality measure data for the purposes of updating quality measure specifications as they undergo yearly and triennial measure maintenance reviews with the NQF. Additionally, complete data is needed to understand the validity and reliability of quality data items, including risk-adjustment models. Finally, we want to ensure complete quality data from IRF providers, which will ultimately be reported to the public, allowing our beneficiaries to gain an understanding of provider performance related to these quality metrics, and helping them to make informed health care choices. Our data suggests that the majority of current IRF

providers are in compliance with, or exceeding this proposed threshold already. However, we take comment on circumstances that might prevent IRFs from meeting this level of compliance. All items that we propose to require under the IRF QRP are identified in Chapter 4 of the IRF PAI Training Manual, which is available for download on the CMS Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/index.html?redirect=/IRF-Quality-Reporting/>. We additionally proposed that any IRF that does not meet the proposed requirement that 95 percent of all IRF-PAI assessments submitted contain 100 percent of all required quality indicator data items, will be subject to a reduction of 2 percentage points to the applicable FY IRF PPS annual increase factor beginning with FY 2016. To establish this program threshold, we analyzed IRF-PAI quality indicator data item submissions from January 2013 through September 2013, and we believe that the majority of IRF providers will be able to meet the proposed 95 percent data completion threshold. It is our intent to raise this threshold over the next 2 years, through the notice and comment rulemaking process. We proposed that this threshold will have to be met by IRFs, in addition to the CDC NHSN threshold discussed below, to avoid receiving a 2 percentage point reduction to the applicable FY IRF PPS annual increase factor.

2. IRF QRP Data Completion Threshold for Measures Submitted Using the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN)

The IRF QRP, through the FY 2012 IRF PPS final rule, CY 2013 OPPTS/ASC final rule, and FY 2014 IRF PPS final rule, requires that IRFs submit CDC-stewarded quality measure data using the CDC's NHSN, including data for the previously finalized CAUTI and Influenza Vaccination Coverage Among Healthcare Personnel (HCP) quality measures. More specifically, we require that IRFs follow CDC quality measure protocols, which require them to complete all data fields required for both numerator and denominator data within NHSN, including the "no events" field for any month during which no infection events were identified. IRFs are required to submit this data on a monthly basis (except for the HCP measure, which is only required to be reported once per year). However, IRFs have until the associated quarterly deadline (135 calendar days

beyond the end of each CY quarter) by which to report infection data to the CDC for each of the 3 months within any give quarter. For more information on the IRF QRP quarterly deadlines, we refer you to Table 10 in section XI.E of this final rule. In the FY 2015 IRF PPS proposed rule (79 FR 26343), we proposed that, beginning with FY 2016 IRF PPS annual increase factor and beyond, this previously finalized requirement for monthly reporting must be met, in addition to the proposed IRF-PAI quality indicator data item completion threshold discussed above, to avoid a 2 percentage point reduction to the applicable FY IRF PPS annual increase factor. That is, we proposed that IRFs must meet a threshold of 100 percent for measures submitted via the NHSN, achieved by submitting relevant infection or vaccination data for each month of any given CY, in addition to meeting the above proposed data item completion threshold for required quality indicator items on the IRF-PAI. As the IRF QRP expands and IRFs begin reporting measures that were previously finalized, but not yet implemented, or newly proposed and finalized measures, we proposed to apply this same threshold.

a. Application of the 2 Percentage Point Reduction for IRF Providers That Fail To Meet the Above-Proposed Data Completion Thresholds

In the FY 2015 IRF PPS proposed rule (79 FR 26343), we proposed that IRFs must meet two separate data completion thresholds to avoid a 2 percentage point reduction to their applicable FY annual increase factor: A data completion threshold of 95 percent for those mandatory data elements collected using the quality indicator items on the IRF-PAI and submitted through QIES; and a second data completion threshold of 100 percent for quality measure data submitted through the CDC's NHSN. We also proposed that these data completion thresholds must be met in addition to the below proposed data accuracy validation threshold of 75 percent, to avoid a 2 percentage point reduction to their applicable FY annual increase factor. While we proposed that IRFs must meet both the data completion and data accuracy thresholds, IRFs cannot have their applicable annual increase factor reduced twice. That is, should an IRF provider fail to meet either one or both of the proposed thresholds, they will only receive one reduction of 2 percentage points to their applicable FY annual increase factor.

We invited comment on these proposals. Our responses to the public

comments we received on this proposal are discussed below.

Comment: A few commenters supported our proposal of data completeness standards, stating that these standards will facilitate more accurate public reporting in the future.

Response: We thank the commenters for taking the time to express their support of our proposal.

Comment: Several commenters believed we should delay the implementation of our data completion threshold. One commenter stated we should not implement this threshold until FY 2016, at the earliest. Other commenters stated that we should apply the standards no earlier than FY 2017.

Response: We would submit that we proposed to begin applying this data completion threshold, beginning with the FY 2016 annual increase factor for IRFs (based on CY 2014 data), and interpret that the commenter stating that we should not implement this proposal until FY 2016, at the earliest, meant that we should apply this threshold to data collected during CY 2016, at the earliest. We believe that it is important that we begin evaluating the completeness of the quality data submitted to CMS as early as possible, in order to ensure the integrity of the IRF QRP data. This data may not only be used for public reporting, but is also used to inform important updates to quality measures undergoing maintenance at the NQF, that occurs on an annual or triennial basis. Additionally, quality data being submitted via the CDC's NHSN during CY 2014, will be used to calculate a baseline "expected" ratio, as well as a Standard Infection Ratio (SIR). Incomplete quality data, including missing monthly submissions of NHSN data, will result in an incomplete, and therefore potentially misleading, SIR. We believe delaying implementation of the application of these data completion thresholds would be a disservice to Medicare beneficiaries, who will eventually use publically reported data to make better informed health care choices for themselves and their families.

Comment: Several commenters stated that CMS should delay implementation and apply these standards no earlier than FY 2017, and additionally commented that it would be inappropriate and unfair to apply the data completeness standards to data submitted before the standards were proposed, and therefore, known to IRFs. One commenter stated that in the hospital IQR program, changes to data submission standards are proposed in advance of—not during or after—the data collection period. One commenter

stated that it would be impermissibly retroactive to apply data completeness thresholds to IRF data submitted prior to October 1, 2014.

Response: We respectfully disagree with the commenters, and believe that we are within our authority to apply these data completion standards to quality data submitted to CMS prior to the effective date of this final rule. Currently, the compliance standard applicable to each IRF is to timely submit all required quality data to CMS, and IRFs should already be ensuring that the data they submit is complete and accurate. Thus, applying a data completion threshold to data submitted during CY 2014 ensures that IRFs are complying with applicable standards, and that payments made to IRFs are based on complete and accurate data.

Comment: One commenter stated that it would be unfair for CMS to apply the proposed data completion threshold to data collected for the first 6 months using the newly revised IRF-PAI that will go into effect on October 1, 2014, and that CMS should only consider the second 6 months of data submitted using the new IRF-PAI when making compliance determinations. The commenter further stated that CMS has, in the past, used a partial year's data to make compliance determinations, and should do so for the FY 2017 compliance determinations, as IRFs will have a greater chance of submitting inaccurate or incomplete data until they are familiar with the updated IRF-PAI.

Response: We thank the commenter for expressing their concern. However, we respectfully disagree with the commenter. While IRFs will be using a new version of the IRF-PAI beginning October 1, 2014, we do not believe that the expanded quality indicator section used for reporting quality data is so substantially different that IRFs will have difficulty submitting complete and accurate data. The newly expanded quality indicator section of the IRF-PAI includes only 1 additional mandatory item compared to the version that is in use currently. Additionally, the data completion threshold, initially, will only look at the mandatory pressure ulcer items, which remain the same; the new mandatory item is related to the Patient Influenza measure, and will not be considered when applying the data completion threshold for FY 2017 compliance determinations. Any expansion of the application of this data completion threshold to IRF quality data will be addressed through notice-and-comment rulemaking.

Final Decision: Having carefully considered the comments we received on the proposed IRF QRP data

completion threshold, and for the reasons discussed above, we are finalizing the IRF data completion threshold for the FY 2016 adjustments to the IRF PPS annual increase factor and beyond, as proposed.

K. Data Validation Process for the FY 2017 Adjustments to the IRF PPS Annual Increase Factor and Beyond

Historically, we have built consistency and internal validation checks into our data submission specifications to ensure that the basic elements of the IRF-PAI assessment conform to requirements such as proper format and facility information. These internal validation checks are automated and occur during the provider submission process, and help ensure the integrity of the data submitted by providers by rejecting submissions or issuing warnings when provider data contain logical inconsistencies. These edit checks are further outlined in the Inpatient Rehabilitation Facility-Patient Assessment Instrument Data Submission Specifications, which are available for download at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Software.html>.

Validation is intended to provide added assurance of the accuracy of the data that will be reported to the public as required by section 1886(j)(7)(E) of the Act. In the FY 2015 IRF PPS proposed rule (79 FR 26343 through 26344), we proposed, for the FY 2016 adjustments to the IRF PPS annual increase factor and subsequent years, to validate the data submitted for quality purposes. Initially, for FY 2016 this data accuracy validation will apply only to the quality indicator items on the IRF-PAI that inform the measure Percent of Patients or Residents with Pressure Ulcers That Are New or Worsened (NQF #0678), including those mandatory data elements that inform the measure calculation, as well as those that inform internal consistency checks for logical inaccuracies. We proposed that as the IRF QRP expands, and as IRFs begin to submit additional data using the quality indicator section of the IRF-PAI, to include those additional data elements in this validation process. We will inform any such expansion of this validation process prior to its occurrence through our routine channels of communication including, but not limited to the IRF QRP Web site, CMS open door forums, national IRF provider trainings, and the Medicare Learning Network Newsletter.

We proposed to validate the data elements submitted to CMS for Percent

of Residents or Patients with Pressure Ulcers That Are New or Have Worsened (Short-Stay) (NQF #0678) under the IRF QRP by requesting the minimum chart data necessary to confirm a statistically valid random sample of 260 providers. From each of those 260 providers, 5 IRF-PAI assessments submitted through National Assessment Collection Database will be randomly selected. In accordance with § 164.512(d)(1)(iii) of the HIPAA Privacy Rule, we will request from these providers the specified portions of the 5 Medicare patient charts that correspond to the randomly selected assessments, which will need to be copied and submitted via traceable mail to a CMS contractor for validation. We proposed that the specific portions of the 5 beneficiary charts will be identified in the written request, but may include: Admission and discharge assessments, relevant nursing notes following the admission, relevant nursing notes preceding the discharge, physician admission summary and discharge summary, and any Assessment of Pressure Ulcer Form the facility may utilize. We proposed that the CMS contractor would utilize the portions of the patient charts to compare that information with the quality data submitted to CMS. Differences that would affect measure outcomes or measure rates would be identified and reported to CMS. These differences could include, but are not limited to, unreported worsened pressure ulcers.

We proposed that all data that has been submitted to the National Assessment Collection Database under the IRF QRP would be subject to the data validation process. Specifically, we proposed that the contractor will request copies of the randomly selected medical charts from each facility via certified mail (or other traceable methods that require a facility representative to sign for CMS correspondence), and the facility will have 45 days from the date of the request (as documented on the request letter) to submit the requested records to the contractor. If the facility does not comply within 30 days, the contractor will send a second certified letter to the facility, reminding the facility that it must return copies of the requested medical records within 45 calendar days following the date of the initial contractor medical record request. If the facility still does not comply, then the contractor will assign a "zero" score to each measure in each missing record. If, however, the facility does comply, the contractor will review the data submitted by the facility using the IRF-

PAI for the mandatory data elements associated with the Pressure Ulcer measure, until such time that IRFs begin to submit additional quality measures that are collected using the quality indicator section of the IRF-PAI. Initially, this review will consist solely of those mandatory data elements that inform the pressure ulcer measure calculations, as well as those that inform checks for logical inconsistencies. We proposed that as IRFs begin to report additional finalized measures, we intend to propose expanding this validation process to other such measures at that time. The contractor will then calculate the percentage of matching data elements which will constitute a validation score. Because we would not be validating all records, we would need to calculate a confidence interval that incorporates a potential sampling error.

To receive the full FY 2016 IRF annual increase factor, we proposed that IRFs in the random sample must attain at least a 75 percent validation score, based upon our validation process, which will use charts requested from patient assessments submitted for FY 2014. We will calculate a 95 percent confidence interval associated with the observed validation score. If the upper bound of this confidence interval is below the 75 percent cutoff point, we will not consider a hospital's data to be "validated" for payment purposes. For example, for a provider who submits all 5 of their charts, each with 9 elements, the provider's score will be based on 45 possible opportunities to report correctly or incorrectly. If the provider correctly scored on 40 of the 45 elements, then their reliability would be 89 percent (40/45). The upper bound of the confidence interval takes into account sampling error and would be higher than this estimated reliability, in this case 96 percent. This number is greater than or equal to 75 percent. Therefore the provider passes validation. We proposed that providers failing the validation requirements would be subject to a 2 percentage point reduction to their applicable annual increase factor. In addition, all providers validated would receive educational feedback, including specific case details.

1. Application of the 2 Percentage Point Reduction for IRF Providers That Fail To Meet the Above-Proposed Data Accuracy Threshold

In the FY 2015 IRF PPS proposed rule (79 FR 26344), we proposed that IRFs must meet a data accuracy threshold of 75 percent to avoid receiving a 2 percentage point reduction to their

applicable FY annual increase factor. We additionally proposed that this data accuracy threshold of 75 percent must be met in addition to the above data completion thresholds (95 percent for data collected using the quality indicator items on the IRF-PAI and submitted using QIES, and 100 percent for data submitted using the CDC's NHSN), to avoid receiving a 2 percentage point reduction to their applicable FY annual increase factor. While we proposed that IRFs must meet both the proposed data accuracy and data completion thresholds, IRFs cannot have their applicable annual payment update reduced twice. That is, should an IRF provider fail to meet either one or both of the proposed thresholds (data completion and/or data accuracy), they will only receive one reduction of 2 percentage points to their applicable FY annual increase factor.

We invited public comment on these proposals and suggestions to improve the utility of the approach and/or reduce the burden on facilities. Our responses to comments we received on this proposal are discussed below.

Comment: One commenter recommended inclusion of NHSN measures in its proposed validation for FY 2017, beginning with the CAUTI measure. Additionally, they suggested CMS explore a secure method of electronic submission of records for the validation process.

Response: We thank the commenter for taking the time to express these views and suggestions regarding validation and will take them into consideration for future validation proposals. The HIPAA Security Rule and HHS policy require CMS to use secure methods of data transmission. We will consider adoption of electronic transmission of records in future rulemaking as a secure file transfer product becomes available to the IRF QRP.

Comment: Several commenters believed that the proposed data validation process is a fundamental step to ensure the accuracy of the IRF quality reporting data.

Response: We thank the commenters for their support of this process.

Comment: One commenter recommended that CMS not move forward with its proposal to complete data validation for the Pressure Ulcer measure or that CMS should delay implementation until at least FY 2016 and should consider the use of a different measure for validation purposes. Additionally the commenter expressed concern that inconsistencies in the medical record would not be the

sole factor used to demonstrate a failure to comply.

Response: We believe that data validation is necessary to ensure the integrity of the data we use in the IRF QRP. We are finalizing that the data validation process for FY 2016 is for the Pressure Ulcer measure. This process would validate those data elements submitted to the QRP that are found in the medical record. We will not be validating individual inconsistencies in each record. However, if we find that record to be non-compliant, yet a facility believed the documentation submitted for validation matches the data elements submitted for the Pressure Ulcer measure, the facility may seek reconsideration of our initial determination.

Comment: One commenter expressed concern that the threshold compliance of 75 percent agreement was too high for this first attempt to validate the Pressure Ulcer data. They stated that there would be a great deal of variability in the reporting of the pressure ulcer measure and that this should be an opportunity for CMS to educate providers on appropriate documentation and reporting to improve the process. Instead, they offered a 60 percent compliance threshold as more appropriate for this initial round of validation.

Response: We thank the commenter for taking time to express concern about possible variability in the pressure ulcer measure. We note that the 75 percent agreement is the single point estimate of the proportion in agreement; we are proposing that the upper bound of a 95 percent confidence interval be the value that must exceed the 75 percent compliance threshold. We believe this takes into account the inherent variability to be found in the Pressure Ulcer measure data. In addition, the 75 percent proportion agreement is consistent with the other data quality programs currently underway, for example, the Hospital Inpatient Quality Reporting Program, 42 CFR 412.140(d)(2), and the Hospital Outpatient Quality Reporting Program, 42 CFR 419.46(e)(2). We believe it is important, where feasible, to promulgate consistent standards when we deal with the various quality data we are collecting.

Final Decision: Having carefully considered the comments we received on the proposed IRF QRP data validation process and data accuracy threshold, and for the reasons discussed above, we are finalizing the IRF data validation process and data accuracy threshold for the FY 2017 adjustments

to the IRF PPS annual increase factor and beyond, as proposed.

L. Electronic Health Record and Health Information Exchange

We believe that all patients, their families, and their health care providers should have consistent and timely access to their health information in a standardized format that can be securely exchanged between the patient, providers, and others involved in the patient's care.²⁹ We are committed to accelerating health information exchange (HIE) through the use of electronic health records (EHRs) and other types of health information technology (HIT) across the broader care continuum through a number of initiatives, including: (1) Alignment of incentives and payment adjustments to encourage provider adoption and optimization of HIT and HIE services through Medicare and Medicaid payment policies; (2) adoption of common standards and certification requirements for interoperable HIT; (3) support for privacy and security of patient information across all HIE-focused initiatives; and (4) governance of health information networks. These initiatives are designed to improve care delivery and coordination across the entire care continuum and encourage HIE among all health care providers, including professionals and hospitals eligible for the Medicare and Medicaid EHR Incentive Programs and those who are not eligible for the EHR Incentive Programs. The Office of the National Coordinator for Health Information Technology (ONC) is currently exploring regulatory ways to expand the ONC HIT Certificate Program to more easily accommodate HIT certification for technology used in other types of health care settings where individual or institutional health care providers are not typically eligible for incentive payments under the EHR Incentive Programs, such as long-term and post-acute care and behavioral health settings. ONC has previously provided guidance for EHR technology developers serving providers ineligible for incentives under the EHR Incentive Programs titled "Certification Guidance for EHR Technology Developers Serving Health Care Providers Ineligible for Medicare and Medicaid EHR Incentive Payments."³⁰

We believe that HIE and the use of certified EHR technology by IRFs (and other providers ineligible for the

Medicare and Medicaid EHR Incentive Programs) can effectively and efficiently help providers improve internal care delivery practices, support management of patient care across the continuum, and enable the reporting of electronically specified clinical quality measures (eCQMs). More information on the identification of EHR certification criteria and development of standards applicable to IRFs can be found at:

- <http://healthit.gov/policy-researchers-implementers/standards-and-certification-regulations>
- <http://www.healthit.gov/facac/FACAS/health-it-policy-committee/htpc-workgroups/certificationadoption>
- <http://wiki.siframework.org/LCC+LTPAC+Care+Transition+SWG>
- <http://wiki.siframework.org/Longitudinal+Coordination+of+Care>

In the FY 2015 IRF PPS proposed rule (79 FR 26344 through 26345), we solicited feedback on the feasibility and desirability of electronic health record adoption and use of HIE in IRFs. We also solicited public comment on the need to develop electronic clinical quality measures, and the benefits and limitations of implementing these measures for IRF providers. Our responses to the comments we received on this topic are discussed below.

Comment: We received several comments in response to its solicitation for input related to EHR adoption and usage and HIE among IRFs. A commenter suggested that we consider a structural measure similar to the Inpatient Psychiatric Facility Quality Reporting Program to gain insight on the feasibility of EHR adoption and use of HIE in IRFs. Some commenters conveyed concerns related to current EHR/HIE adoption in IRFs, including burden associated with EHR use and time and burden associated with the implementation of the technical infrastructure needed to accommodate EHRs. Many commenters noted the lack of EHR incentive funding and integration of IRFs in activities such as those related to the design of the HIE exchanges, electronic health record interoperability standards, electronic health record incentive payment programs, electronic quality measurement development, as well as the Medicare EHR Incentive Programs, and therefore conveyed concerns about the feasibility and appropriateness of requiring electronic clinical quality measure use at this time in the absence of incentive funding for IRFs. Some commenters suggested collaboration with CMS and the IRF community to expand the reach of HIEs and the

interoperability standards to include IRFs. Some commenters also requested that CMS extend incentive payments to IRFs, allowing HIEs to include IRFs in the development of clinically appropriate electronic quality measures for IRFs. A commenter recommended that CMS not apply the requirement of electronic clinical quality measures reporting at this time, and another commenter requested that CMS allow time for the process of data collection using electronic measures to mature before requiring them.

Response: We thank the commenters for their recommendations and concerns. We believe that these recommendations, including interoperability standards which we interpret to mean those that would align with what has been adopted by the Secretary, and concerns are important considerations related to EHR adoption and HIE usage in the IRF setting. We thank the commenter for their suggestion for us to consider the implementation of a structural measure similar to the Inpatient Psychiatric Facility Report Program in the IRF QRP to gain insight on the feasibility of EHR adoption and use of HIE in IRFs, and we will take this suggestion under consideration.

M. Method for Applying the Reduction to the FY 2015 IRF Increase Factor for IRFs That Fail To Meet the Quality Reporting Requirements

As previously noted, section 1886(j)(7)(A)(i) of the Act requires the application of a 2-percentage point reduction of the applicable market basket increase factor for IRFs that fail to comply with the quality data submission requirements. In compliance with 1886(j)(7)(A)(i) of the Act, we will apply a 2-percentage point reduction to the applicable FY 2015 market basket increase factor (2.2 percent) in calculating an adjusted FY 2015 standard payment conversion factor to apply to payments for only those IRFs that failed to comply with the data submission requirements. As previously noted, application of the 2-percentage point reduction may result in an update that is less than 0.0 for a fiscal year and in payment rates for a fiscal year being less than such payment rates for the preceding fiscal year. Also, reporting-based reductions to the market basket increase factor will not be cumulative; they will only apply for the FY involved. Table 12 shows the calculation of the adjusted FY 2015 standard payment conversion factor that will be used to compute IRF PPS payment rates for any IRF that failed to meet the quality reporting requirements

²⁹ The Department of Health & Human Services August 2013 Statement, "Principles and Strategies for Accelerating Health Information Exchange."

³⁰ http://www.healthit.gov/sites/default/files/generalcertexchange_guidance_final_9-9-13.pdf.

for the period from January 1, 2013, through December 31, 2013.

TABLE 12—CALCULATIONS TO DETERMINE THE ADJUSTED FY 2015 STANDARD PAYMENT CONVERSION FACTOR FOR IRFs THAT FAILED TO MEET THE QUALITY REPORTING REQUIREMENT

Explanation for adjustment	Calculations
Standard Payment Conversion Factor for FY 2014	\$14,846
Market Basket Increase Factor for FY 2015 (2.9 percent), reduced by 0.5 percentage point reduction for the productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act, reduced by 0.2 percentage point in accordance with sections 1886(j)(3)(C) and (D) of the Act and further reduced by 2 percentage points for IRFs that failed to meet the quality reporting requirement	× 1.0020
Budget Neutrality Factor for the Wage Index and Labor-Related Share	× 1.0017
Budget Neutrality Factor for the Revisions to the CMG Relative Weights	× 1.0000
Final Adjusted FY 2015 Standard Payment Conversion Factor	= \$14,901

We did not receive any comments on the proposed method for applying the reduction to the FY 2015 IRF increase factor for IRFs that fail to meet the quality reporting requirements.

Final Decision: As we did not receive any comments on the proposed method for applying the reduction to the FY 2015 IRF increase factor for IRFs that fail to meet the quality reporting requirements, we are finalizing the proposed methodology.

XIII. Miscellaneous Comments

Comment: Several commenters suggested that we consider imposing a cap on the amount of outlier payments an individual IRF can receive under the IRF PPS.

Response: As we did not propose any limits on the amount of outlier payments an individual IRF can receive, this comment is outside the scope of the proposed rule. However, any future consideration given to imposing a limit on outlier payments would have to carefully analyze and take into consideration the effect on access to IRF care for certain high-cost patient populations.

Comment: Several commenters requested that we allow IRFs access to the presumptive compliance reports that the MACs use to determine whether or not an IRF has met the 60 percent rule requirements under the presumptive methodology. These same commenters also requested that we provide IRFs with patient-level detail regarding which patients were counted as presumptively meeting the 60 percent rule requirements and which patients were not counted as meeting the requirements. Other commenters requested that we ensure that all MACs allow for a review process prior to an IRF declassification for the IRF to dispute a 60 percent rule determination.

Response: As we did not propose any changes to these operational aspects of the 60 percent rule enforcement, these

comments are outside the scope of the proposed rule. However, we will take these suggestions into consideration for future operational enhancements.

Comment: Several commenters requested that we release the exact software specifications and algorithms for enforcement of the 60 percent rule policies. Other commenters expressed concerns that we are fundamentally altering the technical code specifications that are used in determining an IRF's presumptive compliance with the 60 percent rule. Additionally, some commenters indicated that there is an inconsistency with the software specifications because they mark a record as failing the presumptive methodology test if the case has an IGC and one of the excluded Etiologic Diagnoses, even if the case has a comorbidity that would qualify the case as counting for the presumptive methodology.

Response: As we did not propose changes to the technical specifications, these comments are outside the scope of the proposed rule. The technical specifications for the presumptive methodology determination are available for download from the CMS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Criteria.html>. As we are continually looking to improve the technical specifications and the accuracy with which we evaluate providers' compliance with the 60 percent rule requirements, we will take these commenters' suggestions and concerns into consideration for future updates to the technical specifications.

Comment: Several commenters suggested that we re-examine the conditions that are included on the list of tier comorbidities (otherwise known in this final rule as the "List of Comorbidities") using the most recent 3 years of data, and revise this list for FY

2016. In addition, one commenter suggested that we allow for multiple tier payments if a patient has multiple comorbidities that qualify for tier payments, instead of only recognizing the one comorbidity that qualifies for the highest payment.

Response: As we did not propose any changes to the methodology or policy regarding the determination of the tier comorbidities, these comments are outside the scope of the proposed rule. We appreciate the commenters' suggestions, and will consider these suggestions for future analyses.

Comment: One commenter suggested that we continue to explore ways to ensure comparability of payments across Medicare's post-acute care settings.

Response: We appreciate the commenter's suggestion. Although the comment is beyond the scope of this rule and reaches beyond the IRF PPS, we appreciate the forward thinking nature of this comment and will try to consider ways in which this suggestion may be considered for future analysis.

Comment: Several commenters expressed concern about the proposal that was included in the most recent President's Budget Proposal to increase the compliance threshold for the 60 percent rule to 75 percent.

Response: Since the Secretary does not have the authority to make this change, this comment is outside the scope of the proposed rule.

XIV. Provisions of the Final Regulations

In this final rule, we are adopting the provisions set forth in the FY 2015 IRF proposed rule (79 FR 26308), except as noted elsewhere in the preamble. Specifically:

- We will update the FY 2015 IRF PPS relative weights and average length of stay values using the most current and complete Medicare claims and cost report data in a budget-neutral manner,

as discussed in section IV of this final rule.

- We will freeze the IRF facility-level adjustment factors at FY 2014 levels, as discussed in section V of this final rule.

- We will update the FY 2015 IRF PPS payment rates by the market basket increase factor, based upon the most current data available, with a 0.2 percentage point reduction as required by sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(iv) of the Act and a productivity adjustment required by section 1886(j)(3)(C)(ii)(I) of the Act, as described in section VI of this final rule.

- We will indicate the Secretary's Final Recommendation for updating IRF PPS payments for FY 2015, in accordance with the statutory requirements, as described in section VI of this final rule.

- We will update the FY 2015 IRF PPS payment rates by the FY 2015 wage index and the labor-related share in a budget-neutral manner, as discussed in section VI of this final rule.

- We will calculate the final IRF Standard Payment Conversion Factor for FY 2015, as discussed in section VI of this final rule.

- We will update the outlier threshold amount for FY 2015, as discussed in section VII of this final rule.

- We will update the cost-to-charge ratio (CCR) ceiling and urban/rural average CCRs for FY 2015, as discussed in section VII of this final rule.

- We will adopt revisions to the list of eligible diagnosis codes that are used to determine presumptive compliance under the 60 percent rule in section VIII of this final rule.

- We will adopt revisions to the list of eligible impairment group codes that presumptively meet the 60 percent rule compliance criteria in section VIII of this final rule.

- We will collect data on the amount and mode (that is, of Individual, Concurrent, Group, and Co-Treatment) of therapies provided in IRFs according to occupational, speech, and physical therapy disciplines via the IRF-PAI in section IX of this final rule.

- We will adopt a revision to the IRF-PAI to indicate whether the case meets the regulatory requirements for arthritis cases in section X of this final rule.

- We will adopt the conversion of the IRF PPS to ICD-10-CM, effective when ICD-10-CM becomes the required medical data code set for use on Medicare claims and IRF-PAI submissions, in section XI of this final rule.

- We will adopt revisions and updates to quality measures and reporting requirements under the

quality reporting program for IRFs in accordance with section 1886(j)(7) of the Act, as discussed in section XII of this final rule.

XV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30 days' notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

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

This final rule does not impose any new information collection requirements as outlined in the regulation text. However, this final rule does make reference to associated information collections that are not discussed in the regulation text contained in this document. The following is a discussion of these information collections, some of which have already received OMB approval.

A. ICRs Regarding the IRF QRP

Updates to IRF QRP

As stated in section XI of this final rule, we have finalized 2 new measures for use in the IRF QRP that will affect the increase factor for FY 2017. These quality measures are: National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716) and National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717). We proposed that these measures would be collected via the CDC's NHSN data submission system (<http://www.cdc.gov/nhsn/>). The NHSN is a secure, Internet-based healthcare-associated infection tracking system that is maintained and managed by the CDC.

There are currently approximately 1,140 IRFs in the United States paid

under the IRF PPS that are already required to submit CAUTI data to the CDC's NHSN. We believe that any burden increase related to complying with the IRF QRP requirements for submission of the MRSA and CDI measures will be minimal for those IRFs that are already familiar with the NHSN submission process, for several reasons. First, these IRFs have already completed the initial setup and have become familiar with reporting data in the NHSN system due to the requirement to report the CAUTI measure. Second, due to their participation in a wide range of mandatory reporting and quality improvement programs, there are at least 15 states that require IRFs to report MRSA bacteremia data and CDI data to the NHSN. The most significant burden associated with these quality measures is the time and effort associated with collecting and submitting the data on the MRSA and CDI measures for IRFs that are not currently reporting any measures beyond the current CAUTI data requirement into the CDC's NHSN system.

Based on submissions to the NHSN, we now estimate that each IRF will execute approximately 5 NHSN submissions per month: 1 MRSA bacteremia event, 1 *C. difficile* event and 3 CAUTI events (60 events per IRF annually). This equates to a total of approximately 68,400 submissions of events to the NHSN from all IRFs per year. The CDC estimated the public reporting burden of the collection of information for each measure to include the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. MRSA and *C. difficile* are estimated to be an average of 15 minutes per response (10 minutes of clinical (registered nurse) time, and 5 minutes of clerical (Medical Records or Health Information Technician); CAUTI is estimated to be an average of 29 minutes per response. Each IRF must also complete a Patient Safety Monthly Reporting Plan estimated at 35 minutes and a Denominator for Specialty Care Area, which is estimated at 5 hours per month. Based on this estimate, we expect each IRF would expend 7.53 hours per month reporting to the NHSN. Additionally, each IRF must submit the Healthcare Personnel Vaccination measure, which the CDC estimates will take 10 minutes of clerical time. Based on this estimate, we expect each IRF would expend 78.97 clinical hours per year reporting to the NHSN, or 90,026 hours for all IRFs. According to the U.S.

Bureau of Labor and Statistics, the mean hourly wage for a registered nurse (RN) is \$33.13; the mean hourly wage for a medical records and health information technician is \$16.81. However, to account for overhead and fringe benefits, we have doubled the mean hourly wage, making it \$66.26 for an RN and \$33.62 for a Medical Record or Health Information Technician. We estimate that the annual cost per each IRF would be \$5,162.09 and that the total yearly cost to all IRFs for the submission of data to NHSN would be \$5,882,782.60. While the quality measures previously discussed are subject to the PRA, we believe that the associated burden is approved under OMB control number 0920-0666, with an expiration date of November, 31, 2016.

In the FY 2014 IRF PPS rule (78 FR 47923 through 47925), we provided burden estimates for measures adopted in that rule. Updated Collection of Information Requirements for each of those measures is described below:

a. All-Cause Unplanned Readmission Measure for 30 Days Post Discharge From Inpatient Rehabilitation Facilities

As stated in the FY 2014 IRF PPS rule (78 FR 47923 through 47925), data for this measure will be derived from Medicare claims, and therefore, will not add any additional reporting burden for IRFs.

b. Percent of Residents or Patients With Pressure Ulcers That Are New or Have Worsened (Short-Stay) (NQF #0678)

In the FY 2015 IRF PPS proposed rule (79 FR 26346), we stated that we expect that the admission and discharge pressure ulcer data will be collected by a clinician such as an RN because the assessment and staging of pressure ulcers requires a high degree of clinical judgment and experience. We estimated that it will take approximately 10 minutes of time by the RN to perform the admission pressure ulcer assessment. We further estimated that it will take an additional 15 minutes of time to complete the discharge pressure ulcer assessment.

We estimated that there are 359,000 IRF-PAI submissions per year³ and that there are 1,140 IRFs in the U.S. reporting quality data to CMS. Based on these figures, we estimated that each IRF will submit approximately 315 IRF-PAIs per year. Assuming that each IRF-PAI submission requires 25 minutes of time by an RN at an average hourly wage of \$66.26 (including fringe benefits and overhead), to complete the "Quality Indicator" section, the yearly cost to each IRF would be \$8,696.63 and

the annualized cost across all IRFs would be \$9,914,158.20.

In the FY 2015 IRF PPS proposed rule (79 FR 26346), we also stated we expected that most IRFs will use administrative personnel, such as a medical secretary or medical data entry clerk, to perform the task of entering the IRF-PAI pressure ulcer Assessment data. We estimated that this data entry task will take no more than 3 minutes for the "Quality Indicator" section of each IRF-PAI record or 15.75 hours for each IRF annually. The average hourly wage for a Medical Records & Health Information Technician is \$33.62 (including fringe benefits and overhead). Again, as we noted above, there are approximately 359,000 IRF-PAI submissions per year and 1,140 IRFs reporting quality data to CMS. Given this wage information, the estimated total annual cost across all reporting IRFs for the time required for entry of pressure ulcer data into the IRF-PAI by a medical record or health information technician (including fringe benefits and overhead) is \$603,652.80. We further estimated the average yearly cost to each individual IRF to be \$529.52.

We estimated that the combined annualized time burden related to the pressure ulcer data item set for work performed, by the both clinical and administrative staff, will be 147 hours for each individual IRF and 167,580 hours across all IRFs. The total estimated annualized cost for collection and submission of pressure ulcer data is \$9,226.15 for each IRF and \$10,517,811 across all IRFs. We estimated the cost for each pressure ulcer submission to be \$29.29.

c. Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680)

IRFs are already required to complete and transmit certain IRF-PAI data on all Medicare Part A Fee-for-Service and Medicare Part C (Medicare Advantage) patients to receive payment from Medicare. In the FY 2015 IRF PPS proposed rule (79 FR 26347), we estimated that completion of the Patient Influenza measure data items will take approximately 5 minutes to complete. The Patient Influenza item set consists of three data items (for example, questions). Each item is straightforward and does not require physical assessment of the patient for completion. We estimated that it will take approximately 0.7 minutes to complete each item, or 2.1 minutes to complete all items related to the Patient Influenza measure. However, in some

cases, the person completing this item set may need to consult the patient's medical record to obtain data about the patient's influenza vaccination.

Therefore, we have allotted an additional 1.66 minutes per item, for a total of 7.1 minutes to complete the Patient Influenza measure data items.

In the FY 2015 IRF PPS proposed rule (79 FR 26347), we noted that there are approximately 359,000 IRF-PAIs completed annually across all 1,140 IRFs that report IRF quality data to CMS. This breaks down to approximately 315 IRF-PAIs completed by each IRF yearly. We additionally estimated that the annual time burden for reporting the Patient Influenza measure data is 42,481 hours across all IRFs in the U.S. and 37.26 hours for each individual IRF. Again, we have estimated the mean hourly wage for an RN (including fringe benefits and overhead) to be \$66.26. Taking all of the above information into consideration, we estimate the annual cost across all IRFs for the submission of the Patient Influenza measure data to be \$2,814,791.06. We further estimated the cost for each individual IRF to be \$2,469.11.

Lastly, in the FY 2015 IRF PPS proposed rule (79 FR 26347), we proposed to validate data submitted to CMS by requesting portions of patient's charts be copied and mailed to a CMS validation contractor. We estimated the size of each section we proposed to request as follows: We stated that we anticipate that the first 3 days of nurses notes will be approximately 15 pages; the last 3 days of nurses notes will be approximately 10 pages; the physician or physician's assistant's admission history and physical will be approximately 30 pages; the physician or physician's assistant's discharge summary will be approximately 15 pages; nurses admission database is approximately 40 pages; pressure ulcer assessment assessments will be approximately 30 pages; physicians progress notes will be approximately 30 pages; physicians orders will be approximately 30 pages and lab reports to be approximately 70 pages. We estimated the total submission to be approximately 270 pages in length. The FY 2013 IPPS/LTCH PPS final rule (77 FR 53745) estimates the appropriate cost for chart submission to be 12 cents per page and \$4.00 shipping. Two hundred seventy pages at a rate of \$0.12 per page with a \$4.00 shipping cost would be \$36.40 per chart. We proposed that 260 providers will be randomly selected for validation, and we proposed to request 5 charts from each selected provider for a total cost of \$47,320 for all IRF

providers, or \$182.00 for any randomly selected IRF provider.

We did not receive any public comments on the above IRF QRP Information Collection Request section of the FY 2015 IRF PPS proposed rule. Additionally, in section XI of this final rule, we have finalized the adoption of the following two measures: NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716); and NHSN Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717). We further confirmed that the previously finalized measures discussed in section XII.B. will continue to be required for the IRF QRP.

B. ICRs Regarding Individual, Concurrent, Group, and Co-Treatment Therapy Data on the IRF-PAI

As stated in section IX. of this final rule, we are including a new Therapy Information Section in the IRF-PAI that will require IRF providers to submit data regarding the amount and mode (that is, Individual, Concurrent, Group, and Co-Treatment) of therapy that patients are receiving and in which therapy discipline (PT, OT, speech/language) beginning on October 1, 2015.

Under Medicare's conditions of participation for hospitals that provide rehabilitation, physical therapy, occupational therapy, audiology, or speech pathology services at § 482.56, the provision of care and the personnel qualifications must be in accordance with national acceptable standards of practice and must also meet the requirements at § 409.17, according to which IRFs are required to furnish physical therapy, occupational therapy or speech-language pathology services under a plan that, among other things, "[p]rescribes the type, amount, frequency, and duration of the physical therapy, occupational therapy, or speech-language pathology services to be furnished to the individual." (Such services may also be furnished under plan requirements specific to the payment policy under which the services are rendered, if applicable.) In addition, the IRF coverage requirements at § 412.622(a)(3)(ii), (4), require the IRF to document that the patient "[g]enerally requires and can reasonably be expected to actively participate in, and benefit from, an intensive rehabilitation therapy program." As Medicare already requires extensive documentation of the type, amount, frequency, and duration of physical therapy, occupational therapy, or speech-language pathology services

furnished to individuals in the IRF setting, we do not believe that IRFs will incur any additional burden related to the collection of the data for the proposed new Therapy Information Section. In accordance with 5 CFR 1320.3(b)(2), we believe the burden associated with this requirement is exempt from the PRA as it is a usual and customary business practice. The time, effort, and financial resources necessary to comply with this requirement would be incurred in the course of each IRF conducting its normal business activities.

We anticipate that it will take approximately 4 minutes to retrieve the therapy data from the patient's medical record and transfer the required data to the IRF-PAI for submission. We believe this task can be completed by any clinician in the IRF. To calculate the burden, we obtained hourly wage rates for social worker assistants, licensed practical nurses (LPN), recreational therapists, social workers, dietitians and nutritionists, RN, speech language pathologists, audiologists, occupational therapists, and physical therapists, all of whom may complete the IRF-PAI, from the Bureau of Labor Statistics (<http://www.bls.gov/ooh/healthcare/home.htm>). The \$26.52 rate is a blend of all of these categories, and reflects the fact that IRF providers have historically used all of these clinicians for preparation and coding of the IRF-PAI. However, to account for overhead and fringe benefits, we double the average rate, making it \$53.04. On average, an IRF submits approximately 300 IRF-PAIs annually and when multiplied by 4 minutes to complete the proposed new Therapy Information Section, the total estimated annual hour burden per each IRF is 20 hours. We estimate the total cost burden to each IRF for reporting the proposed therapy data will be \$1,060 annually. Since there are a total of 1,140 IRFs, we estimate the total burden cost across all IRFs for submitting therapy data is \$1.2 million.

We received 40 comments on the information collection requirements regarding the Individual, Concurrent, Group, and Co-Treatment Therapy data on the IRF-PAI, which are summarized below.

Comment: Many commenters suggested that the therapy collection item would be excessively burdensome and should be removed. The commenters suggested that CMS has underestimated the cost and time it would take providers to implement this proposed policy, implying that additional IRF staff would need to be employed to fulfill the data collection requirement. A few commenters even

suggested that the therapy data CMS is proposing to collect is redundant since the data could be found on IRF patient claims. Additionally, commenters suggested that the proposed therapy data collection requirement does not seem to provide any value to the patient and would ultimately divert clinical resources from patient care to administrative functions compromising patients' health outcomes instead of increasing quality of care. Ultimately, the commenters urged CMS to focus on the outcomes of rehabilitative care rather than regulatory mandates.

Response: We recognize and have taken into account that the addition of the therapy collection item will increase the time it takes for providers to complete the IRF-PAI. However, IRF clinicians are currently required to thoroughly document all treatment information in the patients' medical record. We believe that in order to fulfill this requirement, IRFs are already required to document in detail the amount and mode of therapy that a patient receives. We do not believe that it would take an excessive amount of additional time and/or training to transfer that information from the medical record to the IRF-PAI. We certainly do not believe that IRFs would need to employ additional staff to meet this data collection requirement. The additional cost that a facility would incur in making updates to its electronic systems is considered the cost of doing business, and that is not something that we believe should be taken into account when preparing our burden estimates.

In response to the commenters' suggestions to minimize the burden associated with the therapy data collection, we are choosing not to adopt the proposed requirement to record the average number of minutes by mode and type of therapy for weeks 3 and beyond of a patient's IRF stay. Instead, we will require IRFs to report only the total number of minutes of therapy provided to a patient, by mode and type of therapy, for week 1 and week 2 of the IRF stay. Additionally, we are adding Concurrent Therapy and revising the Group Therapy definition so that both types of therapy are clearly differentiated. Providers indicated that this change would be helpful to reduce burden, as this is more consistent with the way they currently keep their records. We believe that these changes will substantially lower the amount of burden associated with this data collection.

We respectfully disagree with the commenters' assertion that this information is included on the IRF claim. The therapy data on the IRF

claim is not reported in a consistent manner, and we do not believe that it would be as beneficial as the proposed data collection when developing future policy regarding IRF therapy. We believe it is important to collect the most accurate and reliable information in order to develop future policy to increase the quality of care for IRF patients. Ultimately, we believe that by requiring providers to report each patient's therapy information, in an effort to develop future policies and procedures regarding the amount and mode of therapy given, we are in fact focusing on improving the outcomes of the intensive rehabilitation that patients receive.

We will be submitting a revision of the IRF-PAI information collection request currently approved under OMB control number 0938-0842.

If you comment on these information collection and recordkeeping requirements, please submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, [CMS-1608-F], Fax: (202) 395-6974; or Email: OIRA_submission@omb.eop.gov.

XVI. Regulatory Impact Analysis

A. Statement of Need

This final rule updates the IRF prospective payment rates for FY 2015 as required under section 1886(j)(3)(C) of the Act. It responds to section 1886(j)(5) of the Act, which requires the Secretary to publish in the **Federal Register** on or before the August 1 that precedes the start of each fiscal year, the classification and weighting factors for the IRF PPS's case-mix groups and a description of the methodology and data used in computing the prospective payment rates for that fiscal year.

This rule implements sections 1886(j)(3)(C) and (D) of the Act. Section 1886(j)(3)(C)(ii)(I) of the Act requires the Secretary to apply a multi-factor productivity adjustment to the market basket increase factor, and to apply other adjustments as defined by the Act. The productivity adjustment applies to FYs from 2012 forward. The other adjustments apply to FYs 2010 through 2019.

This rule also adopts some policy changes within the statutory discretion afforded to the Secretary under section 1886(j) of the Act. We will collect data on the amount and mode (that is, Individual, Concurrent, Group, and Co-Treatment) of therapy provided in the IRF setting according to therapy discipline, revise the list of impairment group codes that presumptively meet

the 60 percent rule compliance criteria, provide a way for IRFs to indicate on the IRF-PAI form whether the prior treatment and severity requirements have been met for arthritis cases to presumptively meet the 60 percent rule compliance criteria, and revise and update quality measures and reporting requirements under the IRF quality reporting program. In this final rule, we also address the implementation of the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) for the IRF prospective payment system (PPS), effective when ICD-10-CM becomes the required medical data code set for use on Medicare claims and IRF-PAI submissions.

B. Overall Impacts

We have examined the impacts of this final rule as required by Executive Order 12866 (September 30, 1993, Regulatory Planning and Review), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (September 19, 1980, Pub. L. 96-354) (RFA), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for a major final rule with economically significant effects (\$100 million or more in any 1 year). We estimate the total impact of the policy updates described in this final rule by comparing the estimated payments in FY 2015 with those in FY 2014. This analysis results in an estimated \$180 million increase for FY 2015 IRF PPS payments. As a result, this final rule is designated as economically "significant" under section 3(f)(1) of Executive Order 12866, and hence a major rule under the Congressional Review Act. Also, the rule has been reviewed by OMB.

The Regulatory Flexibility Act (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 IRFs and most other providers and suppliers are small entities, either by having revenues of \$7 million to \$35.5 million or less in any 1 year depending on industry classification, or by being nonprofit organizations that are not dominant in their markets. (For details, see the Small Business Administration's final rule that set forth size standards for health care industries, at 65 FR 69432 at http://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf, effective March 26, 2012.) Because we lack data on individual hospital receipts, we cannot determine the number of small proprietary IRFs or the proportion of IRFs' revenue that is derived from Medicare payments. Therefore, we assume that all IRFs (an approximate total of 1,100 IRFs, of which approximately 60 percent are nonprofit facilities) are considered small entities and that Medicare payment constitutes the majority of their revenues. 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 13, we estimate that the net revenue impact of this final rule on all IRFs is to increase estimated payments by approximately 2.4 percent. However, we find that certain categories of IRF providers would be expected to experience revenue impacts in the 3 percent range. We estimate a 3.1 percent overall impact for 141 urban IRFs and 15 rural IRFs in the Middle Atlantic region, a 3.2 increase for 101 urban IRFs in the Pacific region, a 3.3 increase for 27 rural IRFs in the West North Central region, and a 4.4 increase for four rural IRFs in the Pacific region. As a result, we anticipate this final rule will have a net positive impact on a substantial number of small entities. Medicare Administrative Contractors 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 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 final rule will not have a significant impact (not greater than 3 percent) on rural hospitals based on the data of the 165 rural units and 17 rural hospitals in our database of 1,142 IRFs for which data were available.

Section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–04, enacted on March 22, 1995) 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 2014, that threshold level is approximately \$141 million. This final rule will not impose spending costs on state, local, or tribal governments, in the aggregate, or by the private sector, of greater than \$141 million.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. As stated above, this final rule will not have a substantial effect on state and local governments, preempt state law, or otherwise have a federalism implication.

C. Detailed Economic Analysis

1. Basis and Methodology of Estimates

This final rule sets forth policy changes and updates to the IRF PPS rates contained in the FY 2014 IRF PPS final rule (78 FR 47860). Specifically, this final rule updates the CMG relative weights and average length of stay values, the wage index, and the outlier threshold for high-cost cases. This final rule also applies a MFP adjustment to the FY 2015 RPL market basket increase factor in accordance with section 1886(j)(3)(C)(ii)(I) of the Act, and a 0.2 percentage point reduction to the FY 2015 RPL market basket increase factor in accordance with sections 1886(j)(3)(C)(ii)(II) and –(D)(iv) of the Act. Further, this final rule contains additional changes to the presumptive methodology and additional therapy and quality data collection that are expected to result in some additional financial effects on IRFs. In addition, section XII of this rule discusses the implementation of the required 2 percentage point reduction of the market basket increase factor for any IRF that fails to meet the IRF quality reporting requirements, in accordance with section 1886(j)(7) of the Act.

We estimate that the impact of the changes and updates described in this final rule will be a net estimated increase of \$180 million in payments to IRF providers. This estimate does not include the estimated impacts of the additional changes to the presumptive compliance method and the additional therapy and quality data collection, as discussed in section 8 of this Economic Analysis. In addition, it does not include the implementation of the required 2 percentage point reduction of the market basket increase factor for any IRF that fails to meet the IRF quality reporting requirements (as discussed in section 9 of this Economic Analysis). The impact analysis in Table 13 of this final rule represents the projected effects of the updates to IRF PPS payments for FY 2015 compared with the estimated IRF PPS payments in FY 2014. We determine the effects by estimating payments while holding all other payment variables constant. We use the best data available, but we do not attempt to predict behavioral responses to these changes, and we do not make adjustments for future changes in such variables as number of discharges or case-mix.

We note that certain events may combine to limit the scope or accuracy of our impact analysis, because such an analysis is future-oriented and, thus, susceptible to forecasting errors because of other changes in the forecasted impact time period. Some examples could be legislative changes made by the Congress to the Medicare program that would impact program funding, or changes specifically related to IRFs. Although some of these changes may not necessarily be specific to the IRF PPS, the nature of the Medicare program is such that the changes may interact, and the complexity of the interaction of these changes could make it difficult to predict accurately the full scope of the impact upon IRFs.

In updating the rates for FY 2015, we are adopting standard annual revisions described in this final rule (for example, the update to the wage and market basket indexes used to adjust the federal rates). We are also implementing a productivity adjustment to the FY 2015 RPL market basket increase factor in accordance with section 1886(j)(3)(C)(ii)(I) of the Act, and a 0.2 percentage point reduction to the FY 2015 RPL market basket increase factor in accordance with sections 1886(j)(3)(C)(ii)(II) and –(D)(iv) of the Act. We estimate the total increase in payments to IRFs in FY 2015, relative to FY 2014, will be approximately \$180 million.

This estimate is derived from the application of the FY 2015 RPL market basket increase factor, as reduced by a productivity adjustment in accordance with section 1886(j)(3)(C)(ii)(I) of the Act, and a 0.2 percentage point reduction in accordance with sections 1886(j)(3)(C)(ii)(II) and –(D)(iv) of the Act, which yields an estimated increase in aggregate payments to IRFs of \$165 million. Furthermore, there is an additional estimated \$15 million increase in aggregate payments to IRFs due to the update to the outlier threshold amount. Outlier payments are estimated to increase from approximately 2.8 percent in FY 2014 to 3.0 percent in FY 2015. Therefore, summed together, we estimate that these updates will result in a net increase in estimated payments of \$180 million from FY 2014 to FY 2015.

The effects of the updates that impact IRF PPS payment rates are shown in Table 13. The following updates that affect the IRF PPS payment rates are discussed separately below:

- The effects of the update to the outlier threshold amount, from approximately 2.8 percent to 3.0 percent of total estimated payments for FY 2015, consistent with section 1886(j)(4) of the Act.
- The effects of the annual market basket update (using the RPL market basket) to IRF PPS payment rates, as required by section 1886(j)(3)(A)(i) and sections 1886(j)(3)(C) and –(D) of the Act, including a productivity adjustment in accordance with section 1886(j)(3)(C)(i)(I) of the Act, and a 0.2 percentage point reduction in accordance with sections 1886(j)(3)(C) and –(D) of the Act.
- The effects of applying the budget-neutral labor-related share and wage index adjustment, as required under section 1886(j)(6) of the Act.
- The effects of the budget-neutral changes to the CMG relative weights and average length of stay values, under the authority of section 1886(j)(2)(C)(i) of the Act.
- The total change in estimated payments based on the FY 2015 payment changes relative to the estimated FY 2014 payments.

2. Description of Table 13

Table 13 categorizes IRFs by geographic location, including urban or rural location, and location for CMS's 9 census divisions (as defined on the cost report) of the country. In addition, the table divides IRFs into those that are separate rehabilitation hospitals (otherwise called freestanding hospitals in this section), those that are rehabilitation units of a hospital

(otherwise called hospital units in this section), rural or urban facilities, ownership (otherwise called for-profit, non-profit, and government), by teaching status, and by disproportionate share patient percentage (DSH PP). The top row of Table 13 shows the overall impact on the 1,142 IRFs included in the analysis.

The next 12 rows of Table 13 contain IRFs categorized according to their geographic location, designation as either a freestanding hospital or a unit of a hospital, and by type of ownership; all urban, which is further divided into urban units of a hospital, urban freestanding hospitals, and by type of ownership; and all rural, which is further divided into rural units of a hospital, rural freestanding hospitals, and by type of ownership. There are 960 IRFs located in urban areas included in our analysis. Among these, there are 732 IRF units of hospitals located in urban areas and 228 freestanding IRF hospitals located in urban areas. There are 182 IRFs located in rural areas included in our analysis. Among these, there are 165 IRF units of hospitals located in rural areas and 17 freestanding IRF hospitals located in rural areas. There are 339 for-profit IRFs. Among these, there are 335 IRFs in urban areas and 64 IRFs in rural areas. There are 673 non-profit IRFs. Among these, there are 567 urban IRFs and 106 rural IRFs. There are 70 government-owned IRFs. Among these, there are 58 urban IRFs and 12 rural IRFs.

The remaining four parts of Table 13 show IRFs grouped by their geographic location within a region, by teaching status, and by DSH PP. First, IRFs located in urban areas are categorized for their location within a particular one

of the nine Census geographic regions. Second, IRFs located in rural areas are categorized for their location within a particular one of the nine Census geographic regions. In some cases, especially for rural IRFs located in the New England, Mountain, and Pacific regions, the number of IRFs represented is small. IRFs are then grouped by teaching status, including non-teaching IRFs, IRFs with an intern and resident to average daily census (ADC) ratio less than 10 percent, IRFs with an intern and resident to ADC ratio greater than or equal to 10 percent and less than or equal to 19 percent, and IRFs with an intern and resident to ADC ratio greater than 19 percent. Finally, IRFs are grouped by DSH PP, including IRFs with zero DSH PP, IRFs with a DSH PP less than 5 percent, IRFs with a DSH PP between 5 and less than 10 percent, IRFs with a DSH PP between 10 and 20 percent, and IRFs with a DSH PP greater than 20 percent.

The estimated impacts of each policy described in this final rule to the facility categories listed above are shown in the columns of Table 13. The description of each column is as follows:

- Column (1) shows the facility classification categories described above.
- Column (2) shows the number of IRFs in each category in our FY 2013 analysis file.
- Column (3) shows the number of cases in each category in our FY 2013 analysis file.
- Column (4) shows the estimated effect of the adjustment to the outlier threshold amount.
- Column (5) shows the estimated effect of the update to the IRF PPS payment rates, which includes a

productivity adjustment in accordance with section 1886(j)(3)(C)(ii)(I) of the Act, and a 0.2 percentage point reduction in accordance with sections 1886(j)(3)(C)(ii)(II) and –(D)(iv) of the Act.

- Column (6) shows the estimated effect of the update to the IRF labor-related share and wage index, in a budget-neutral manner.
- Column (7) shows the estimated effect of the update to the CMG relative weights and average length of stay values, in a budget-neutral manner.
- Column (8) compares our estimates of the payments per discharge, incorporating all of the proposed policies reflected in this final rule for FY 2015 to our estimates of payments per discharge in FY 2014.

The average estimated increase for all IRFs is approximately 2.4 percent. This estimated net increase includes the effects of the RPL market basket increase factor for FY 2015 of 2.9 percent, reduced by a productivity adjustment of 0.5 percentage point in accordance with section 1886(j)(3)(C)(ii)(I) of the Act, and further reduced by 0.2 percentage point in accordance with sections 1886(j)(3)(C)(ii)(II) and –(D)(iv) of the Act. It also includes the approximate 0.2 percent overall increase in estimated IRF outlier payments from the update to the outlier threshold amount. Since we are making the updates to the IRF wage index and the CMG relative weights in a budget-neutral manner, they will not be expected to affect total estimated IRF payments in the aggregate. However, as described in more detail in each section, they will be expected to affect the estimated distribution of payments among providers.

TABLE 13—IRF IMPACT TABLE FOR FY 2015

[Columns 4–9 in %]

Facility classification	Number of IRFs	Number of cases	Outlier	Adjusted market basket increase factor for FY 2015 ¹	FY 2015 CBSA wage index and labor-share	CMG	Total percent change
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(9)
Total	1,142	389,157	0.2	2.2	0.0	0.0	2.4
Urban unit	732	179,336	0.3	2.2	0.0	0.0	2.6
Rural unit	165	26,444	0.3	2.2	0.0	0.1	2.6
Urban hospital	228	177,726	0.1	2.2	0.0	0.0	2.2
Rural hospital	17	5,651	0.1	2.2	–0.1	0.0	2.2
Urban For-Profit	335	165,971	0.1	2.2	–0.2	0.0	2.1
Rural For-Profit	64	12,484	0.2	2.2	–0.2	0.1	2.4
Urban Non-Profit	567	175,276	0.3	2.2	0.2	0.0	2.6
Rural Non-Profit	106	17,698	0.3	2.2	0.1	0.1	2.7
Urban Government	58	15,815	0.3	2.2	–0.1	0.0	2.4
Rural Government	12	1,913	0.4	2.2	–0.5	0.1	2.2
Urban	960	357,062	0.2	2.2	0.0	0.0	2.4

TABLE 13—IRF IMPACT TABLE FOR FY 2015—Continued
[Columns 4–9 in %]

Facility classification	Number of IRFs	Number of cases	Outlier	Adjusted market basket increase factor for FY 2015 ¹	FY 2015 CBSA wage index and labor-share	CMG	Total percent change
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(9)
Rural	182	32,095	0.3	2.2	−0.1	0.1	2.5
Urban by Region							
Urban New England	30	16,946	0.1	2.2	0.4	−0.1	2.6
Urban Middle Atlantic	141	58,438	0.2	2.2	0.8	0.0	3.1
Urban South Atlantic	138	64,756	0.2	2.2	−0.1	−0.1	2.2
Urban East North Central	180	53,400	0.2	2.2	−0.2	0.0	2.2
Urban East South Central	50	24,482	0.1	2.2	−0.5	−0.1	1.7
Urban West North Central	73	18,700	0.2	2.2	−0.4	0.0	2.0
Urban West South Central	173	71,028	0.2	2.2	−0.3	0.1	2.1
Urban Mountain	74	23,158	0.2	2.2	−0.7	0.0	1.7
Urban Pacific	101	26,154	0.4	2.2	0.6	0.0	3.2
Rural by Region							
Rural New England	5	1,270	0.2	2.2	0.0	−0.1	2.3
Rural Middle Atlantic	15	2,557	0.2	2.2	0.5	0.2	3.1
Rural South Atlantic	24	6,028	0.1	2.2	−0.1	0.1	2.4
Rural East North Central	31	5,244	0.3	2.2	−0.2	0.1	2.4
Rural East South Central	21	3,497	0.3	2.2	−0.1	0.1	2.5
Rural West North Central	27	3,460	0.5	2.2	0.5	0.1	3.3
Rural West South Central	48	8,974	0.2	2.2	−0.4	0.2	2.2
Rural Mountain	7	683	0.7	2.2	−0.1	0.0	2.8
Rural Pacific	4	382	0.9	2.2	1.2	0.0	4.4
Teaching Status							
Non-teaching	1,033	343,078	0.2	2.2	0.0	0.0	2.4
Resident to ADC less than 10%	60	31,090	0.2	2.2	0.3	−0.1	2.6
Resident to ADC 10%–19%	39	13,981	0.3	2.2	−0.1	−0.1	2.4
Resident to ADC greater than 19%	10	1,008	0.2	2.2	0.2	0.0	2.5
Disproportionate Share Patient Percentage (DSH PP)							
DSH PP = 0%	37	6,323	0.5	2.2	0.0	0.0	2.8
DSH PP less than 5%	185	65,137	0.2	2.2	0.1	0.1	2.6
DSH PP 5%–10%	333	130,367	0.2	2.2	−0.1	0.0	2.3
DSH PP 10%–20%	362	126,848	0.2	2.2	0.1	0.0	2.5
DSH PP greater than 20%	225	60,482	0.3	2.2	−0.1	−0.1	2.3

¹ This column reflects the impact of the RPL market basket increase factor for FY 2015 (2.9 percent), reduced by a 0.5 percentage point reduction for the productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act, and reduced by 0.2 percentage points in accordance with paragraphs 1886(j)(3)(C) and (D) of the Act.

3. Impact of the Update to the Outlier Threshold Amount

The estimated effects of the update to the outlier threshold adjustment are presented in column 4 of Table 13. In the FY 2014 IRF PPS final rule (78 FR 47860), we used FY 2012 IRF claims data (the best, most complete data available at that time) to set the outlier threshold amount for FY 2014 so that estimated outlier payments would equal 3 percent of total estimated payments for FY 2014.

For this final rule, we are updating our analysis using FY 2013 IRF claims data and, based on this updated

analysis, we estimate that IRF outlier payments as a percentage of total estimated IRF payments are 2.8 percent in FY 2014. Thus, we are adjusting the outlier threshold amount in this final rule to set total estimated outlier payments equal to 3 percent of total estimated payments in FY 2015. The estimated change in total IRF payments for FY 2015, therefore, includes an approximate 0.2 percent increase in payments because the estimated outlier portion of total payments is estimated to increase from approximately 2.8 percent to 3 percent.

The impact of this outlier adjustment update (as shown in column 4 of Table

13) is to increase estimated overall payments to IRFs by about 0.2 percent. We estimate the largest increase in payments from the update to the outlier threshold amount to be 0.9 percent for rural IRFs in the Pacific region. We do not estimate that any group of IRFs would experience a decrease in payments from this proposed update.

4. Impact of the Market Basket Update to the IRF PPS Payment Rates

The estimated effects of the market basket update to the IRF PPS payment rates are presented in column 5 of Table 13. In the aggregate the update would result in a net 2.2 percent increase in

overall estimated payments to IRFs. This net increase reflects the estimated RPL market basket increase factor for FY 2014 of 2.9 percent, reduced by the 0.2 percentage point in accordance with sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(iv) of the Act, and further reduced by a 0.5 percentage point productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act.

5. Impact of the CBSA Wage Index and Labor-Related Share

In column 6 of Table 13, we present the effects of the budget-neutral update of the wage index and labor-related share. The changes to the wage index and the labor-related share are discussed together because the wage index is applied to the labor-related share portion of payments, so the proposed changes in the two have a combined effect on payments to providers. As discussed in section VI.D. of this final rule, we will decrease the labor-related share from 69.494 percent in FY 2014 to 69.294 percent in FY 2015.

In the aggregate, since these updates to the wage index and the labor-related share are applied in a budget-neutral manner as required under section 1886(j)(6) of the Act, we do not estimate that these updates will affect overall estimated payments to IRFs. However, we estimate that these updates will have small distributional effects. For example, we estimate the largest increase in payments from the update to the CBSA wage index and labor-related share of 1.2 percent for rural IRFs in the Pacific region. We estimate the largest decrease in payments from the update to the CBSA wage index and labor-related share to be a 0.7 percent decrease for urban IRFs in the Mountain region.

6. Impact of the Update to the CMG Relative Weights and Average Length of Stay Values

In column 7 of Table 13, we present the effects of the budget-neutral update of the CMG relative weights and average length of stay values. In the aggregate, we do not estimate that these updates will affect overall estimated payments of IRFs. However, we do expect these updates to have small distributional effects. The largest estimated increase in payments is a 0.2 percent increase in rural Middle Atlantic and rural West South Central IRFs. Urban areas in New England, South Atlantic, and East South Central and rural New England are estimated to experience a 0.1 percent decrease in payments due to the CMG relative weights change.

7. Effects of the Changes to the Presumptive Compliance Method for Compliance Review Periods Beginning on or After October 1, 2014

As discussed in section VIII. of this final rule, we are making some additional changes to the presumptive compliance method for compliance review periods beginning on or after October 1, 2015. We do not estimate that the removal of the "amputation status" codes will have any significant financial effects on IRFs, as our data analysis indicates that IRFs are only using these codes for about 2 percent of cases and these codes are only being used to count patients towards the 60 percent rule in 0.3 percent of cases. Similarly, we do not estimate that the proposed exclusion of the non-specific Etiologic Diagnosis codes from the IGCs will have any significant financial effects on IRFs, as we estimate that IRFs will be able to switch to using the more specific codes that are available for the Etiologic Diagnoses instead.

We do, however, believe that there could be a financial effect on IRFs from the removal of the Unilateral Upper Extremity Amputations and Arthritis IGCs from the presumptive compliance method, as the removal of these IGCs from presumptively counting toward meeting the 60 percent rule compliance threshold could result in more IRFs failing to meet the requirements solely on the basis of the presumptive compliance method and being required to be evaluated using the medical review method. We estimate that these effects would be concentrated in approximately 10 percent of IRFs that admit a high number of patients with Unilateral Upper Extremity Amputation and Arthritis conditions, and that the effects would vary substantially among IRFs. As discussed in section X. of this final rule, we are providing IRFs with the ability to indicate on the IRF-PAI that a particular arthritis case meets the severity and prior treatment regulatory requirements, the purpose of which is to mitigate some of the financial effects for these IRFs while still allowing Medicare to ensure that the regulatory requirements are being met.

Comment: One commenter disagreed with our statement that the removal of non-specific codes from the presumptive methodology determination will not have a financial effect on IRFs because they will be able to change their coding practices to use more specific diagnosis codes instead. This commenter said that the information needed to report more specific diagnosis codes is not always available to IRFs.

Response: As we indicated in the FY 2014 IRF PPS final rule (78 FR 47860, 47887), we previously decided to allow some non-specific codes to count toward the presumptive methodology because we recognized that it would be extremely difficult for IRFs to gather the necessary information to code a more specific code in those particular cases. However, after careful analysis, we believe that the remaining non-specific codes that will not count toward an IRF's presumptive compliance with the 60 percent rule are ones that the IRF can and should make every effort to code more specifically. Even if the necessary information to code more specifically is not available in the acute care medical record, we believe that the IRF should make every effort to obtain the necessary information to code more specifically. This is consistent with reduction in the use of non-specific codes for other Medicare settings.

8. Effects of New Therapy Information Section

Because the type, amount, frequency, and duration of therapy provided in IRFs is documented in detail in the IRF medical records as part of the requirements for meeting Medicare's conditions of participation and IRF coverage requirements, we estimate that the additional costs incurred by IRFs for FY 2016 for the new proposed Therapy Information Section of the IRF-PAI would be based on the 4 additional minutes per IRF-PAI form to transfer the information from the IRF medical record to the IRF-PAI form. We estimate that this would result in an additional cost of \$1.2 million to all IRFs for FY 2016.

Comment: Many commenters said that our estimates of the overall costs to IRFs of the therapy data collection on the IRF-PAI are too low. They said that the costs of making the necessary modifications to their medical record systems and the training that will be required for therapists, nurses, and other clinical staff to ensure that they can record the data in a form and manner that will be compatible with the new data collection requirements will be substantial. In addition, there were comments regarding the added burden due to our original proposal to include the average number of minutes by mode and type of therapy for weeks 3 and beyond of a patient's IRF stay.

Response: We appreciate the detailed comments that we received on this issue, and we understand, based on these comments, that the proposed collection of average number of minutes by mode and type of therapy for weeks 3 and beyond of a patient's IRF stay

would require additional resources from the IRFs to operationalize. For this reason, we have withdrawn the proposal to collect the average number of minutes for weeks 3 and beyond. Instead, we will require IRFs to report on the IRF-PAI the total number of minutes of therapy provided to a patient, by mode and therapy discipline, for only week 1 and week 2 of the IRF stay. As described in section IX of this final rule, we believe that this will give us the minimum information that we need to develop future policy and to understand the nature of the services that Medicare is paying for under the IRF PPS, while also minimizing the costs to providers. We carefully considered commenters' suggestions that we add the collection of Concurrent Therapy as a mode and revise the definition of Group Therapy so that new data collection items would be consistent with the way in which facilities were already recording the information in the patient's medical record. We believe this will reduce the need for training and help to minimize burden. Finally, although we understand that updating specific software that IRFs use to collect this information can include additional costs, we view this as a provider business decision. Providers may always opt to use the IRVEN software supplied by CMS for collecting and submitting the IRF-PAI information. Given the revisions to the data collection described in section IX of this final rule, we believe that the cost estimate indicated for this data collection in the proposed rule is accurate.

9. Effects of Updates to the IRF QRP

As discussed in section XI.A. of this final rule and in accordance with section 1886(j)(7) of the Act, we will implement a 2 percentage point reduction in the FY 2015 increase factor for IRFs that have failed to report the required quality reporting data to us during the most recent IRF quality reporting period. In section XI.A of this final rule, we discuss how the 2 percentage point reduction will be applied. Only a few IRFs received the 2 percentage point reduction in the FY 2014 increase factor for failure to report the required quality reporting data last year, and we would anticipate that even fewer IRFs will receive the reduction for FY 2015 as they are now more familiar with the IRF QRP reporting requirements.

In sections XI.K and XI.L of this final rule, we have finalized our proposal to adopt a new data completion threshold as well as a new data accuracy validation policy. While we cannot

estimate the increase in the number of IRFs that will not meet our proposed requirements at this time, we believe that these finalized policies may increase the number of IRFs that receive a 2 percent point reduction to their FY annual increase factor for FY 2016 and beyond. Thus, we estimate that this policy will increase impact on overall IRF payments, by increasing the rate of non-compliance by an estimated 5 percent, for FY 2016 and beyond, decreasing the number of IRF providers that will receive their full annual increase factor for FY 2016 and beyond.

In this FY 2015 IRF PPS final rule, we finalized our proposal to adopt two new quality measures (MRSA and CDI), as well as to adopt a new data accuracy validation policy. Together, we estimate that these proposals will increase the cost to all IRF providers by \$852,238 annually, for an average cost to IRF providers of \$747.57 annually. This is an average increase of approximately 4.43 percent to all IRF providers over the FY 2014 burden. While we also proposed to adopt a data completion threshold policy, this policy, if finalized, will have no associated cost burden beyond that discussed in the first paragraph of this section (XI.C.9) of this final rule.

We intend to closely monitor the effects of this new quality reporting program on IRF providers and help perpetuate successful reporting outcomes through ongoing stakeholder education, national trainings, CMS Open Door Forums, and general and technical help desks. We did not receive any public comments with regard to this section of the proposed rule.

D. Alternatives Considered

The following is a discussion of the alternatives considered for the IRF PPS updates contained in this final rule.

Section 1886(j)(3)(C) of the Act requires the Secretary to update the IRF PPS payment rates by an increase factor that reflects changes over time in the prices of an appropriate mix of goods and services included in the covered IRF services. Thus, we did not consider alternatives to updating payments using the estimated RPL market basket increase factor for FY 2015. However, as noted previously in this final rule, section 1886(j)(3)(C)(ii)(I) of the Act requires the Secretary to apply a productivity adjustment to the market basket increase factor for FY 2015, and sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(iv) of the Act require the Secretary to apply a 0.2 percentage point reduction to the market basket increase factor for FY 2015. Thus, in accordance with section 1886(j)(3)(C) of

the Act, we are updating the IRF federal prospective payments in this final rule by 2.2 percent (which equals the 2.9 percent estimated RPL market basket increase factor for FY 2015 reduced by 0.2 percentage points, and further reduced by a 0.5 percentage point productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act).

We considered maintaining the existing CMG relative weights and average length of stay values for FY 2015. However, in light of recently available data and our desire to ensure that the CMG relative weights and average length of stay values are as reflective as possible of recent changes in IRF utilization and case mix, we believe that it is appropriate to update the CMG relative weights and average length of stay values at this time to ensure that IRF PPS payments continue to reflect as accurately as possible the current costs of care in IRFs.

We considered updating facility-level adjustment factors for FY 2015. However, as discussed in more detail in section V.B. of this final rule, we believe that freezing the facility-level adjustments at FY 2014 levels for FY 2015 and all subsequent years (unless and until the data indicate that they need to be further updated) will allow us an opportunity to monitor the effects of the substantial changes to the adjustment factors for FY 2014, and will allow IRFs time to adjust to last year's changes.

We considered maintaining the existing outlier threshold amount for FY 2015. However, analysis of updated FY 2013 data indicates that estimated outlier payments would be lower than 3 percent of total estimated payments for FY 2015, by approximately 0.2 percent, unless we updated the outlier threshold amount. Consequently, we are adjusting the outlier threshold amount in this final rule to reflect a 0.2 percent increase thereby setting the total outlier payments equal to 3 percent, instead of 2.8 percent, of aggregate estimated payments in FY 2015.

We considered making no further changes to the presumptive compliance method in this final rule. However, to be consistent with the changes to the presumptive compliance method that we implemented in the FY 2014 IRF PPS final rule, and to correct some inadvertent omissions in last year's final rule, we believe it is important to make further changes in this final rule.

However, to ensure that the IRF-PAI item designed to mitigate some of the burden of additional medical reviews that could result from the changes to the presumptive compliance method is available on the IRF-PAI on the same

date or prior to the effective date of those changes, we are delaying the effective date of the changes to the presumptive compliance method. Both the changes to the presumptive compliance method that we finalized in the FY 2014 IRF PPS final rule and the additional changes to the presumptive compliance method that are finalized in this rule will become effective for compliance review periods beginning on or after October 1, 2015.

We considered not including the new Therapy Information Section on the

IRF-PAI. However, we believe that it is vitally important for Medicare to better understand the ways in which therapy services are currently being provided in IRFs and, most importantly, what services Medicare is paying for under the IRF benefit.

E. Accounting Statement

As required by OMB Circular A-4 (available at <http://www.whitehouse.gov/sites/default/files/omb/assets/omb/circulars/a004/a-4.pdf>), in Table 14, we have prepared an

accounting statement showing the classification of the expenditures associated with the provisions of this final rule. Table 14 provides our best estimate of the increase in Medicare payments under the IRF PPS as a result of the updates presented in this final rule based on the data for 1,142 IRFs in our database. In addition, Table 14 presents the costs associated with the new IRF quality reporting program and therapy reporting requirements for FY 2015.

TABLE 14—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES

Category	Transfers
Change in Estimated Transfers from FY 2014 IRF PPS to FY 2015 IRF PPS	
Annualized Monetized Transfers	\$180 million.
From Whom to Whom?	Federal Government to IRF Medicare Providers.
Category	Costs
FY 2015 Cost to Updating the Quality Reporting Program	
Cost for IRFs to Submit Data for the Quality Reporting Program	\$852,238.
FY 2016 Cost for Therapy Data Collection	
Cost for IRFs to Submit Therapy Data	\$1.2 million.

F. Conclusion

Overall, the estimated payments per discharge for IRFs in FY 2015 are projected to increase by 2.4 percent, compared with the estimated payments in FY 2014, as reflected in column 9 of Table 13. IRF payments per discharge are estimated to increase by 2.4 percent in urban areas and by 2.5 percent in rural areas, compared with estimated FY 2014 payments. Payments per discharge to rehabilitation units are estimated to

increase 2.6 percent in urban and rural areas. Payments per discharge to freestanding rehabilitation hospitals are estimated to increase 2.2 percent in urban and rural areas.

Overall, IRFs are estimated to experience a net increase in payments as a result of the policies in final rule. The largest payment increase is estimated to be a 4.4 percent increase for rural IRFs located in the Pacific region.

Dated: July 24, 2014.

Marilyn Tavenner,
Administrator, Centers for Medicare & Medicaid Services.

Approved: July 30, 2014.

Sylvia M. Burwell,
Secretary, Department of Health and Human Services.

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