**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

**42 CFR Part 412**

**[CMS–1671–F]**

**RIN 0938–AS99**

# Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2018

**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) 2018 as required by the statute. As required by section 1886(j)(5) of the Social Security Act (the Act), this rule includes the classification and weighting factors for the IRF prospective payment system's (IRF PPS) case-mix groups and a description of the methodologies and data used in computing the prospective payment rates for FY 2018. This final rule also revises the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) diagnosis codes that are used to determine presumptive compliance under the ''60 percent rule,'' removes the 25 percent payment penalty for inpatient rehabilitation facility patient assessment instrument (IRF–PAI) late transmissions, removes the voluntary swallowing status item (Item 27) from the IRF–PAI, summarizes comments regarding the criteria used to classify facilities for payment under the IRF PPS, provides for a subregulatory process for certain annual updates to the presumptive methodology diagnosis code lists, adopts the use of height/weight items on the IRF–PAI to determine patient body mass index (BMI) greater than 50 for cases of single-joint replacement under the presumptive methodology, and revises and updates measures and reporting requirements under the IRF quality reporting program (QRP).

**DATES:**

*Effective Dates:* These regulations are effective on October 1, 2017.

*Applicability Dates:* The updated IRF prospective payment rates are applicable for IRF discharges occurring on or after October 1, 2017, and on or before September 30, 2018 (FY 2018). All other changes discussed in this final rule, including the revisions to the ICD–10–CM diagnosis codes that are used to determine presumptive compliance under the 60 percent rule, removal of the 25 percent payment penalty for IRF–PAI late transmissions, removal of the voluntary swallowing status item (Item 27) from the IRF–PAI, provision for a subregulatory process for certain annual updates to the presumptive methodology diagnosis code lists, use of height/weight items on the IRF–PAI to determine patient BMI greater than 50 for cases of single-joint replacement under the presumptive methodology, and the updated measures and reporting requirements under the IRF QRP, are applicable for IRF discharges occurring on or after October 1, 2017.

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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 *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/index.html.*

## Executive Summary

### *A. Purpose*

This final rule updates the prospective payment rates for IRFs for FY 2018 (that is, for discharges occurring on or after October 1, 2017, and on or before September 30, 2018) as required under section 1886(j)(3)(C) of the Act. As required by section 1886(j)(5) of the Act, this rule includes the classification and weighting factors for the IRF PPS's case-mix groups and a description of the methodologies and data used in computing the prospective payment rates for FY 2018. This final rule also revises the ICD–10–CM diagnosis codes that are used to determine presumptive compliance under the 60 percent rule, removes the 25 percent payment penalty for IRF–PAI late transmissions, removes the voluntary swallowing status item (Item 27) from the IRF–PAI, provides for a subregulatory process for certain annual updates to the presumptive methodology diagnosis code lists, summarizes comments regarding the criteria used to classify facilities for payment under the IRF PPS, adopts the use of height/weight items from the IRF–PAI to determine patient BMI greater than 50 for cases of lower extremity single joint replacement under the presumptive methodology, and revises and updates the measures and reporting requirements under the IRF QRP.

### *B. Summary of Major Provisions*

In this final rule, we use the methods described in the FY 2017 IRF PPS final rule (81 FR 52056) to update the prospective payment rates for FY 2018 using updated FY 2016 IRF claims and the most recent available IRF cost report data, which is FY 2015 IRF cost report data. (*Note:* In the interest of brevity, the rates previously referred to as the ''Federal prospective payment rates'' are now referred to as the ''prospective payment rates''. No change in meaning is intended.) We are also finalizing revisions and updates to the quality measures and reporting requirements under the IRF QRP.

### *C. Summary of Impacts*

| Provision description | Transfers |
|---|---|
| FY 2018 IRF PPS payment rate update. | The overall economic impact of this final rule is an estimated $75 million in increased payments from the Federal government to IRFs during FY 2018. |
| | Costs |
| New quality reporting program requirements. | The total reduction in costs in FY 2018 for IRFs for the new quality reporting requirements is estimated to be $2.6 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.

The Act The Social Security Act
AHA American Hospital Association
AHRQ Agency for Healthcare Research and Quality
ASAP Assessment Submission and Processing
ASCA The Administrative Simplification Compliance Act of 2002 (Pub. L. 107–105, enacted on December 27, 2002)
ASPE Office of the Assistant Secretary for Planning and Evaluation
BIMS Brief Interview for Mental Status
BiPAP Bilevel Positive Airway Pressure
BLS U.S. Bureau of Labor Statistics
BMI Body Mass Index
CAM Confusion Assessment Method
CARE Continuity Assessment Record and Evaluation
CAUTI Catheter-Associated Urinary Tract Infection
CBSA Core-Based Statistical Area
CCR Cost-to-Charge Ratio
CDI Clostridium difficile Infection
CMG Case-Mix Group
CMS Centers for Medicare & Medicaid Services
CPAP Continuous Positive Airway Pressure
CY Calendar year
DRA Deficit Reduction Act of 2005 (Pub. L. 109–171, enacted on February 8, 2006)
DSH Disproportionate Share Hospital
DTI Deep Tissue Injury
FFS Fee-for-Service
FISS Fiscal Intermediary Shared System
FR Federal Register
FY Federal Fiscal Year
GAO Government Accountability Office
GEMS General Equivalence Mapping
HHA Home Health Agency
HHS U.S. Department of Health and Human Services
HIPAA Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191, enacted on August 21, 1996)
ICD–9–CM International Classification of Diseases, 9th Revision, Clinical Modification
ICD–10–CM International Classification of Diseases, 10th Revision, Clinical Modification
IGC Impairment Group Code
IGI IHS Global Insight
IMPACT Act Improving Medicare Post-Acute Care Transformation Act of 2014 (Pub. L. 113–185, enacted on October 6, 2014)
IPPS Inpatient prospective payment system
IRF Inpatient Rehabilitation Facility
IRF–PAI Inpatient Rehabilitation Facility-Patient Assessment Instrument
IRF PPS Inpatient Rehabilitation Facility Prospective Payment System
IRF QRP Inpatient Rehabilitation Facility Quality Reporting Program
IRVEN Inpatient Rehabilitation Validation and Entry
IV Intravenous
LIP Low-Income Percentage
LTCH Long-Term Care Hospital
MA Medicare Advantage (formerly known as Medicare Part C)
MAC Medicare Administrative Contractor
MACRA Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10, enacted on April 16, 2015)
MAP Measures Application Partnership
MedPAC Medicare Payment Advisory Commission
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
MSPB Medicare Spending Per Beneficiary

NCHS National Center for Health Statistics
NHSN National Healthcare Safety Network
NPUAP National Pressure Ulcer Advisory Panel
NQF National Quality Forum
OMB Office of Management and Budget
ONC Office of the National Coordinator for Health Information Technology
OPPS/ASC Outpatient Prospective Payment System/Ambulatory Surgical Center
PAC Post-Acute Care
PAC/LTC Post-Acute Care/Long-Term Care
PAI Patient Assessment Instrument
PHQ Patient Health Questionnaire
PPACA Patient Protection and Affordable Care Act (Pub. L. 111–148, enacted on March 23, 2010)
PPR Potentially Preventable Readmissions
PPS Prospective Payment System
PRA Paperwork Reduction Act of 1995 (Pub. L. 104–13, enacted on May 22, 1995)
QIES Quality Improvement Evaluation System
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
RTI International Research Triangle Institute International
SME Subject Matter Experts
SNF Skilled Nursing Facility
SODF Special Open Door Forum
SSI Supplemental Security Income
TEP Technical Expert Panel
TPN Total Parenteral Nutrition

## I. Background

### *A. Historical Overview of the 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 a general description of the IRF PPS for FYs 2002 through 2017.

Under the IRF PPS from FY 2002 through FY 2005, the prospective payment rates were computed across 100 distinct case-mix groups (CMGs), as described in the FY 2002 IRF PPS final rule (66 FR 41316). 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 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 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 was a market basket reflecting the operating and capital cost structures for freestanding IRFs, freestanding inpatient psychiatric facilities, and long-term care hospitals (LTCHs) (hereinafter 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 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 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 prospective payment rates for each FY. Based on the legislative change to the increase factor, we revised the FY 2008 prospective payment rates for IRF discharges occurring on or after April 1, 2008. Thus, the final FY 2008 IRF 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 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 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 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 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) (formerly called 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 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, hereinafter referred to as ''PPACA''), 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 multifactor productivity (MFP) 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 PPACA, 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 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 prospective payment rates applied to discharges occurring on or after April 1, 2010, and on or before September 30, 2010. The adjusted FY 2010 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 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 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 prospective payment rates, rebased and revised the RPL market basket, and established a new QRP 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 prospective payment rates.

The FY 2013 IRF PPS notice (77 FR 44618) described the required adjustments to the FY 2013 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 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 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 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 QRP. 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 prospective payment rates.

In the FY 2015 IRF PPS final rule (79 FR 45872), we updated the prospective payment rates, the CMG relative weights, and the outlier threshold amount. We also further 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 IRF–PAI, and revised and updated quality measures and reporting requirements under the IRF QRP. For more information on the policy changes implemented for FY 2015, please refer to the FY 2015 IRF PPS final rule (79 FR 45872) and the FY 2015 IRF PPS correction notice (79 FR 59121).

In the FY 2016 IRF PPS final rule (80 FR 47036), we updated the prospective payment rates, the CMG relative weights, and the outlier threshold amount. We also adopted an IRF-specific market basket that reflects the cost structures of only IRF providers, a blended one-year transition wage index based on the adoption of new OMB area delineations, a 3-year phase-out of the rural adjustment for certain IRFs due to the new OMB area delineations, and revisions and updates to the IRF QRP. For more information on the policy changes implemented for FY 2016, please refer to the FY 2016 IRF PPS final rule (80 FR 47036).

In the FY 2017 IRF PPS final rule (81 FR 52056), we updated the prospective payment rates, the CMG relative weights, and the outlier threshold amount. We also revised and updated quality measures and reporting requirements under the IRF QRP. For more information on the policy changes implemented for FY 2017, please refer to the FY 2017 IRF PPS final rule (81 FR 52056) and the FY 2017 IRF PPS correction notice (81 FR 59901).

### *B. Provisions of the PPACA Affecting the IRF PPS in FY 2012 and Beyond*

The PPACA included several provisions that affect the IRF PPS in FYs 2012 and beyond. In addition to what was previously discussed, section 3401(d) of the PPACA 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 2018 is discussed in section VI.B. of this final rule. Section 3401(d) of the PPACA requires an additional 0.75 percentage point adjustment to the IRF increase factor for each of FYs 2017, 2018, and 2019. The applicable adjustment for FY 2018 is discussed in section V.B. 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 PPACA also addressed the IRF PPS. 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 QRP 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 QRP 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.

### *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 (FFS) 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 MA 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 Part A FFS 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 MA 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 (Type of Bill (TOB) 111), which includes Condition Code 04 to their MAC. This will ensure that the MA days are included in the hospital's Supplemental Security Income (SSI) ratio (used in calculating the IRF LIP 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).

*D. Advancing Health Information Exchange*

The Department of Health and Human Services (HHS) has a number of initiatives designed to encourage and support the adoption of health information technology and to promote nationwide health information exchange to improve health care. As discussed in the August 2013 Statement ''Principles and Strategies for Accelerating Health Information Exchange'' (available at *http://www.healthit.gov/sites/default/files/advancinghieprinciples_strategy.pdf*), we believe that all individuals, their families, their healthcare and social service providers, and payers should have consistent and timely access to health information in a standardized format that can be securely exchanged between the patient, providers, and others involved in the individual's care. Health information technology (health IT) that facilitates the secure, efficient, and effective sharing and use of health-related information when and where it is needed is an important tool for settings across the continuum of care, including inpatient rehabilitation facilities. The effective adoption and use of health information exchange and health IT tools will be essential as IRFs seek to improve quality and lower costs through value-based care.

The Office of the National Coordinator for Health Information Technology (ONC) has released a document entitled ''Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap'' (Roadmap) (available at *https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf*). In the near term, the Roadmap focuses on actions that will enable individuals and providers across the care continuum to send, receive, find, and use a common set of electronic clinical information at the nationwide level by the end of 2017. The Roadmap's goals also align with the Improving Medicare Post-Acute Care Transformation Act of 2014 (Pub. L. 113–185, enacted on October 6, 2014) (IMPACT Act), which requires assessment data to be standardized and interoperable to allow for exchange of the data.

The Roadmap identifies four critical pathways that health IT stakeholders should focus on now to create a foundation for long-term success: (1) Improve technical standards and implementation guidance for priority data domains and associated elements; (2) rapidly shift and align federal, state, and commercial payment policies from FFS to value-based models to stimulate the demand for interoperability; (3) clarify and align federal and state privacy and security requirements that enable interoperability; and (4) align and promote the use of consistent policies and business practices that support interoperability, in coordination with stakeholders. In addition, ONC has released the final version of the 2017 Interoperability Standards Advisory (available at *https://www.healthit.gov/standards-advisory*), a coordinated catalog of standards and implementation specifications to enable priority health information exchange functions. Providers, payers, and vendors are encouraged to take these health IT standards into account as they implement interoperable health information exchange across the continuum of care, including care settings such as inpatient rehabilitation facilities.

We encourage stakeholders to utilize health information exchange and certified health IT to effectively and efficiently help providers improve internal care delivery practices, engage patients in their care, support management of care across the continuum, enable the reporting of electronically specified clinical quality measures, and improve efficiencies and reduce unnecessary costs. As adoption of certified health IT increases and interoperability standards continue to mature, HHS will seek to reinforce

standards through relevant policies and programs.

**II. Summary of Provisions of the Proposed Rule**

In the FY 2018 IRF PPS proposed rule (82 FR 20690), we proposed to update the IRF prospective payment rates for FY 2018, revise the lists of ICD–10–CM diagnosis codes that are used to determine presumptive compliance under the 60 percent rule, remove the 25 percent penalty for IRF–PAI late transmissions, remove the voluntary swallowing status item (Item 27) from the IRF–PAI, provide for a subregulatory process for certain annual updates to the presumptive methodology diagnosis code lists, use height/weight items from the IRF–PAI to determine patient BMI greater than 50 for cases of lower extremity single-joint replacement under the presumptive methodology, and revise and update measures and reporting requirements under the IRF QRP. We also solicited comments regarding the criteria used to classify facilities for payment under the IRF PPS.

The proposed updates to the IRF prospective payment rates for FY 2018 were as follows:

- Update the FY 2018 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 2018 IRF PPS proposed rule (82 FR 20690, 20697 through 20699).
- Describe the continued use of FY 2014 facility-level adjustment factors, as discussed in section IV. of the FY 2018 IRF PPS proposed rule (82 FR 20690, 20699 through 20700).
- Update the FY 2018 IRF PPS payment rates by the proposed market basket increase factor, as required by section 1886(j)(3)(C)(iii) of the Act, as described in section V. of the FY 2018 IRF PPS proposed rule (82 FR 20690 at 20700).
- Update the FY 2018 IRF PPS payment rates by the FY 2018 wage index and the labor-related share in a budget-neutral manner, as discussed in section V. of the FY 2018 IRF PPS proposed rule (82 FR 20690, 20700 through 20703).
- Describe the calculation of the IRF standard payment conversion factor for FY 2018, as discussed in section V. of the FY 2018 IRF PPS proposed rule (82 FR 20690, 20703 through 20705).
- Update the outlier threshold amount for FY 2018, as discussed in section VI. of the FY 2018 IRF PPS proposed rule (82 FR 20690, 20705 through 20706).
- Update the cost-to-charge ratio (CCR) ceiling and urban/rural average CCRs for FY 2018, as discussed in section VI. of the FY 2018 IRF PPS proposed rule (82 FR 20690 at 20706).
- Describe the proposed removal of the 25 percent payment penalty for IRF–PAI late transmissions, as discussed in section VII. of the FY 2018 IRF PPS proposed rule (82 FR 20690, 20706 through 20707).
- Describe proposed revisions to the IRF–PAI to remove the voluntary swallowing status item, as discussed in section VIII. of the FY 2018 IRF PPS proposed rule (82 FR 20690 at 20707).
- Describe proposed refinements to the presumptive compliance methodology ICD–10–CM diagnosis codes, as discussed in section IX. of the FY 2018 IRF PPS proposed rule (82 FR 20690, 20707 through 20711).
- Solicit comments regarding the criteria used to classify facilities for payment under the IRF PPS, as discussed in section IX. of the FY 2018 IRF PPS proposed rule (82 FR 20690 at 20712).
- Describe the proposed subregulatory process for certain annual updates to the presumptive methodology diagnosis code lists, as discussed in section X. of the FY 2018 IRF PPS proposed rule (82 FR 20690, 20713 through 20714).
- Describe the proposed use of height/weight items on the IRF–PAI to determine patient BMI greater than 50 for cases of lower extremity single joint replacement under the presumptive methodology, as discussed in section XI. of the FY 2018 IRF PPS proposed rule (82 FR 20690 at 20714).
- Describe proposed revisions and updates to quality measures and reporting requirements under the IRF QRP in accordance with section 1886(j)(7), which in part requires IRFs to report certain data specified under section 1899B of the Act, as discussed in section XII. of the FY 2018 IRF PPS proposed rule (82 FR 20690, 20714 through 20742).

**III. Analysis and Responses to Public Comments**

We received 76 timely responses from the public, many of which contained multiple comments on the FY 2018 IRF PPS proposed rule (82 FR 20690). We received comments from various trade associations, inpatient rehabilitation facilities, individual physicians, therapists, clinicians, health care industry organizations, 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 2018**

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 2018 IRF PPS proposed rule (82 FR 20690, 20697 through 20699), we proposed to update the CMG relative weights and average length of stay values for FY 2018. 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 2018, we proposed to use the FY 2016 IRF claims and FY 2015 IRF cost report data. These data are the most current and complete data available at this time. We note that, as we typically do, we updated our data between the FY 2018 IRF PPS proposed and final rules to ensure that we use the most recent available data in calculating IRF PPS payments. This updated data reflects a more complete set of claims for FY 2016 and additional cost report data for FY 2015.

In the FY 2018 IRF PPS proposed rule, 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 CCR 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 final 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 2018 CMG relative weights to the same average CMG relative weight from the CMG relative weights implemented in the FY 2017 IRF PPS final rule (81 FR 52056).

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 2018 in such a way that total estimated aggregate payments to IRFs for FY 2018 are the same with or without the changes (that is, in a budget-neutral manner) by applying a budget neutrality factor to the standard payment amount. To calculate the appropriate budget neutrality factor for use in updating the FY 2018 CMG relative weights, we use the following steps:

*Step 1.* Calculate the estimated total amount of IRF PPS payments for FY 2018 (with no changes to the CMG relative weights).

*Step 2.* Calculate the estimated total amount of IRF PPS payments for FY 2018 by applying the changes to the CMG relative weights (as discussed in this final rule).

*Step 3.* Divide the amount calculated in step 1 by the amount calculated in step 2 to determine the budget neutrality factor (0.9976) that would maintain the same total estimated aggregate payments in FY 2018 with and without the changes to the CMG relative weights.

*Step 4.* Apply the budget neutrality factor (0.9976) to the FY 2017 IRF PPS standard payment amount after the application of the budget-neutral wage adjustment factor.

In section VI.E. of this final rule, we discuss the use of the existing methodology to calculate the standard payment conversion factor for FY 2018.

In Table 1, ''Relative Weights and Average Length of Stay Values for Case-Mix Groups,'' we present the CMGs, the comorbidity tiers, the corresponding relative weights, and the average length of stay values for each CMG and tier for FY 2018. 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 | No comorbidities tier | Tier 1 | Tier 2 | Tier 3 | No comorbidities tier |
| 0101 | Stroke M>51.05 | 0.8505 | 0.7289 | 0.6734 | 0.6435 | 9 | 9 | 9 | 8 |
| 0102 | Stroke M>44.45 and M<51.05 and C>18.5 | 1.0680 | 0.9152 | 0.8455 | 0.8080 | 11 | 12 | 10 | 10 |
| 0103 | Stroke M>44.45 and M<51.05 and C<18.5 | 1.2076 | 1.0349 | 0.9560 | 0.9136 | 13 | 13 | 12 | 11 |
| 0104 | Stroke M>38.85 and M<44.45 | 1.2954 | 1.1102 | 1.0256 | 0.9800 | 13 | 13 | 12 | 12 |
| 0105 | Stroke M>34.25 and M<38.85 | 1.5073 | 1.2918 | 1.1933 | 1.1404 | 14 | 14 | 14 | 13 |
| 0106 | Stroke M>30.05 and M<34.25 | 1.6695 | 1.4307 | 1.3217 | 1.2630 | 16 | 16 | 15 | 15 |
| 0107 | Stroke M>26.15 and M<30.05 | 1.8640 | 1.5975 | 1.4758 | 1.4103 | 17 | 17 | 16 | 16 |
| 0108 | Stroke M<26.15 and A>84.5 | 2.3689 | 2.0301 | 1.8754 | 1.7922 | 21 | 23 | 21 | 20 |
| 0109 | Stroke M>22.35 and M<26.15 and A<84.5 | 2.1373 | 1.8317 | 1.6921 | 1.6170 | 19 | 19 | 19 | 19 |
| 0110 | Stroke M<22.35 and A<84.5 | 2.7867 | 2.3882 | 2.2063 | 2.1083 | 27 | 26 | 23 | 24 |
| 0201 | Traumatic brain injury M>53.35 and C>23.5 | 0.8537 | 0.6885 | 0.6269 | 0.5749 | 9 | 9 | 9 | 7 |
| 0202 | Traumatic brain injury M>44.25 and M<53.35 and C>23.5 | 1.0944 | 0.8827 | 0.8037 | 0.7369 | 12 | 11 | 10 | 9 |
| 0203 | Traumatic brain injury M>44.25 and C<23.5 | 1.2638 | 1.0192 | 0.9280 | 0.8510 | 12 | 13 | 11 | 11 |
| 0204 | Traumatic brain injury M>40.65 and M<44.25 | 1.3883 | 1.1197 | 1.0195 | 0.9348 | 11 | 12 | 12 | 12 |
| 0205 | Traumatic brain injury M>28.75 and M<40.65 | 1.6317 | 1.3160 | 1.1982 | 1.0987 | 15 | 15 | 14 | 13 |
| 0206 | Traumatic brain injury M>22.05 and M<28.75 | 1.9691 | 1.5881 | 1.4460 | 1.3259 | 18 | 18 | 16 | 15 |
| 0207 | Traumatic brain injury M<22.05 | 2.5114 | 2.0255 | 1.8443 | 1.6911 | 28 | 23 | 19 | 18 |
| 0301 | Non-traumatic brain injury M>41.05 | 1.1608 | 0.9425 | 0.8574 | 0.8103 | 10 | 11 | 10 | 10 |
| 0302 | Non-traumatic brain injury M>35.05 and M<41.05 | 1.4099 | 1.1447 | 1.0414 | 0.9842 | 13 | 13 | 12 | 12 |
| 0303 | Non-traumatic brain injury M>26.15 and M<35.05 | 1.6565 | 1.3450 | 1.2236 | 1.1563 | 15 | 15 | 13 | 13 |
| 0304 | Non-traumatic brain injury M<26.15 | 2.1517 | 1.7470 | 1.5893 | 1.5020 | 21 | 19 | 17 | 16 |
| 0401 | Traumatic spinal cord injury M>48.45 | 0.9016 | 0.8476 | 0.7569 | 0.6842 | 12 | 12 | 10 | 9 |
| 0402 | Traumatic spinal cord injury M>30.35 and M<48.45 | 1.2903 | 1.2130 | 1.0831 | 0.9792 | 13 | 14 | 13 | 12 |
| 0403 | Traumatic spinal cord injury M>16.05 and M<30.35 | 2.0938 | 1.9683 | 1.7576 | 1.5889 | 22 | 22 | 19 | 18 |
| 0404 | Traumatic spinal cord injury M<16.05 and A>63.5 | 3.6744 | 3.4541 | 3.0844 | 2.7884 | 42 | 36 | 31 | 32 |
| 0405 | Traumatic spinal cord injury M<16.05 and A<63.5 | 3.3965 | 3.1929 | 2.8512 | 2.5776 | 33 | 35 | 31 | 27 |
| 0501 | Non-traumatic spinal cord injury M>51.35 | 0.9313 | 0.7002 | 0.6637 | 0.6090 | 9 | 9 | 9 | 7 |
| 0502 | Non-traumatic spinal cord injury M>40.15 and M<51.35 | 1.2192 | 0.9167 | 0.8689 | 0.7973 | 12 | 10 | 10 | 10 |
| 0503 | Non-traumatic spinal cord injury M>31.25 and M<40.15 | 1.5288 | 1.1495 | 1.0895 | 0.9998 | 16 | 13 | 12 | 12 |
| 0504 | Non-traumatic spinal cord injury M>29.25 and M<31.25 | 1.7362 | 1.3054 | 1.2373 | 1.1354 | 17 | 15 | 14 | 13 |
| 0505 | Non-traumatic spinal cord injury M>23.75 and M<29.25 | 1.9897 | 1.4960 | 1.4179 | 1.3011 | 18 | 17 | 16 | 15 |
| 0506 | Non-traumatic spinal cord injury M<23.75 | 2.7549 | 2.0714 | 1.9632 | 1.8015 | 26 | 23 | 21 | 20 |
| 0601 | Neurological M>47.75 | 1.0661 | 0.8148 | 0.7562 | 0.6879 | 10 | 9 | 9 | 8 |
| 0602 | Neurological M>37.35 and M<47.75 | 1.3922 | 1.0640 | 0.9876 | 0.8984 | 12 | 12 | 11 | 11 |
| 0603 | Neurological M>25.85 and M<37.35 | 1.7073 | 1.3049 | 1.2111 | 1.1017 | 14 | 14 | 13 | 13 |
| 0604 | Neurological M<25.85 | 2.2213 | 1.6977 | 1.5757 | 1.4334 | 19 | 18 | 16 | 16 |
| 0701 | Fracture of lower extremity M>42.15 | 1.0372 | 0.8298 | 0.7877 | 0.7175 | 12 | 11 | 10 | 9 |
| 0702 | Fracture of lower extremity M>34.15 and M<42.15 | 1.3168 | 1.0534 | 1.0001 | 0.9109 | 12 | 12 | 11 | 11 |
| 0703 | Fracture of lower extremity M>28.15 and M<34.15 | 1.5903 | 1.2722 | 1.2078 | 1.1001 | 15 | 14 | 14 | 13 |
| 0704 | Fracture of lower extremity M<28.15 | 2.0160 | 1.6128 | 1.5311 | 1.3946 | 18 | 18 | 17 | 16 |
| 0801 | Replacement of lower extremity joint M>49.55 | 0.8710 | 0.6418 | 0.6113 | 0.5644 | 8 | 8 | 7 | 7 |
| 0802 | Replacement of lower extremity joint M>37.05 and M<49.55 | 1.1197 | 0.8249 | 0.7858 | 0.7255 | 11 | 10 | 9 | 9 |
| 0803 | Replacement of lower extremity joint M>28.65 and M<37.05 and A>83.5. | 1.4515 | 1.0694 | 1.0187 | 0.9406 | 13 | 13 | 12 | 11 |
| 0804 | Replacement of lower extremity joint M>28.65 and M<37.05 and A<83.5. | 1.3342 | 0.9830 | 0.9363 | 0.8645 | 12 | 11 | 11 | 10 |
| 0805 | Replacement of lower extremity joint M>22.05 and M<28.65 | 1.5821 | 1.1657 | 1.1103 | 1.0252 | 14 | 13 | 12 | 12 |
| 0806 | Replacement of lower extremity joint M<22.05 | 1.9159 | 1.4116 | 1.3445 | 1.2415 | 16 | 16 | 15 | 14 |
| 0901 | Other orthopedic M>44.75 | 1.0053 | 0.8078 | 0.7245 | 0.6736 | 10 | 10 | 9 | 8 |
| 0902 | Other orthopedic M>34.35 and M<44.75 | 1.3219 | 1.0621 | 0.9526 | 0.8858 | 12 | 12 | 11 | 10 |

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 | No comorbidities tier | Tier 1 | Tier 2 | Tier 3 | No comorbidities tier |
| 0903 | Other orthopedic M>24.15 and M<34.35 | 1.6223 | 1.3035 | 1.1691 | 1.0870 | 15 | 14 | 13 | 13 |
| 0904 | Other orthopedic M<24.15 | 2.0319 | 1.6327 | 1.4643 | 1.3615 | 18 | 18 | 16 | 15 |
| 1001 | Amputation, lower extremity M>47.65 | 1.0461 | 0.9022 | 0.7937 | 0.7245 | 10 | 11 | 10 | 9 |
| 1002 | Amputation, lower extremity M>36.25 and M<47.65 | 1.3734 | 1.1844 | 1.0421 | 0.9512 | 13 | 13 | 12 | 11 |
| 1003 | Amputation, lower extremity M<36.25 | 2.0115 | 1.7348 | 1.5262 | 1.3931 | 18 | 18 | 17 | 16 |
| 1101 | Amputation, non-lower extremity M>36.35 | 1.3160 | 1.1741 | 1.0154 | 0.8714 | 12 | 14 | 12 | 10 |
| 1102 | Amputation, non-lower extremity M<36.35 | 1.9052 | 1.6998 | 1.4701 | 1.2615 | 17 | 23 | 15 | 14 |
| 1201 | Osteoarthritis M>37.65 | 1.2296 | 0.9239 | 0.8627 | 0.7939 | 9 | 11 | 10 | 10 |
| 1202 | Osteoarthritis M>30.75 and M<37.65 | 1.5807 | 1.1877 | 1.1090 | 1.0206 | 11 | 13 | 13 | 12 |
| 1203 | Osteoarthritis M<30.75 | 1.9306 | 1.4506 | 1.3545 | 1.2466 | 12 | 15 | 15 | 14 |
| 1301 | Rheumatoid, other arthritis M>36.35 | 1.2253 | 0.9248 | 0.8323 | 0.7983 | 10 | 10 | 10 | 9 |
| 1302 | Rheumatoid, other arthritis M>26.15 and M<36.35 | 1.6852 | 1.2720 | 1.1447 | 1.0980 | 16 | 14 | 12 | 13 |
| 1303 | Rheumatoid, other arthritis M<26.15 | 2.1972 | 1.6584 | 1.4925 | 1.4315 | 18 | 18 | 16 | 16 |
| 1401 | Cardiac M>48.85 | 0.9289 | 0.7480 | 0.6832 | 0.6204 | 10 | 8 | 8 | 8 |
| 1402 | Cardiac M>38.55 and M<48.85 | 1.2231 | 0.9849 | 0.8997 | 0.8169 | 12 | 11 | 10 | 10 |
| 1403 | Cardiac M>31.15 and M<38.55 | 1.4635 | 1.1785 | 1.0764 | 0.9774 | 13 | 13 | 12 | 11 |
| 1404 | Cardiac M<31.15 | 1.8540 | 1.4929 | 1.3637 | 1.2382 | 17 | 16 | 15 | 14 |
| 1501 | Pulmonary M>49.25 | 1.0171 | 0.8497 | 0.7768 | 0.7449 | 10 | 9 | 9 | 8 |
| 1502 | Pulmonary M>39.05 and M<49.25 | 1.3119 | 1.0959 | 1.0020 | 0.9607 | 11 | 12 | 11 | 10 |
| 1503 | Pulmonary M>29.15 and M<39.05 | 1.5971 | 1.3341 | 1.2197 | 1.1696 | 14 | 14 | 12 | 12 |
| 1504 | Pulmonary M<29.15 | 1.9783 | 1.6526 | 1.5109 | 1.4487 | 20 | 16 | 15 | 14 |
| 1601 | Pain syndrome M>37.15 | 1.1488 | 0.9072 | 0.8293 | 0.7609 | 10 | 11 | 10 | 9 |
| 1602 | Pain syndrome M>26.75 and M<37.15 | 1.5294 | 1.2078 | 1.1040 | 1.0130 | 12 | 14 | 13 | 12 |
| 1603 | Pain syndrome M<26.75 | 1.9062 | 1.5054 | 1.3759 | 1.2625 | 14 | 16 | 15 | 14 |
| 1701 | Major multiple trauma without brain or spinal cord injury M>39.25. | 1.1972 | 0.9344 | 0.8406 | 0.7717 | 10 | 10 | 10 | 9 |
| 1702 | Major multiple trauma without brain or spinal cord injury M>31.05 and M<39.25. | 1.5294 | 1.1936 | 1.0739 | 0.9858 | 14 | 14 | 12 | 12 |
| 1703 | Major multiple trauma without brain or spinal cord injury M>25.55 and M<31.05. | 1.8066 | 1.4100 | 1.2686 | 1.1645 | 17 | 15 | 14 | 14 |
| 1704 | Major multiple trauma without brain or spinal cord injury M<25.55. | 2.2842 | 1.7827 | 1.6039 | 1.4723 | 21 | 19 | 17 | 17 |
| 1801 | Major multiple trauma with brain or spinal cord injury M>40.85. | 1.2772 | 0.9992 | 0.8861 | 0.8123 | 12 | 11 | 10 | 10 |
| 1802 | Major multiple trauma with brain or spinal cord injury M>23.05 and M<40.85. | 1.8275 | 1.4298 | 1.2679 | 1.1624 | 17 | 16 | 14 | 14 |
| 1803 | Major multiple trauma with brain or spinal cord injury M<23.05. | 2.8872 | 2.2589 | 2.0031 | 1.8364 | 33 | 26 | 21 | 20 |
| 1901 | Guillian Barre M>35.95 | 1.2930 | 1.0758 | 0.9919 | 0.9474 | 13 | 12 | 12 | 11 |
| 1902 | Guillian Barre M>18.05 and M<35.95 | 2.2297 | 1.8550 | 1.7103 | 1.6336 | 23 | 20 | 21 | 18 |
| 1903 | Guillian Barre M<18.05 | 3.7343 | 3.1069 | 2.8646 | 2.7361 | 41 | 32 | 28 | 30 |
| 2001 | Miscellaneous M>49.15 | 0.9444 | 0.7644 | 0.6979 | 0.6338 | 9 | 9 | 8 | 8 |
| 2002 | Miscellaneous M>38.75 and M<49.15 | 1.2403 | 1.0039 | 0.9167 | 0.8325 | 11 | 11 | 10 | 10 |
| 2003 | Miscellaneous M>27.85 and M<38.75 | 1.5431 | 1.2490 | 1.1404 | 1.0357 | 14 | 14 | 13 | 12 |
| 2004 | Miscellaneous M<27.85 | 1.9716 | 1.5958 | 1.4571 | 1.3233 | 18 | 17 | 15 | 15 |
| 2101 | Burns M>0 | 1.8289 | 1.8238 | 1.3855 | 1.2884 | 29 | 17 | 15 | 14 |
| 5001 | Short-stay cases, length of stay is 3 days or fewer | | | | 0.1565 | | | | 2 |
| 5101 | Expired, orthopedic, length of stay is 13 days or fewer | | | | 0.6581 | | | | 7 |
| 5102 | Expired, orthopedic, length of stay is 14 days or more | | | | 1.6393 | | | | 18 |
| 5103 | Expired, not orthopedic, length of stay is 15 days or fewer | | | | 0.8132 | | | | 9 |
| 5104 | Expired, not orthopedic, length of stay is 16 days or more | | | | 2.0334 | | | | 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 revisions for FY 2018 would affect particular CMG relative weight values, which would affect the overall distribution of payments within CMGs and tiers. Note that, because we proposed to implement the CMG relative weight revisions in a budget-neutral manner (as previously described), total estimated aggregate payments to IRFs for FY 2018 would not be affected as a result of the CMG relative weight revisions. However, the revisions would affect the distribution of payments within CMGs and tiers.

TABLE 2—DISTRIBUTIONAL EFFECTS OF THE CHANGES TO THE CMG RELATIVE WEIGHTS

[FY 2017 values compared with FY 2018 values]

| Percentage change in CMG relative weights | Number of cases affected | Percentage of cases affected |
|---|---|---|
| Increased by 15% or more | 51 | 0.0 |
| Increased by between 5% and 15% | 1,802 | 0.5 |
| Changed by less than 5% | 397,273 | 99.% |
| Decreased by between 5% and 15% | 999 | 0.2 |
| Decreased by 15% or more | 0 | 0.0 |

As Table 2 shows, 99.3 percent of all IRF cases are in CMGs and tiers that would 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 2018. The largest estimated increase in the CMG relative weight values that affects the largest number of IRF discharges would be a 4.0 percent change in the CMG relative weight value for CMG 0603—Neurological, with a motor score greater than 25.85 and less than 37.35—in tier 1. In the FY 2016 claims data, 1,334 IRF discharges (0.3 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 would be a 3.6 percent decrease in the CMG relative weight for CMG 0506—Non-traumatic spinal cord injury, with a motor score less than 23.75—in tier 3. In the FY 2016 IRF claims data, this change would have affected 2,421 cases (0.6 percent of all IRF cases).

The proposed changes in the average length of stay values for FY 2018, compared with the FY 2017 average length of stay values, are small and do not show any particular trends in IRF length of stay patterns.

We received 3 comments on the proposed update to the CMG relative weights and average length of stay values for FY 2018, which are summarized below.

*Comment:* The commenters were supportive of our proposal to use the most recent data available to update the relative weights and average length of stays values for FY 2018. The commenters encouraged CMS to assess costs within CMGs and requested that CMS make available a report or analysis that is performed to update the relative weights as well as provide cost data related to comorbidities. Additionally, a commenter requested that we outline the methodology used to calculate the average length of stay values in the FY 2018 IRF PPS proposed rule.

*Response:* We appreciate the commenters' support of our proposal to use the most recent data available to update the relative weights and average length of stays values for FY 2018. We note that we are conducting ongoing evaluation of costs across CMGs and those related to comorbidities and will take the commenter's request for a report or analysis into consideration when developing future updates to the CMG relative weights. As we most recently discussed in the FY 2017 IRF PPS final rule (81 FR 52071), the methodology for calculating the average length of stay values is available for download from the IRF PPS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Research.html.*

*Final Decision:* After consideration of the public comments, we are finalizing our proposal to update the CMG relative weight and average length of stay values for FY 2018, as shown in Table 1 of this final rule. These updates are effective October 1, 2017.

## V. Facility-Level Adjustment Factors

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. Under this authority, we currently adjust the 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).

Based on the substantive changes to the facility-level adjustment factors that were adopted in the FY IRF PPS 2014 final rule (78 FR 47860, 47868 through 47872), in the FY 2015 IRF PPS final rule (79 FR 45872, 45882 through 45883), we froze the facility-level adjustment factors at the 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). For FY 2018, we will continue to hold the adjustment factors at the FY 2014 levels as we continue to monitor the most current IRF claims data available and continue to evaluate and monitor the effects of the FY 2014 changes.

## VI. FY 2018 IRF PPS Payment Update

### *A. Background*

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 IRF PPS payment, 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 prospective payment rates for each FY. Section 1886(j)(3)(C)(ii)(I) of the Act requires the application of a productivity adjustment. In addition, sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(v) of the Act require the application of a 0.75 percentage point reduction to the market basket increase factor for FY 2018. However, section 411(b) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) amended section 1886(j)(3)(C) of the Act by adding clause (iii), which provides that the increase factor for fiscal year 2018, after the application of the productivity adjustment and other adjustment, must be 1.0 percent. In accordance with section 1886(j)(3)(C)(iii) of the Act, we are applying an increase factor of 1.0 percent to update the IRF prospective payment rates for FY 2018 in this final rule.

For FY 2015, IRF PPS payments were updated using the 2008-based RPL market basket. Beginning with the FY 2016 IRF PPS, we created and adopted a stand-alone IRF market basket, which was referred to as the 2012-based IRF market basket, reflecting the operating and capital cost structures for freestanding IRFs and hospital-based IRFs. The general structure of the 2012-based IRF market basket is similar to the 2008-based RPL market basket; however, we made several notable changes. In developing the 2012-based IRF market basket, we derived cost weights from Medicare cost report data for both freestanding and hospital-based IRFs (the 2008-based RPL market basket was based on freestanding data only), incorporated the 2007 Input-Output data from the Bureau of Economic Analysis (the 2008-based RPL market basket was based on the 2002 Input-Output data); used new price proxy blends for two cost categories (Fuel, Oil, and Gasoline and Medical Instruments); added one additional cost category (Installation, Maintenance, and Repair), which was previously included in the residual All Other Services: Labor-Related cost category of the 2008-based RPL market basket; and eliminated three cost categories (Apparel, Machinery & Equipment, and Postage). The FY 2016 IRF PPS final rule (80 FR 47046 through 47068) contains a complete discussion of the development of the 2012-based IRF market basket.

### *B. FY 2018 Market Basket Update and Productivity Adjustment*

As previously noted, in accordance with section 1886(j)(3)(C)(iii) of the Act, as added by section 411(b) of MACRA, we are applying an increase factor of 1.0 percent to update the IRF prospective payment rates for FY 2018 in this final rule. For comparison purposes, we are providing a current estimate of what the proposed IRF increase factor would have been for FY 2018 prior to the enactment of section 411(b) of MACRA.

This estimate is based on the same methodology described in the FY 2017 IRF PPS final rule (81 FR 52071) and IHS Global Inc.'s (IGI) second quarter

2017 forecast of the market basket update and MFP adjustment with historical data through the first quarter 2017. IGI is a nationally recognized economic and financial forecasting firm with which CMS contracts to forecast the components of the market baskets and MFP.

Using this methodology, the FY 2018 payment increase factor would be 1.25 percent (based on IGI's second quarter 2017 forecast with historical data through the first quarter of 2017), reflecting a FY 2018 estimated market basket update of 2.6 percent as required by section 1886(j)(3)(C) of the Act, with an estimated productivity adjustment of 0.6 percentage point as required by section 1886(j)(3)(C)(ii)(I) of the Act, and a 0.75 percentage point reduction as required by sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(v) of the Act. However, section 411(b) of MACRA amended section 1886(j)(3)(C) of the Act by adding clause (iii), which provides that the increase factor for fiscal year 2018, after the application of the productivity adjustment and other adjustment, must be 1.0 percent.

For FY 2018, the Medicare Payment Advisory Commission (MedPAC) recommends that we reduce IRF PPS payment rates by 5 percent. As discussed, and in accordance with sections 1886(j)(3)(C) and 1886(j)(3)(D) of the Act, as amended by MACRA, the Secretary will update the IRF PPS payment rates for FY 2018 by 1.0 percent, as section 1886(j)(3)(C)(iii) of the Act does not provide the Secretary with the authority to apply a different update factor to IRF PPS payment rates for FY 2018.

We received eight public comments on the proposed payment update and productivity adjustment, which are summarized below.

*Comment:* Several commenters generally supported the proposed payment update for FY 2018.

*Response:* We appreciate the commenters' support for the proposed payment update for FY 2018.

*Comment:* A few commenters stated that the payment update does not keep up with inflationary costs in healthcare or the effects of the sequestration, and is therefore effectively a reduction in payments. As a result, the commenters expressed concern that their hospitals' financial viability and their ability to care for their patients will be threatened.

*Response:* As discussed, and in accordance with section 1886(j)(3)(C)(iii) of the Act, as added by section 411(b) of MACRA, we are applying an increase factor of 1.0 percent to update the IRF prospective payment rates for FY 2018 in this final rule. Section 1886(j)(3)(C)(iii) of the Act does not provide the Secretary with the authority to apply a different update factor to IRF PPS payment rates for FY 2018.

*Comment:* Several commenters expressed concerns regarding the applicability of the PPACA-mandated MFP to the IRF setting. Commenters stated their belief that the theory underlying the productivity adjustment is that Medicare providers should be able to achieve the same level of productivity improvement as workers across the U.S. economy since the MFP adjustment is applied using a measure based on the total private nonfarm business sector rather than the rehabilitation sector. However, several commenters claimed that it is unlikely, given that IRF services are so labor-intensive, that productivity improvements will be generated by the rehabilitation hospital industry at a pace matching the productivity of the economy at large on an ongoing, consistent basis as currently contemplated by the PPACA.

Several commenters noted that general economic growth could lead to larger productivity adjustments that may not be correlated to gains in the IRF sector. One commenter noted that the requirements applicable to IRFs (for example, the intensity of therapy requirements, pre-admission screening requirements, and medical director coverage requirements) also make it difficult for the IRF industry to achieve significant productivity gains. Commenters generally expressed concerns that, while other medical fields may benefit from improved technology that yields increased productivity, rehabilitation, by its nature and by virtue of the requirements applicable to it, cannot advance productivity through technology or other means in the same way other medical fields can. Additionally, commenters expressed concerns that if the economy grows at a faster rate and IRFs' costs related to the IRF QRP increase, the productivity adjustments will likely also become more pronounced.

Finally, these commenters respectfully requested that we carefully monitor the impact these productivity adjustments have on the rehabilitation hospital sector, provide feedback to Congress as appropriate, and utilize any authority the agency has to reduce the productivity adjustment.

*Response:* We acknowledge the commenters' concerns regarding MFP growth at the economy-wide level and its application to IRFs. As stated above, section 1886(j)(3)(C)(ii)(I) of the Act requires the application of a productivity adjustment to the IRF PPS market basket increase factor. Under section 1886(j)(3)(C)(ii)(I) of the Act, the productivity adjustment is required to be equal to the 10-year moving average changes in annual economy-wide private nonfarm business MFP (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period).

However, as stated above, in accordance with section 1886(j)(3)(C)(iii) of the Act, as added by section 411(b) of MACRA, the increase factor for FY 2018, after the application of the productivity adjustment and other adjustment, must be 1.0 percent. Section 1886(j)(3)(C)(iii) of the Act does not provide the Secretary with the authority to apply a different update factor to IRF PPS payment rates for FY 2018. We will continue to monitor the impact of the payment updates, including the effects of the productivity adjustment, on IRFs as well as beneficiary access to care.

*Comment:* One commenter (MedPAC) stated that they understand CMS is required to implement the statutory update; however, the commenter noted that after reviewing many factors, they determined that Medicare's current payment rates for IRFs appear to be more than adequate and therefore recommended that the Congress reduce the IRF payment rate by 5 percent for FY 2018. The commenter appreciated that CMS cited its recommendation even while noting that the Secretary does not have the authority to deviate from statutorily mandated updates.

*Response:* As discussed, in accordance with section 1886(j)(3)(C)(iii) of the Act, as added by section 411(b) of MACRA, the increase factor for FY 2018, after the application of the productivity adjustment and other adjustment, must be 1.0 percent. Section 1886(j)(3)(C)(iii) of the Act does not provide the Secretary with the authority to apply a different update factor to IRF PPS payment rates for FY 2018.

*Final Decision:* Based on careful consideration of the comments, we are finalizing the FY 2018 payment update for IRF payments of 1.0 percent, as required by section 1886(j)(3)(C)(iii) of the Act, as added by section 411(b) of MACRA.

*C. Labor-Related Share for FY 2018*

Section 1886(j)(6) of the Act specifies that the Secretary is to adjust the proportion (as estimated by the Secretary from time to time) of rehabilitation facilities' costs which are attributable to wages and wage-related

costs of the prospective payment rates computed under section 1886(j)(3) for area differences in wage levels 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 such facilities. The labor-related share is determined by identifying the national average proportion of total costs that are related to, influenced by, or vary with the local labor market. We continue to classify a cost category as labor-related if the costs are labor-intensive and vary with the local labor market.

Based on our definition of the labor-related share and the cost categories in the 2012-based IRF market basket, we proposed to calculate the labor-related share for FY 2018 as the sum of the FY 2018 relative importance of Wages and Salaries, Employee Benefits, Professional Fees: Labor-Related, Administrative and Facilities Support Services, Installation, Maintenance, and Repair Services, All Other: Labor-related Services, and a portion of the Capital-Related cost weight from the 2012-based IRF market basket. For more details regarding the methodology for determining specific cost categories for inclusion in the 2012-based IRF labor-related share, see the FY 2016 IRF final rule (80 FR 47066 through 47068).

Using this method and IGI's first quarter 2017 forecast for the 2012-based IRF market basket, the proposed IRF labor-related share for FY 2018 was 70.7 percent. We proposed that if more recent data were subsequently available, we would use such data to determine the FY 2018 IRF labor-related share in the final rule.

Incorporating the most recent estimate of the 2012-based IRF market basket based on IGI's second quarter 2017 forecast with historical data through the first quarter of 2017, the sum of the relative importance for FY 2018 operating costs (Wages and Salaries, Employee Benefits, Professional Fees: Labor-related, Administrative and Facilities Support Services, Installation Maintenance & Repair Services, and All Other: Labor-related Services) using the 2012-based IRF market basket is 66.9 percent. We proposed that the portion of Capital-Related Costs that is influenced by the local labor market is estimated to be 46 percent. Incorporating the most recent estimate of the FY 2018 relative importance of Capital-Related costs from the 2012-based IRF market basket based on IGI's second quarter 2017 forecast with historical data through the first quarter of 2017, which is 8.3 percent, we take 46 percent of 8.3 percent to determine the labor-related share of Capital for FY 2018. As we proposed, we then add this amount (3.8 percent) to the sum of the relative importance for FY 2018 operating costs (66.9 percent) to determine the total labor-related share for FY 2018 of 70.7 percent.

TABLE 3—IRF LABOR-RELATED SHARE

| | FY 2018 Final labor-related share [1] | FY 2017 Final labor related share [2] |
|---|---|---|
| Wages and Salaries | 47.8 | 47.7 |
| Employee Benefits | 11.2 | 11.3 |
| Professional Fees: Labor-related | 3.4 | 3.5 |
| Administrative and Facilities Support Services | 0.8 | 0.8 |
| Installation, Maintenance, and Repair Services | 1.9 | 1.9 |
| All Other: Labor-related Services | 1.8 | 1.8 |
| Subtotal | 66.9 | 67.0 |
| Labor-related portion of capital (46%) | 3.8 | 3.9 |
| Total Labor-Related Share | 70.7 | 70.9 |

[1] Based on the 2012-based IRF Market Basket, IHS Global Inc. 2nd quarter 2017 forecast with historical data through the first quarter of 2017.
[2] **Federal Register** (81 FR 52073).

*Final Decision:* We did not receive any public comments on the proposed labor-related share for FY 2018. We are finalizing the FY 2018 labor-related share of 70.7 percent as proposed.

*D. Wage Adjustment*

1. Background

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 2018, we proposed to maintain the policies and methodologies described in the FY 2017 IRF PPS final rule (81 FR 52055, 52073 through 52074) related to the labor market area definitions and the wage index methodology for areas with wage data. Thus, we proposed to use the CBSA labor market area definitions and the FY 2017 pre-reclassification and pre-floor hospital wage index data. In accordance with section 1886(d)(3)(E) of the Act, the FY 2017 pre-reclassification and pre-floor hospital wage index is based on data submitted for hospital cost reporting periods beginning on or after October 1, 2012, and before October 1, 2013 (that is, FY 2013 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 proposed to 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 2018 IRF PPS wage index.

We received 4 public comments on these proposals, which are summarized below.

*Comment:* Commenters suggested that we should use the FY 2018 IPPS pre-reclassified acute care hospital wage index in the calculation of the FY 2018

IRF PPS wage index, as other post-acute and acute care settings do, rather than using the FY 2017 IPPS pre-reclassified acute care hospital wage index, as we do in the IRF PPS. Commenters indicated that using the same wage index data for the IRF PPS that is used in other post-acute care settings would eliminate one difference between Medicare payments for IRFs and Medicare payments for other post-acute care providers, thereby allowing IRFs to demonstrate their cost-effectiveness relative to other competing post-acute care service providers in the alternative payment models.

*Response:* Consistent with historical practice, we proposed to update the IRF wage index for FY 2018 using the FY 2017 pre-reclassification acute care hospital wage index (that is, using a one-year lag of the hospital wage index). At the point we use these data for the IRF wage index, these values are more stable and do not tend to change. The FY 2017 pre-reclassification and pre-floor hospital wage index values are based on data collected from the Medicare cost reports submitted by hospitals for cost reporting periods beginning in FY 2013. We believe that data from the FY 2013 cost reporting periods are appropriate to determine the applicable wage index values under the IRF PPS in this final rule as they are the most recent final data available.

*Comment:* One commenter requested that, until a new wage index system is implemented, we should institute a smoothing variable to be applied to the current IRF wage index to reduce the fluctuations IRFs experience annually.

*Response:* As stated above, under section 1886(j)(6) of the Act, we adjust IRF PPS rates to account for differences in area wage levels. Any perceived volatility in the wage index is predicated upon volatility in actual wages in that area and reflects real differences in area wage levels. As we believe that the application of a smoothing variable would make the wage index values less reflective of the area wage levels, it would not be appropriate to implement such a change to the IRF wage index policy.

As we most recently discussed in the FY 2017 IRF PPS final rule (81 FR 52075), section 3137(b) of the PPACA required us to submit a report to the Congress by December 31, 2011 that included a plan to reform the hospital wage index system. This report describes the concept of a Commuting Based Wage Index as a potential replacement to the current Medicare wage index methodology. While this report addresses the goals of broad based Medicare wage index reform, no consensus has been achieved regarding how best to implement a replacement system. This concern will be taken into consideration while we continue to explore potential wage index reforms. The report that we submitted is available online at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Reform.html.*

*Final Decision:* After careful consideration of the comments, we are finalizing our proposal to use the CBSA labor market area definitions and the FY 2017 pre-reclassification and pre-floor hospital wage index data for areas with wage data. We are also finalizing our proposal to 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.

2. Update

The wage index used for the IRF PPS is calculated using the pre-reclassification and pre-floor acute care hospital wage index data and is assigned to the IRF on the basis of the labor market area in which the IRF is geographically located. IRF labor market areas are delineated based on the CBSAs established by the OMB. In the FY 2016 IRF PPS final rule (80 FR 47036, 47068), we established an IRF wage index based on FY 2011 acute care hospital wage data to adjust the FY 2016 IRF payment rates. We also adopted the revised CBSAs set forth by OMB. The current CBSA delineations (which were implemented for the IRF PPS beginning with FY 2016) are based on revised OMB delineations issued on February 28, 2013, in OMB Bulletin No. 13–01. OMB Bulletin No. 13–01 established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas in the United States and Puerto Rico, and provided guidance on the use of the delineations of these statistical areas based on new standards published on June 28, 2010, in the **Federal Register** (75 FR 37246 through 37252). A copy of this bulletin may be obtained at *https://obamawhitehouse.archives.gov/sites/default/files/omb/bulletins/2013/b13-01.pdf.*

Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. However, OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses. On July 15, 2015, OMB issued OMB Bulletin No. 15–01, which provides minor updates to and supersedes OMB Bulletin No. 13–01 that was issued on February 28, 2013. The attachment to OMB Bulletin No. 15–01 provides detailed information on the update to statistical areas since February 28, 2013. The updates provided in OMB Bulletin No. 15–01 are based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2012 and July 1, 2013. The complete list of statistical areas incorporating these changes is provided in OMB Bulletin No. 15–01. A copy of this bulletin may be obtained at *https://obamawhitehouse.archives.gov/sites/default/files/omb/bulletins/2015/15-01.pdf.*

According to OMB, the bulletin establishes revised delineations for the Nation's Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas. The bulletin also provides delineations of Metropolitan Divisions as well as delineations of New England City and Town Areas. OMB Bulletin No. 15–01 made the following changes that are relevant to the IRF wage index:

- Garfield County, OK, with principal city Enid, OK, which was a Micropolitan (geographically rural) area, now qualifies as an urban new CBSA 21420 called Enid, OK.
- The county of Bedford City, VA, a component of the Lynchburg, VA CBSA 31340, changed to town status and is added to Bedford County. Therefore, the county of Bedford City (SSA State county code 49088, FIPS State County Code 51515) is now part of the county of Bedford, VA (SSA State county code 49090, FIPS State County Code 51019). However, the CBSA remains Lynchburg, VA, 31340.
- The name of Macon, GA, CBSA 31420, as well as a principal city of the Macon-Warner Robins, GA combined statistical area, is now Macon-Bibb County, GA. The CBSA code remains as 31420.

We believe that it is important for the IRF PPS to use the latest labor market area delineations available as soon as is reasonably possible to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions. As discussed in the FY 2017 Inpatient prospective payment system (IPPS) and Long-Term Care Hospital (LTCH) PPS final rule (81 FR 56913), these updated labor market area definitions were implemented under the IPPS beginning on October 1, 2016. Therefore, we proposed to implement these revisions for the IRF PPS beginning October 1,

2017, consistent with our historical practice of modeling IRF PPS adoption of the labor market area delineations after IPPS adoption of these delineations.

We did not receive any comments on our proposal to adopt the revised OMB delineations.

*Final Decision:* As we did not receive any comments on our proposal to adopt the new OMB delineations, we are finalizing the implementation of the revised OMB delineations as described in the July 15, 2015 OMB Bulletin No. 15–01, effective beginning October 1, 2017 with the FY 2018 IRF PPS wage index.

3. Transition Period

In FY 2016, we applied a transition period when implementing the OMB delineations as described in the February 28, 2013 OMB Bulletin No. 13–01, as this bulletin contained a number of significant changes that resulted in substantial payment implications for some IRF providers. We proposed to incorporate the CBSA changes published in the most recent OMB bulletin without a transition period as we anticipate that these changes will have minor effects for a single IRF provider. One provider, located in Garfield County, OK and designated as rural in FY 2017, will be designated as urban in FY 2018. While this provider will no longer have the 14.9 percent rural adjustment in FY 2018, this provider will experience an increase of 13 percent in their wage index value. As this provider is not expected to experience as steep of a reduction in payments as the majority of facilities for which a phase out of the rural adjustment was implemented, we do not believe it is appropriate or necessary to adopt a transition policy. As the changes made in OMB Bulletin No 15–01 are minor and do not have a large effect on a substantial number of providers, we did not propose a transition period to adopt these updates.

In FY 2016, we applied a 1-year blended wage index for all IRF providers to mitigate the impact of the wage index change due to the implementation of the revised CBSA delineations. In FY 2016, all IRF providers received a blended wage index using 50 percent of their FY 2016 wage index based on the revised OMB CBSA delineations and 50 percent of their FY 2016 wage index based on the OMB delineations used in FY 2015. This 1-year blended wage index became effective on October 1, 2015 and expired on September 30, 2016.

For FY 2016, in addition to the blended wage index, we also adopted a three-year budget neutral phase out of the rural adjustment for FY 2015 rural IRFs that became urban in FY 2016 under the revised CBSA delineations. In FY 2016, IRFs that were designated as rural in FY 2015 and became designated as urban in FY 2016 received two-thirds of the 2015 rural adjustment of 14.9 percent. In FY 2017, the second year of the 3-year phase out, these IRFs received one-third of the 2015 rural adjustment of 14.9 percent, as finalized in the FY 2017 IRF PPS final rule (81 FR 52055, 52074 through 52076). FY 2018 represents the third and final year of the three-year phase out of the rural adjustment. We will no longer apply any portion of the rural adjustment for IRFs that became urban in FY 2016 under the revised CBSA delineations, as finalized in the FY 2016 IRF PPS final rule (80 FR 47036, 47073 through 47074). We did not propose any additional wage index transition adjustments for IRF providers due to the adoption of the new OMB delineations in FY 2016. We refer readers to the FY 2016 IRF PPS final rule (80 FR 47036, 47068 through 47076) for a full discussion of our implementation of the new OMB labor market area delineations for the FY 2016 wage index. The wage index applicable to FY 2018 is available on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Data-Files.html.* Table A is for urban areas, and Table B is for rural areas.

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 2018 labor-related share based on the 2012-based IRF market basket (70.7 percent) to determine the labor-related portion of the standard payment amount. A full discussion of the calculation of the labor-related share is located in section VI.C of this final rule. 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.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Data-Files.html.*

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 proposed to 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 proposed to use the listed steps to ensure that the FY 2018 IRF standard payment conversion factor reflects the update to the wage indexes (based on the FY 2013 hospital cost report data) and the labor-related share in a budget-neutral manner:

*Step 1.* Determine the total amount of the estimated FY 2017 IRF PPS payments, using the FY 2017 standard payment conversion factor and the labor-related share and the wage indexes from FY 2017 (as published in the FY 2017 IRF PPS final rule (81 FR 52056)).

*Step 2.* Calculate the total amount of estimated IRF PPS payments using the FY 2018 standard payment conversion factor and the FY 2018 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 2018 budget-neutral wage adjustment factor of 1.0007.

*Step 4.* Apply the FY 2018 budget-neutral wage adjustment factor from step 3 to the FY 2017 IRF PPS standard payment conversion factor after the application of the increase factor to determine the FY 2018 standard payment conversion factor.

We discuss the calculation of the standard payment conversion factor for FY 2018 in section VI.E of this final rule.

We invited public comment on the proposed IRF wage adjustment for FY 2018. We did not receive any comments on the proposed IRF wage adjustment for FY 2018.

*Final Decision:* As we did not receive any comments on the proposed IRF wage adjustment for FY 2018, we are finalizing a budget-neutral wage adjustment factor of 1.0007 for FY 2018.

*E. Description of the IRF Standard Payment Conversion Factor and Payment Rates for FY 2018*

To calculate the standard payment conversion factor for FY 2018, as illustrated in Table 4, we begin by applying the increase factor for FY 2018, as adjusted in accordance with sections 1886(j)(3)(C)(iii) of the Act, as added by MACRA, to the standard payment conversion factor for FY 2017 ($15,708). Applying the 1.0 percent increase factor for FY 2018 to the standard payment conversion factor for FY 2017 of $15,708 yields a standard payment amount of $15,865. Then, we apply the budget neutrality factor for the FY 2018 wage index and labor-related share of 1.0007, which results in a standard payment amount of $15,876. We next apply the budget neutrality factor for the revised CMG relative weights of 0.9976, which

results in the standard payment conversion factor of $15,838 for FY 2018.

TABLE 4—CALCULATIONS TO DETERMINE THE FY 2018 STANDARD PAYMENT CONVERSION FACTOR

| Explanation for adjustment | Calculations |
|---|---|
| Standard Payment Conversion Factor for FY 2017 | $15,708 |
| Market Basket Increase Factor for FY 2018 (1.0 percent), as required by section 1886(j)(3)(C)(iii) of the Act | × 1.0100 |
| Budget Neutrality Factor for the Wage Index and Labor-Related Share | × 1.0007 |
| Budget Neutrality Factor for the Revisions to the CMG Relative Weights | × 0.9976 |
| FY 2018 Standard Payment Conversion Factor | = $15,838 |

We received four comments on the proposed FY 2018 standard payment conversion factor.

*Comment:* The commenters noted that the FY 2018 standard payment conversion factor does not include any additional payment to IRFs for the time and resources needed to complete assessments for quality reporting.

*Response:* Section 1886(j)(3) of the Act does not provide the Secretary with the authority to adjust payments to reflect increases in costs due to quality reporting requirements. We will continue to monitor the impact of the FY 2018 payment updates and quality reporting requirements on IRF providers.

*Final Decision:* After careful consideration of the comments we received, we are finalizing the IRF standard payment conversion factor of $15,838 for FY 2018.

After the application of the CMG relative weights described in section IV of this final rule to the FY 2018 standard payment conversion factor ($15,838), the resulting unadjusted IRF prospective payment rates for FY 2018 are shown in Table 5.

TABLE 5—FY 2018 PAYMENT RATES

| CMG | Payment rate tier 1 | Payment rate tier 2 | Payment rate tier 3 | Payment rate no comorbidity |
|---|---|---|---|---|
| 0101 | $13,470.22 | $11,544.32 | $10,665.31 | $10,191.75 |
| 0102 | 16,914.98 | 14,494.94 | 13,391.03 | 12,797.10 |
| 0103 | 19,125.97 | 16,390.75 | 15,141.13 | 14,469.60 |
| 0104 | 20,516.55 | 17,583.35 | 16,243.45 | 15,521.24 |
| 0105 | 23,872.62 | 20,459.53 | 18,899.49 | 18,061.66 |
| 0106 | 26,441.54 | 22,659.43 | 20,933.08 | 20,003.39 |
| 0107 | 29,522.03 | 25,301.21 | 23,373.72 | 22,336.33 |
| 0108 | 37,518.64 | 32,152.72 | 29,702.59 | 28,384.86 |
| 0109 | 33,850.56 | 29,010.46 | 26,799.48 | 25,610.05 |
| 0110 | 44,135.75 | 37,824.31 | 34,943.38 | 33,391.26 |
| 0201 | 13,520.90 | 10,904.46 | 9,928.84 | 9,105.27 |
| 0202 | 17,333.11 | 13,980.20 | 12,729.00 | 11,671.02 |
| 0203 | 20,016.06 | 16,142.09 | 14,697.66 | 13,478.14 |
| 0204 | 21,987.90 | 17,733.81 | 16,146.84 | 14,805.36 |
| 0205 | 25,842.86 | 20,842.81 | 18,977.09 | 17,401.21 |
| 0206 | 31,186.61 | 25,152.33 | 22,901.75 | 20,999.60 |
| 0207 | 39,775.55 | 32,079.87 | 29,210.02 | 26,783.64 |
| 0301 | 18,384.75 | 14,927.32 | 13,579.50 | 12,833.53 |
| 0302 | 22,330.00 | 18,129.76 | 16,493.69 | 15,587.76 |
| 0303 | 26,235.65 | 21,302.11 | 19,379.38 | 18,313.48 |
| 0304 | 34,078.62 | 27,668.99 | 25,171.33 | 23,788.68 |
| 0401 | 14,279.54 | 13,424.29 | 11,987.78 | 10,836.36 |
| 0402 | 20,435.77 | 19,211.49 | 17,154.14 | 15,508.57 |
| 0403 | 33,161.60 | 31,173.94 | 27,836.87 | 25,165.00 |
| 0404 | 58,195.15 | 54,706.04 | 48,850.73 | 44,162.68 |
| 0405 | 53,793.77 | 50,569.15 | 45,157.31 | 40,824.03 |
| 0501 | 14,749.93 | 11,089.77 | 10,511.68 | 9,645.34 |
| 0502 | 19,309.69 | 14,518.69 | 13,761.64 | 12,627.64 |
| 0503 | 24,213.13 | 18,205.78 | 17,255.50 | 15,834.83 |
| 0504 | 27,497.94 | 20,674.93 | 19,596.36 | 17,982.47 |
| 0505 | 31,512.87 | 23,693.65 | 22,456.70 | 20,606.82 |
| 0506 | 43,632.11 | 32,806.83 | 31,093.16 | 28,532.16 |
| 0601 | 16,884.89 | 12,904.80 | 11,976.70 | 10,894.96 |
| 0602 | 22,049.66 | 16,851.63 | 15,641.61 | 14,228.86 |
| 0603 | 27,040.22 | 20,667.01 | 19,181.40 | 17,448.72 |
| 0604 | 35,180.95 | 26,888.17 | 24,955.94 | 22,702.19 |
| 0701 | 16,427.17 | 13,142.37 | 12,475.59 | 11,363.77 |
| 0702 | 20,855.48 | 16,683.75 | 15,839.58 | 14,426.83 |
| 0703 | 25,187.17 | 20,149.10 | 19,129.14 | 17,423.38 |
| 0704 | 31,929.41 | 25,543.53 | 24,249.56 | 22,087.67 |
| 0801 | 13,794.90 | 10,164.83 | 9,681.77 | 8,938.97 |
| 0802 | 17,733.81 | 13,064.77 | 12,445.50 | 11,490.47 |
| 0803 | 22,988.86 | 16,937.16 | 16,134.17 | 14,897.22 |
| 0804 | 21,131.06 | 15,568.75 | 14,829.12 | 13,691.95 |

TABLE 5—FY 2018 PAYMENT RATES—Continued

| CMG | Payment rate tier 1 | Payment rate tier 2 | Payment rate tier 3 | Payment rate no comorbidity |
|---|---|---|---|---|
| 0805 | 25,057.30 | 18,462.36 | 17,584.93 | 16,237.12 |
| 0806 | 30,344.02 | 22,356.92 | 21,294.19 | 19,662.88 |
| 0901 | 15,921.94 | 12,793.94 | 11,474.63 | 10,668.48 |
| 0902 | 20,936.25 | 16,821.54 | 15,087.28 | 14,029.30 |
| 0903 | 25,693.99 | 20,644.83 | 18,516.21 | 17,215.91 |
| 0904 | 32,181.23 | 25,858.70 | 23,191.58 | 21,563.44 |
| 1001 | 16,568.13 | 14,289.04 | 12,570.62 | 11,474.63 |
| 1002 | 21,751.91 | 18,758.53 | 16,504.78 | 15,065.11 |
| 1003 | 31,858.14 | 27,475.76 | 24,171.96 | 22,063.92 |
| 1101 | 20,842.81 | 18,595.40 | 16,081.91 | 13,801.23 |
| 1102 | 30,174.56 | 26,921.43 | 23,283.44 | 19,979.64 |
| 1201 | 19,474.40 | 14,632.73 | 13,663.44 | 12,573.79 |
| 1202 | 25,035.13 | 18,810.79 | 17,564.34 | 16,164.26 |
| 1203 | 30,576.84 | 22,974.60 | 21,452.57 | 19,743.65 |
| 1301 | 19,406.30 | 14,646.98 | 13,181.97 | 12,643.48 |
| 1302 | 26,690.20 | 20,145.94 | 18,129.76 | 17,390.12 |
| 1303 | 34,799.25 | 26,265.74 | 23,638.22 | 22,672.10 |
| 1401 | 14,711.92 | 11,846.82 | 10,820.52 | 9,825.90 |
| 1402 | 19,371.46 | 15,598.85 | 14,249.45 | 12,938.06 |
| 1403 | 23,178.91 | 18,665.08 | 17,048.02 | 15,480.06 |
| 1404 | 29,363.65 | 23,644.55 | 21,598.28 | 19,610.61 |
| 1501 | 16,108.83 | 13,457.55 | 12,302.96 | 11,797.73 |
| 1502 | 20,777.87 | 17,356.86 | 15,869.68 | 15,215.57 |
| 1503 | 25,294.87 | 21,129.48 | 19,317.61 | 18,524.12 |
| 1504 | 31,332.32 | 26,173.88 | 23,929.63 | 22,944.51 |
| 1601 | 18,194.69 | 14,368.23 | 13,134.45 | 12,051.13 |
| 1602 | 24,222.64 | 19,129.14 | 17,485.15 | 16,043.89 |
| 1603 | 30,190.40 | 23,842.53 | 21,791.50 | 19,995.48 |
| 1701 | 18,961.25 | 14,799.03 | 13,313.42 | 12,222.18 |
| 1702 | 24,222.64 | 18,904.24 | 17,008.43 | 15,613.10 |
| 1703 | 28,612.93 | 22,331.58 | 20,092.09 | 18,443.35 |
| 1704 | 36,177.16 | 28,234.40 | 25,402.57 | 23,318.29 |
| 1801 | 20,228.29 | 15,825.33 | 14,034.05 | 12,865.21 |
| 1802 | 28,943.95 | 22,645.17 | 20,081.00 | 18,410.09 |
| 1803 | 45,727.47 | 35,776.46 | 31,725.10 | 29,084.90 |
| 1901 | 20,478.53 | 17,038.52 | 15,709.71 | 15,004.92 |
| 1902 | 35,313.99 | 29,379.49 | 27,087.73 | 25,872.96 |
| 1903 | 59,143.84 | 49,207.08 | 45,369.53 | 43,334.35 |
| 2001 | 14,957.41 | 12,106.57 | 11,053.34 | 10,038.12 |
| 2002 | 19,643.87 | 15,899.77 | 14,518.69 | 13,185.14 |
| 2003 | 24,439.62 | 19,781.66 | 18,061.66 | 16,403.42 |
| 2004 | 31,226.20 | 25,274.28 | 23,077.55 | 20,958.43 |
| 2101 | 28,966.12 | 28,885.34 | 21,943.55 | 20,405.68 |
| 5001 | | | | 2,478.65 |
| 5101 | | | | 10,422.99 |
| 5102 | | | | 25,963.23 |
| 5103 | | | | 12,879.46 |
| 5104 | | | | 32,204.99 |

*F. Example of the Methodology for Adjusting the 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 prospective payment rate for CMG 0110 (without comorbidities) appears in Table 5.

*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 0.8167, 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 0.8859, and a teaching status adjustment of 0.0784.

To calculate each IRF's labor and non-labor portion of the prospective payment, we begin by taking the unadjusted prospective payment rate for CMG 0110 (without comorbidities) from Table 5. Then, we multiply the labor-related share for FY 2018 (70.7 percent) described in section VI.C. of this final rule by the unadjusted prospective payment rate. To determine the non-labor portion of the prospective payment rate, we subtract the labor portion of the federal payment from the unadjusted prospective payment.

To compute the wage-adjusted prospective payment, we multiply the labor portion of the federal payment by the appropriate wage index located in Tables A and B. These tables are available on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehab*

*FacPPS/Data-Files.html.* 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 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 prospective payment rates. Table 6 illustrates the components of the adjusted payment calculation.

TABLE 6—EXAMPLE OF COMPUTING THE FY 2018 IRF PROSPECTIVE PAYMENT

| Steps | Rural Facility A (Spencer Co., IN) | Urban Facility B (Harrison Co., IN) |
|---|---|---|
| 1. Unadjusted Payment | $33,391.26 | $33,391.26 |
| 2. Labor Share | × 0.707 | × 0.707 |
| 3. Labor Portion of Payment | = $23,607.62 | = $23,607.62 |
| 4. CBSA-Based Wage Index (shown in the Addendum, Tables A and B) | × 0.8167 | × 0.8859 |
| 5. Wage-Adjusted Amount | = $19,280.34 | = $20,913.99 |
| 6. Non-Labor Amount | + $9,783.64 | + $9,783.64 |
| 7. Wage-Adjusted Payment | = $29,063.98 | = $30,697.63 |
| 8. Rural Adjustment | × 1.149 | × 1.000 |
| 9. Wage- and Rural-Adjusted Payment | = $33,394.51 | = $30,697.63 |
| 10. LIP Adjustment | × 1.0156 | × 1.0454 |
| 11. Wage-, Rural- and LIP-Adjusted Payment | = $33,915.46 | = $32,091.30 |
| 12. Wage- and Rural-Adjusted Payment | $33,394.51 | $30,697.63 |
| 13. Teaching Status Adjustment | × 0 | × 0.0784 |
| 14. Teaching Status Adjustment Amount | = $0.00 | = $2,406.69 |
| 15. Wage-, Rural-, and LIP-Adjusted Payment | + $33,915.46 | + $32,091.30 |
| 16. Total Adjusted Payment | = $33,915.46 | = $34,497.99 |

Thus, the adjusted payment for Facility A would be $33,915.46, and the adjusted payment for Facility B would be $34,497.99.

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

### *A. Update to the Outlier Threshold Amount for FY 2018*

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 2017 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, 79 FR 45872, 80 FR 47036, 81 FR 52056, 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 2018, we proposed to use FY 2016 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 2017. Based on an analysis of the preliminary data used for the proposed rule, we estimated that IRF outlier payments as a percentage of total estimated payments would be approximately 3.0 percent in FY 2017. Therefore, we proposed to update the outlier threshold amount from $7,984 for FY 2017 to $8,656 for FY 2018 to maintain estimated outlier payments at approximately 3 percent of total estimated aggregate IRF payments for FY 2018.

We note that, as we typically do, we updated our data between the FY 2018 IRF PPS proposed and final rules to ensure that we use the most recent available data in calculating IRF PPS payments. This updated data includes a more complete set of claims for FY 2016. Based on our analysis using this updated data, we now estimate that IRF outlier payments as a percentage of total estimated payments are approximately 3.1 percent in FY 2017. In addition, we stated that we still need to adjust the IRF outlier threshold to reflect changes in estimated costs and payments for IRFs in FY 2018. That is, as discussed previously in this final rule, we are increasing IRF PPS payment rates by 1.0 percent, in accordance with section 1886(j)(3)(C)(iii) of the Act. Similarly,

IRF estimated costs for FY 2018 are expected to increase. Therefore, we will update the outlier threshold amount from $7,984 for FY 2017 to $8,679 for FY 2018 to account for the increases in IRF PPS payments and estimated costs and to maintain estimated outlier payments at approximately 3 percent of total estimated aggregate IRF payments for FY 2018.

We received 4 public comments on the proposed update to the FY 2018 outlier threshold amount to maintain estimated outlier payments at approximately 3 percent of total estimated IRF payments, which are summarized below.

*Comment:* Some commenters were supportive of maintaining estimated payments for outlier payments at approximately 3 percent and requested that CMS update the outlier threshold amount in the final rule using the latest available data. One commenter reiterated their recommendation to expand the outlier pool from 3 to 5 percent to redistribute payments within the IRF PPS and to reduce the impact of misalignments between IRF payments and costs. Specifically, the commenter suggested that expanding the outlier pool would help to ameliorate the financial burden on IRFs that have a relatively high share of costly cases. However, this same commenter noted that such an expansion in the outlier pool could inappropriately reward some facilities for inefficiencies. Another commenter suggested that CMS should lower the outlier pool below 3 percent.

*Response:* We agree that we should use the most recent data available to calculate the outlier threshold. Therefore, as previously stated, we updated the data used to calculate the outlier threshold between the FY 2018 IRF PPS proposed and final rule.

We refer readers to the 2002 IRF PPS final rule (66 FR 41316, 41362 through 41363), for a discussion of the 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. We continue to believe that the outlier policy of 3 percent of total estimated aggregate payments accomplishes this objective. Increasing the outlier pool would leave less money available to cover the costs of non-outlier cases, due to the fact that we would implement such a change in a budget-neutral manner. We believe that our current outlier policy, to set outlier payments at 3 percent of total estimated aggregate payments, is consistent with the statute and the goals of the IRF PPS.

*Comment:* Several commenters suggested that CMS should modify the methodology for determining the outlier threshold so that the full 3 percent outlier pool is paid out to providers, as they indicated that CMS has paid out less than the estimated 3 percent for each of the past several years. Some commenters suggested implementing a forecast error correction if the full amount of the outlier pool is not paid out.

*Response:* We appreciate the commenters' analyses and suggestions regarding the outlier threshold calculations. As previously noted, we updated our data between the FY 2018 IRF PPS proposed and final rules to ensure that we use the most recent available data in calculating IRF PPS payments. Based on our analysis using this updated data, we now estimate that IRF outlier payments as a percentage of total estimated aggregate payments are approximately 3.1 percent in FY 2017, thus indicating that we paid out more than 3 percent, not less, in this most recent fiscal year.

We will continue to monitor our IRF outlier policies to ensure that they continue to compensate IRFs appropriately for treating unusually high-cost patients and do not limit access to care for patients who are likely to require unusually high-cost care. As we most recently noted in the FY 2017 IRF PPS final rule (81 FR 52079), 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 to help ensure that estimated outlier payments for that fiscal year will equal 3 percent of total estimated IRF PPS payments. We analyze 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 to recoup or make excess payments to hospitals.

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 prospective 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.

*Comment:* Several commenters suggested that we consider implementing a cap on the amount of outlier payments an individual IRF can receive under the IRF PPS to ensure that outliers are fairly distributed.

*Response:* As we did not propose to implement a cap on the amount of outlier payments an individual IRF can receive under the IRF PPS, these comments are outside the scope of this 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 populations.

*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 $8,679 to maintain estimated outlier payments at approximately 3 percent of total estimated aggregate IRF payments for FY 2018.

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

Cost-to-charge ratios are used to adjust charges from Medicare claims to costs and are computed annually from facility-specific data obtained from Medicare cost reports. IRF specific cost-to-charge ratios are used in the development of the CMG relative weights and the calculation of outlier payments under the IRF prospective payment system. In accordance with the methodology stated in the FY 2004 IRF PPS final rule (68 FR 45674, 45692 through 45694), we proposed to apply a ceiling to IRFs' CCRs. Using the methodology described in that final rule, we proposed to update the national urban and rural CCRs for IRFs, as well as the national CCR ceiling for FY 2017, 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 2018, as discussed below in this section.

• Other IRFs for which accurate data to calculate an overall CCR are not available.

Specifically, for FY 2018, we proposed to estimate a national average CCR of 0.516 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 proposed to estimate a national average CCR of 0.416 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 total costs factor more heavily into the averages than the CCRs of IRFs with lower total costs. For this final rule, we have used the most recent available cost report data (FY 2015). This includes all IRFs whose cost reporting periods begin on or after October 1, 2014, and before October 1, 2015. If, for any IRF, the FY 2015 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 2014) 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. Using updated FY 2015 cost report data for this final rule, we estimate a national average CCR of 0.518 for rural IRFs, and a national average CCR of 0.416 for urban IRFs.

In accordance with past practice, we proposed to set the national CCR ceiling at 3 standard deviations above the mean CCR. Using this method, we proposed a national CCR ceiling of 1.28 for FY 2018. This means that, if an individual IRF's CCR were to exceed this proposed ceiling of 1.28 for FY 2018, we would replace the IRF's CCR with the appropriate proposed national average CCR (either rural or urban, depending on the geographic location of the IRF). We calculated the proposed national CCR ceiling by:

*Step 1.* Taking the national average CCR (weighted by each IRF's total costs, as previously discussed) 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.

Using the updated FY 2015 cost report data for this final rule, we estimate a national average CCR ceiling of 1.31, using the same methodology.

We did not receive any comments on the proposed update to the IRF CCR ceiling and the urban/rural averages for FY 2018.

*Final Decision:* As we did not receive any comments on the proposed update to the IRF CCR ceiling and the urban/rural averages for FY 2018, we are finalizing the national average urban CCR at 0.416, the national average rural CCR at 0.518, and the national CCR ceiling at 1.31 for FY 2018.

## VIII. Removal of the 25 Percent Payment Penalty for IRF–PAI Late Submissions

Under section 1886(j)(2)(D) of the Act, the Secretary is authorized to require rehabilitation facilities that provide inpatient hospital services to submit such data as the Secretary deems necessary to establish and administer the IRF PPS. The timely collection of patient data is indispensable for the successful operation of the IRF PPS. A comprehensive, reliable system for collecting standardized patient assessment data is necessary to assign beneficiaries to the appropriate CMGs, to monitor the effects of the IRF PPS on patient care and outcomes, and to determine whether adjustments to the CMGs are warranted.

In the FY 2002 IRF PPS final rule (66 FR 41316), we implemented the IRF–PAI data collection instrument, through which IRFs are required to collect and electronically submit patient data for all Medicare Part A FFS patients. IRFs are required to submit their IRF–PAI to CMS through its contractor, currently the CMS National Assessment Collection Database, in accordance with the requirements in §§ 412.610(c)(2)(i)(B), 412.610(d), and 412.614(c). To encourage timely filling, the requirement at § 412.614(d)(1)(ii) provides that failure to submit the IRF–PAI on Medicare Part A FFS patients within the required deadline would result in the imposition of a 25 percent payment penalty.

The FY 2010 IRF PPS final rule (74 FR 39798 through 39800) expanded collection of IRF–PAI data to Medicare Part C (Medicare Advantage) IRF patients. IRFs that failed to timely submit IRF–PAIs on their Part C patients would forfeit their ability to have any of their Part C data used in the calculations for determining their eligibility for exclusion under § 412.23(b). We did not propose any changes to the Medicare Part C IRF–PAI submission requirements or the consequences of failure to submit complete and timely IRF–PAI data for Medicare Part C (Medicare Advantage) patients in the proposed rule.

Effective October 1, 2012, we issued a change request (CR 7760) that created a new edit within the Fiscal Intermediary Shared System (FISS) for IRF PPS claim submissions. In the event that an IRF attempts to submit a Medicare Part A FFS claim for a patient, and there is not a corresponding IRF–PAI for the patient on file to match the claim with, the FISS edit will return an error to the IRF provider advising that an IRF–PAI needs to be submitted. Since IRFs can now only receive payment from Medicare for a Medicare Part A FFS patient when both an IRF claim and an IRF–PAI are submitted and matched accordingly, we believe that they will be financially motivated to file a patient's claim and the patient's corresponding IRF–PAI in a timely manner. Therefore, we believe that the 25 percent payment penalty for late transmission of the IRF–PAI is no longer needed to encourage providers to submit data to CMS.

Furthermore, we believe that the 25 percent payment penalty is no longer necessary, and we also believe it is placing an unnecessary burden on IRFs when they need to apply for a waiver from the penalty. Section 412.614(e) enables CMS to waive the 25 percent payment penalty in extraordinary situations that are beyond the control of the IRF. These include, but are not limited to, fires, floods, earthquakes, or similar unusual events that inflict extensive damage to an inpatient facility as well as situations in which data transmission issues beyond the control of the IRF have made it impossible for the IRF to submit IRF–PAIs in the required timeframe. In such instances, IRFs have generally filed waiver requests under the waiver provision. We review each waiver request on a case-by-case basis and have found that the vast majority of the requests that we received since October 2012 met the waiver criteria. In such cases, the penalty is waived per § 412.614(e), the claim is reprocessed, and the IRF is paid for the claim in full. Of the approximately 10,000 fee-for-service IRF–PAIs that we estimate (based on FY 2015 data) are transmitted late each year, amounting to a total payment penalty of approximately $37.6 million per year, the vast majority qualify for a

waiver under § 412.614(e). Thus, based on our review of our records, we have found that the vast majority of these cases incurred the expenses of the IRF requesting a waiver, CMS reviewing the waiver request, and CMS reprocessing the applicable claims. Without the 25 percent payment penalty, this process, where the vast majority of cases ultimately meet the waiver criteria, would also no longer by necessary. Therefore, in the FY 2018 IRF PPS proposed rule (82 FR 20706 through 20707), we proposed to remove the 25 percent payment penalty for late IRF–PAI transmissions.

We did not propose any changes to the timely filing requirements at § 412.614(c). However, we did propose to remove the payment penalty by revising the following regulations that pertain to the application of the 25 percent payment penalty for late transmission of the IRF–PAI effective for all discharges beginning on or after October 1, 2017.

- Revise § 412.614(d) Consequences of failure to submit complete and timely IRF–PAI data.
- Revise § 412.614 (d)(1).
- Revise § 412.614(d)(1)(i)
- Revise § 412.614(d)(1)(ii).
- Revise § 412.614(e) Exemption to the consequences for transmitting the IRF–PAI data late.

We received 16 comments on the proposed removal of the 25 percent payment penalty for late IRF–PAI transmissions, which are summarized below.

*Comment:* All comments that we received regarding the proposed removal of the 25 percent payment penalty were supportive. The commenters agreed with our assessment that IRFs already have sufficient incentive to submit the IRF–PAI in a timely manner because it is required for IRF payment. Some of the commenters also stated that they agreed with our proposal, because it would decrease the administrative burden placed on providers needing to request a waiver.

*Response:* We appreciate the support from the commenters regarding the removal of the 25 percent payment penalty.

*Final Decision:* After careful consideration of the comments we received, we are finalizing our proposal to remove the 25 percent payment penalty for late IRF–PAI transmissions, including our proposed revisions to the regulation text that pertain to the application of the 25 percent payment penalty for late transmission of the IRF–PAI, effective for all IRF discharges beginning on and after October 1, 2017.

## IX. Removal of the Voluntary Item 27 (Swallowing Status) From the IRF–PAI

In the FY 2014 IRF PPS final rule (78 FR 47896 through 47897), we removed the voluntary Items 25, 26, and 28 from the IRF–PAI. We chose not to remove the voluntary Item 27: Swallowing status, from the IRF–PAI at the time because we believed that it was an integral part of the patient's IRF care and should continue to be evaluated and monitored. However, in the FY 2016 IRF PPS final rule (80 FR 47113 through 47117), we revised the IRF–PAI to include Section K—Swallowing/Nutritional Status, as a risk adjustor for the functional outcome measures. We believe that this new quality item captures very similar data as Item 27. Thus, in the FY 2018 IRF PPS proposed rule (82 FR 20707), we proposed to remove this item from the IRF–PAI for all IRF discharges beginning on or after October 1, 2017, as we no longer believe that this item is necessary.

We received 10 comments on the proposed removal of Item 27 from the IRF–PAI for all discharges beginning on or after October 1, 2017, which are summarized below.

*Comment:* Overall, the majority of commenters supported the removal of this voluntary item from the IRF–PAI, in order to reduce the burden of data collection and reporting of a duplicate item.

*Response:* We appreciate the support from the commenters regarding the removal of this voluntary item from the IRF–PAI. We believe this change will further reduce unnecessary provider burden as this item is duplicative since the new quality item on the IRF–PAI, Section K—Swallowing/Nutritional Status, captures very similar data.

*Comment:* One commenter did not support the proposed removal of Item 27 from the IRF–PAI stating that, as a voluntarily reported item, Item 27 is not burdensome. The commenter also stated that only Item 27 tracks patients' feeding modalities at both admission and discharge and thereby captures information on a patient's improvement through the course of their IRF stay. Lastly, the commenter suggested that we retain Item 27 until October 1, 2018 when IRF–PAI version 2.0 is implemented, adding Item K0520—Nutritional Approaches to admission and discharge assessment (if adopted as proposed).

*Response:* We respectfully disagree with this commenter and continue to believe that removing the voluntary Item 27 from the IRF–PAI is appropriate because it is duplicative with the new quality item on the IRF–PAI, Section K—Swallowing/Nutritional Status, and is burdensome for providers to complete. Additionally, we believe that if an IRF provider has supplementary information pertaining to a patient's swallowing status beyond completing Section K—Swallowing/Nutritional Status, it will be thoroughly documented in the patient's medical record.

*Final Decision:* Upon careful consideration of the comments we received we are finalizing our proposal to remove voluntary Item 27: Swallowing status from the IRF–PAI, effective for all IRF discharges beginning on or after October 1, 2017.

## X. Refinements to the Presumptive Compliance Methodology ICD–10–CM Diagnosis Codes

### *A. Background on the IRF 60 Percent Rule*

The compliance percentage has been part of the criteria for defining IRFs since implementation of the IPPS in 1983. In the FY 2015 IRF PPS final rule (79 FR 45872, 45891 through 45892), we discussed the development of the compliance percentage or the ''60 percent rule.'' We refer readers to that discussion for background on the 60 percent rule and the IRF PPS.

### *B. Enforcement of the IRF 60 Percent Rule*

As described in detail in Chapter 3, section 140.1.3 of the Medicare Claims Processing Manual (Pub. 100–04), which is located on the Web site at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs.html,* the MACs evaluate IRFs' compliance with the 60 percent rule policies annually, using two different methods. One of these methods is called the presumptive compliance method, and the other method is called the medical review method.

1. Presumptive Compliance Method

The presumptive compliance method is typically the first method MACs use to evaluate an IRF's compliance with the 60 percent rule. To use the presumptive compliance method, an IRF must first demonstrate that it treats a patient population that consists of at least 50 percent Medicare FFS or MA patients. If it cannot meet this requirement, then the MAC is required to evaluate the IRF's compliance using the medical review method (described below in this section).

The presumptive compliance method relies on a computerized algorithm that compares lists of diagnosis codes with

the diagnosis codes that IRFs report on patients' IRF–PAIs. First, the computer algorithm compares the impairment group codes (IGCs), which represent the primary reason the patient is being treated in the IRF, with the list of IGCs that presumptively meets the 60 percent rule requirements (which can be downloaded from the IRF PPS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Criteria.html*). If the computer algorithm finds a match, then the computer algorithm examines further to determine whether there are any etiologic diagnosis exclusions on the list that match with any etiologic diagnosis codes (ICD–10–CM codes in item #22 of the IRF–PAI). If the IGC on the IRF–PAI matches an IGC that presumptively meets the 60 percent rule requirements, and there are no etiologic diagnosis exclusions (or there are no matches with the etiologic diagnoses on the IRF–PAI), then the case is counted as meeting the requirements. If the IGC on the IRF–PAI matches one of the presumptive IGCs, but there is an etiologic diagnosis exclusion that matches one of the etiologic diagnoses on the IRF–PAI, then the case is not counted as meeting the requirements. If the IGC on the IRF–PAI does not match one of the presumptive IGCs, then the computer algorithm goes a further step to examine the comorbid conditions listed in item #24 on the IRF–PAI. If, in this second step, one or more comorbid conditions listed in item #24 match one of the ICD–10–CM diagnosis codes (or code combinations) listed on the presumptive compliance list (which can also be downloaded from the IRF PPS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Criteria.html*), then the case is counted as presumptively meeting the 60 percent rule requirements. Otherwise, the case is not counted as meeting the requirements.

2. Medical Review Method

The medical review method of determining an IRF's compliance with the 60 percent rule requirements must be used if the IRF's Medicare FFS and MA population makes up less than 50 percent of its total patient population, or for some reason the MAC is unable to generate a valid compliance percentage for the IRF using the presumptive compliance method, or the IRF fails to meet the 60 percent rule requirements using the presumptive compliance method. However, the MAC is always permitted to use the medical review method for an IRF if the MAC determines that this method will result in the most accurate portrayal of the IRF's compliance with the 60 percent rule requirements.

Under the medical review method, the MAC takes a statistically valid random sample of an IRF's claims for the 12-month compliance review period, and requests the complete medical records for this sample of claims from the IRF. The MAC then reviews this sample of medical records to determine whether the IRF is in compliance with the 60 percent rule requirements.

Thus, if an IRF fails to meet the requirements according to the presumptive compliance method, the MAC must always perform the medical review method to determine whether the IRF has met the requirements. An IRF cannot fail to meet the requirements based solely on the outcome of the presumptive compliance method.

*C. Background on the Use of ICD–10–CM Diagnosis Codes in the Presumptive Compliance Method*

We developed the presumptive compliance method to simplify the process of determining whether an IRF meets the 60 percent rule requirements. By using a computerized algorithm that looks for diagnosis codes on the IRF–PAI and attempts to match them to diagnosis codes on the lists of codes that presumptively meet the requirements, the presumptive compliance method can be performed quickly and efficiently. However, in order to accurately reflect whether an IRF meets the 60 percent rule requirements using the presumptive compliance method, we must ensure that the lists of diagnosis codes (IGCs, etiologic diagnosis exclusions, and comorbid condition codes) that are used in the presumptive compliance method are accurate and updated. That is, we must ensure that each code used in the presumptive compliance method, 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.

To ensure that the diagnosis codes used in the presumptive compliance method were accurately reflecting this, in the FY 2014 IRF PPS final rule (78 FR 47860, 47879 through 47895), we implemented the first updates and revisions in nearly a decade to the list of International Classification of Diseases, 9th Revision, Clinical Modification (ICD–9–CM) codes then used in determining presumptive compliance with the 60 percent rule when we revised the Presumptive Methodology list (then, ''ICD–9–CM Codes That Meet Presumptive Compliance Criteria''). At the time, our examination found that changes over time (including changes in the use of the individual codes, changes in clinical practice, changes in the frequency of various types of illness and disability, and changes to the application of 60 percent rule itself) supported our updating the diagnosis codes that are deemed appropriate to count toward a facility's 60 percent rule compliance calculation. Such updates ensured that the codes better reflected the regulations at § 412.29(b). We performed a clinical analysis of the ICD–9–CM Presumptive Methodology code list to determine the clinical appropriateness of each individual ICD–9–CM code's inclusion on the list, and a statistical analysis of the ICD–9–CM diagnoses code list to enhance our understanding of how individual ICD–9–CM codes were being used by IRFs. For example, one revision we made was to remove non-specific codes where we believed more specific codes were available for coding. These changes were in line with our overall goal to encourage more specific coding on the IRF–PAI.

As a follow up to the revisions we implemented in the FY 2014 IRF PPS final rule, in the FY 2015 IRF PPS final rule (79 FR 45872, 45896 through 45900), we revised the ICD–9–CM diagnosis codes on the ''IGCs That Meet Presumptive Compliance Criteria'' list. 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. Our objective in revising the list was to make conforming changes to the IGC list that we had made to the Presumptive Methodology list in the FY 2014 IRF PPS final rule. We also revised the diagnosis codes listed as exclusions on the ''IGCs That Meet Presumptive Compliance Criteria'' list. In the IRF PPS, 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 the FY 2015 IRF PPS final rule (79 FR 45872, 45905 through 45908), we

also finalized our translation of the diagnosis code lists from ICD–9–CM to ICD–10–CM, effective for use when ICD–10 would become the required medical code data set for use on Medicare claims and IRF–PAI submissions (which occurred on October 1, 2015). As discussed in that rule, we translated the ICD–9–CM code lists used in the IRF PPS presumptive compliance methodology into ICD–10–CM using the General Equivalence Mappings (GEMs) tool. Our intention was to perform a straightforward translation of these codes from ICD–9–CM to ICD–10–CM using the GEMs tool. That is, we made no policy or clinical analysis of the codes under their ICD–10–CM code definition or label, but merely registered the ICD–10 diagnosis codes generated through the GEMS tool. Our intention in converting the ICD–9–CM diagnosis codes to ICD–10–CM diagnosis codes was for the converted codes to reflect the same ''meaning'' as the original codes. That is, we did not intend to add conditions to, or remove conditions from, the ICD–9–CM codes used in the IRF PPS at that time.

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 and posted to the CMS Web site the resulting ICD–10–CM lists. 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 finalized the ICD–10–CM lists in the FY 2015 IRF PPS final rule. The current ICD–10–CM lists are available for download from the CMS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Downloads/ICD-10-CM-DataFiles.zip.*

We stated in the FY 2014 and FY 2015 final rules that, after the adoption of the ICD–10 medical code set, we would review the lists in ICD–10 (once we had enough ICD–10 data available) and make any necessary changes to the lists.

*D. Changes to the Presumptive Methodology Diagnosis Code List*

Over the past year, we have performed a comprehensive analysis of the presumptive methodology diagnosis code lists in ICD–10–CM. Overall, our analysis shows that the process we implemented for updating, revising, and converting the ICD–9–CM diagnosis codes to ICD–10–CM (in the FY 2014 and FY 2015 final rules) worked as intended. However, our analysis indicates that there are areas for improvement. Though we did not propose any specific proposals for changes to the presumptive methodology diagnosis code lists in ICD–10–CM or the presumptive compliance criteria in the FY 2017 IRF PPS proposed rule (81 FR 24178), we received several miscellaneous public comments on the ICD–10–CM diagnosis codes, some of which we summarized in the FY 2017 IRF PPS final rule (81 FR 52132). Our analysis and the public comments show the following areas for improvement:

- Issues with ICD–10–CM diagnosis codes that were added to the list of IGC exclusions through the ICD–9–CM to ICD–10–CM conversion process for patients with traumatic brain injury conditions and hip fracture conditions.
- Issues with identification of major multiple trauma codes that did not translate exactly from ICD–9–CM to ICD–10–CM.
- Issues with certain non-specific and arthritis diagnosis codes that were re-introduced back onto the lists through the ICD–10–CM conversion process.
- One ICD–10–CM code, G72.89—Other specified myopathies, that we believe may currently be inappropriately applied.

Thus, to ensure that the ICD–10–CM diagnosis code lists reflect as accurately as possible the relevant conditions that we believe should count presumptively toward the 60 percent rule, we proposed revisions to the codes on the list. The proposed revisions were designed to maximize the extent to which the presumptive methodology is in alignment with the 60 percent rule in § 412.29(b), the policies that we finalized in the FY 2014 and FY 2015 IRF PPS final rules (78 FR 47860 and 79 FR 45872, respectively), and the ICD–10–CM coding guidelines, ''ICD–10–CM Official Guidelines for Coding and Reporting.'' CMS and the National Center for Health Statistics (NCHS) provide the guidelines for coding and reporting using ICD–10–CM. The current ICD–10–CM coding guidelines are located on the CMS Web site at *https://www.cms.gov/medicare/coding/icd10/2017-icd-10-cm-and-gems.html.*

*E. Revisions Involving Traumatic Brain Injury and Hip Fracture Codes*

Our comprehensive review of the ICD–10–CM code lists for the presumptive methodology showed that excluded diagnosis codes listed in two IGC categories were affected by the ICD–10–CM translation: Traumatic brain injury (TBI) and hip fracture(s).

The excluded diagnosis codes on the IGC list fall into the following IGC categories:

- Brain Dysfunction—0002.21 Traumatic, Open Injury
- Brain Dysfunction—0002.22 Traumatic, Closed Injury
- Orthopedic Disorders—0008.11 Status Post Unilateral Hip Fracture
- Orthopedic Disorders—0008.12 Status Post Bilateral Hip Fractures

1. Traumatic Brain Injury Code Exclusions on the IGC List

We used the GEMs tool purely to translate the ICD–9–CM diagnosis codes used in the presumptive compliance methodology lists to ICD–10–CM diagnosis code lists. We intended the breadth of conditions covered in the former would be equivalent to the latter. However, under ICD–10–CM, the code labels for certain etiologic diagnoses for traumatic brain injuries changed from the meaning of the diagnosis codes for traumatic brain injuries under ICD–9–CM. Thus, for the proposed rule, we analyzed the ICD–10–CM traumatic brain injury diagnosis codes listed as exclusions on the IGC list based on the ICD–10–CM code labels (diagnosis descriptions). Based on that analysis, we proposed to remove some of the traumatic brain injury codes listed as exclusions on the IGC list (that is, if listed as an Etiologic Diagnosis on the IRF–PAI, these diagnosis codes would count toward the presumptive compliance criteria). However, we proposed to retain S06.9X9A—Unspecified intracranial injury with loss of consciousness of unspecified duration, initial encounter as an excluded code under ''IGC Brain Dysfunction—0002.22 Traumatic, Closed Injury'' as part of an excluded combination diagnosis code (meaning that one code contains more than one diagnosis) because we believe other, more specific codes are available on the presumptive compliance list that would be more appropriate for coding conditions suitable for inclusion in the presumptive compliance count for a facility.

2. Hip Fracture(s) Code Exclusions on the IGC List

In the FY 2014 IRF PPS final rule (78 FR 47860, 47894), we removed ICD–9–CM diagnosis codes 820.8—Closed fracture of unspecified part of neck of femur, and 820.9—Open fracture of unspecified part of neck of femur, from the ICD–9–CM Codes That Meet Presumptive Compliance Criteria list. In the FY 2015 IRF PPS final rule (79 FR 45872, 45897), we excluded 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) under IGC 0008.11—Orthopedic Disorders-Status

Post Unilateral Hip Fracture, and IGC 0008.12—Orthopedic Disorders-Status Post Bilateral Hip Fractures. Also, in the FY 2015 IRF PPS final rule (79 FR 45872, 458905 through 45908), we adopted the ICD–10 medical code set for the IRF PPS, in which we translated these ICD–9–CM diagnosis codes to ICD–10–CM diagnosis codes.

For the proposed rule, we reviewed the IGC ICD–10–CM diagnosis code exclusions under IGC 0008.11 and IGC 0008.12. After a thorough review of the codes listed as exclusions under these IGCs, we proposed to remove some of the exclusion codes for these two IGCs, to allow them to count under the presumptive compliance methodology. In the FY 2014 IRF PPS final rule (78 FR 47860, 47885), we agreed with commenters that treatment for a femoral neck fracture is the same regardless of the level of the fracture line within the capsule of the hip or the trochanteric region. During the ICD–10–CM conversion, some hip fracture codes were inadvertently added as exclusions to IGC 0008.11—Orthopedic Disorders-Status Post Unilateral Hip Fracture, and IGC 0008.12—Orthopedic Disorders-Status Post Bilateral Hip Fractures. Consistent with our decision described in the FY 2014 IRF PPS final rule, we proposed to remove the diagnosis code exclusions for a fracture of ''*unspecified* part of neck of femur.'' However, we proposed to retain the diagnosis code exclusions with the code label, ''fracture of unspecified part of neck of *unspecified femur*'' because we believe that documentation should support which femur (left/right or bilateral) is injured.

In Table 1—ICD–10–CM Excluded Codes Removed From IGC List, we list the TBI and hip fracture diagnosis code exclusions removed from the IGC list (that is, if listed as an Etiologic Diagnosis on the IRF–PAI, these diagnosis codes would count toward the presumptive compliance criteria).

Table 1 is available for download on the CMS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Downloads/ICD-10-CM-DataFiles.zip*.

We received 18 public comments on our proposed revisions involving TBI and hip fracture codes, which are summarized below.

*Comment:* Several commenters stated that they appreciated that CMS had performed a comprehensive analysis of the presumptive methodology diagnosis code lists in ICD–10–CM for TBI and hip fracture conditions and that CMS seemed to listen to IRF services providers' concerns.

*Response:* We appreciate the commenters' support for our proposed revisions involving TBI and hip fracture codes.

*Comment:* Several commenters stated that S06.9X9A—Unspecified intracranial injury with loss of consciousness of unspecified duration, initial encounter should not be listed as an exclusion on the IGC list. These commenters expressed concerns that the information to code the specific cause of a patient's injury and the duration of a patient's loss of consciousness is often unavailable to the IRF because it is not in the records from the transferring facility (for example, an acute care hospital) and the IRF is unable administratively or clinically to retrieve this information. Several commenters also noted that the clinical treatment of patients is not necessarily affected by whether or not the IRF can determine the exact cause of the patient's injury or the duration of the patient's loss of consciousness. Thus, commenters expressed concerns that the IRF would, in effect, be unfairly ''penalized'' in that it would have a more difficult time meeting the 60 percent rule requirements under the presumptive methodology if it is unable to obtain the necessary information to code more specifically.

*Response:* We recognize that the IRF builds its understanding of its patients that are admitted to the IRF from the acute care hospital in part from the acute care medical record, and that very rarely the information needed to code a more specific diagnosis is not available in that record. However, as a required part of the IRF's admission process (in accordance with the regulations at § 412.622(a)(4)(i)), the IRF must perform a comprehensive preadmission screening on each Medicare Part A fee-for-service patient. To meet the requirements of the comprehensive preadmission screening, the IRF clinical staff may, on rare occasions, need to consult diagnostic reports, radiological reports, and consultation notes, among other informational documentation. This information should provide the IRF clinicians enough of a clinical basis for determining a more specific diagnosis code for the patient. As stated in the proposed rule, we believe other more specific codes are available, such as those codes listed under subcategory S06.89-, Other specified intracranial injury. We believe that the IRF should make every effort to obtain the necessary information to code more specifically. Thus, we will retain S06.9X9A as an excluded code under IGC 0002.22—Brain Dysfunction, Traumatic, Closed Injury, and continue to review the presumptive compliance methodology code lists to ensure that the ICD–10–CM codes on the lists reflect as accurately as possible the conditions listed in § 412.29(b)(2).

*Comment:* Several commenters expressed concerns that the following ICD–10–CM codes were listed as exclusions on the draft IGC list posted to the CMS Web site contemporaneously with the proposed rule under IGC 0002.21—Brain Dysfunction, Traumatic, Open Injury and IGC 0002.22—Brain Dysfunction Traumatic, Closed Injury:

- S02.101B—Fracture of base of skull, right side, initial encounter for open fracture;
- S02.102B—Fracture of base of skull, left side, initial encounter for open fracture;
- S02.101A—Fracture of base of skull, right side, initial encounter for closed fracture;
- S02.102A—Fracture of base of skull, left side, initial encounter for closed fracture.

These commenters suggested that we should remove these ICD–10–CM codes as exclusions from the IGC list under IGC 0002.21—Brain Dysfunction, Traumatic, Open Injury and IGC 0002.22—Brain Dysfunction Traumatic, Closed Injury (thereby allowing these codes to count toward the presumptive compliance criteria) because these codes conform with ICD–10–CM coding guidelines, reflect serious injuries, and are representative of the types of conditions that fall under the 60 percent rule.

*Response:* Diagnosis codes S02.10XA—Unspecified fracture of base of skull, initial encounter for closed fracture and S02.10XB—Unspecified fracture of base of skull, initial encounter for open fracture were listed as excluded diagnosis codes on the IGC list prior to medical code data set updates. However, with the updates to the ICD–10–CM medical data code set (for ICD–10–CM coding updates see *https://www.cms.gov/Medicare/Coding/ICD10/2018-ICD-10-PCS-and-GEMs.html* and *https://www.cms.gov/Medicare/Coding/ICD10/2017-ICD-10-PCS-and-GEMs.html*), S02.10XA—Unspecified fracture of base of skull, initial encounter for closed fracture and S02.10XB—Unspecified fracture of base of skull, initial encounter for open fracture were removed from the ICD–10–CM medical code data set. These codes were replaced with the added codes: S02.101B—Fracture of base of skull, right side, initial encounter for open fracture; S02.102B—Fracture of base of skull, left side, initial encounter for open fracture; S02.101A—Fracture of

base of skull, right side, initial encounter for closed fracture; and S02.102A—Fracture of base of skull, left side, initial encounter for closed fracture. On the draft IGC list posted to the CMS Web site contemporaneously with the proposed rule, we retained the combination code exclusions that included these new added codes (that is, if listed as an Etiologic Diagnosis on the IRF–PAI, these diagnosis codes would not count toward the presumptive compliance criteria). In consideration of the comments and in light of the recent update to the ICD–10–CM medical code data set, we agree with the commenters that these codes indicate serious injuries and are representative of the conditions that are listed in 42 CFR 412.29(b)(2) as meeting the 60 percent rule criteria. Moreover, these codes provide more specificity than the prior codes S02.10XA and S02.10XB because they indicate the anatomic location of the injury. Accordingly, we are removing the combination code exclusions on the IGC list that contain S02.101B—Fracture of base of skull, right side, initial encounter for open fracture; S02.102B—Fracture of base of skull, left side, initial encounter for open fracture; S02.101A—Fracture of base of skull, right side, initial encounter for closed fracture; and S02.102A—Fracture of base of skull, left side, initial encounter for closed fracture from the IGC exclusion list (thereby allowing these codes to count toward the presumptive compliance criteria).

*Comment:* Commenters generally agreed with the proposed removal of the diagnosis code exclusions for a fracture of ''*unspecified* part of neck of femur'' from the IGC list for unilateral and bilateral hip fracture(s). However, one commenter stated that code exclusions with the code label, ''fracture of unspecified part of neck of *unspecified femur*'' should be retained on the list as the patient record should identify the right or left femur.

*Response:* As discussed, we are removing the diagnosis code exclusions for a fracture of ''*unspecified* part of neck of femur'' consistent with our decision in the FY 2014 IRF PPS final rule. However, we will retain the 3 code exclusions for S72.009-, Fracture of unspecified part of neck of *unspecified femur,* as we continue to review the presumptive compliance methodology code lists to ensure that the ICD–10–CM codes on the lists reflect as accurately as possible the conditions listed in § 412.29(b)(2). We agree with the commenter that there should be sufficient documentation in the patient's medical record in order to appropriately code whether the location of the fracture affects the right or left femur.

*Final Decision:* After carefully considering the comments we received on our proposed revisions involving TBI and hip fracture codes, we are modifying our proposal, based on our own reassessment of the code exclusions and on commenters' suggestions. That is, we are finalizing the proposed revisions involving TBI and hip fracture codes for IGCs 0002.21, 0002.22, 0008.11, and 0008.12, with the additional removal of the following ICD–10–CM codes from the list of ''Impairment Group Codes that Meet Presumptive Compliance Criteria'' (allowing these codes to count toward the presumptive methodology):

- S02.101B—Fracture of base of skull, right side, initial encounter for open fracture;
- S02.102B—Fracture of base of skull, left side, initial encounter for open fracture;
- S02.101A—Fracture of base of skull, right side, initial encounter for closed fracture; and
- S02.102A—Fracture of base of skull, left side, initial encounter for closed fracture.

In addition, we are finalizing our proposals to retain S06.9X9A—Unspecified intracranial injury with loss of consciousness of unspecified duration, initial encounter as an excluded code under IGC 0002.22—Brain Dysfunction, Traumatic, Closed Injury. We are also finalizing our proposal to retain the diagnosis code exclusions with the code label, ''fracture of unspecified part of neck of unspecified femur'', specifically the 3 code exclusions for S72.009-, Fracture of unspecified park of neck of unspecified femur.

These changes are effective for IRF discharges occurring on and after October 1, 2017. The revised IGC list is available for download from the CMS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Downloads/ICD-10-CM-DataFiles.zip.*

### *F. Revisions Regarding Major Multiple Trauma Codes*

Under ICD–9–CM, diagnosis codes 828.0—Closed multiple fractures involving both lower limbs, lower with upper limb, and lower limb(s) with rib(s) and sternum, and 828.1—Open multiple fractures involving both lower limbs, lower with upper limb, and lower limb(s) with rib(s) and sternum, would count a case as meeting the 60 percent rule requirements under the presumptive compliance method. However, similar codes do not exist in ICD–10–CM. The GEMs tool translates these ICD–9–CM codes to the ICD–10–CM code of T07—Unspecified multiple injuries. IRF providers have communicated to CMS their understanding that they would be violating *ICD–10–CM Official Guidelines for Coding and Reporting* if they were to use code T07 for patients with multiple fractures, unless they truly do not know where any of the patient's fractures are located. The IRFs stated that *ICD–10–CM Official Guidelines for Coding and Reporting* indicates that codes for specific bones fractured should be reported. As such, providers state that they no longer are able to code for these patients in a manner that allows them to count under presumptive compliance. The ICD–10–CM Official Guidelines for Coding and Reporting is located on the CMS Web site at *https://www.cms.gov/medicare/coding/icd10/2017-icd-10-cm-and-gems.html.*

Under the IRF PPS, the GEMs translation provides the following ICD–10–CM combination codes as eligible codes for multiple trauma cases:

S42.90XA A Fracture of unspecified shoulder girdle, part unspecified, initial encounter for closed fracture
S52.90XA A Unspecified fracture of unspecified forearm, initial encounter for closed fracture
S22.20XA B Unspecified fracture of sternum, initial encounter for closed fracture
S22.49XA C Multiple fractures of ribs, unspecified side, initial encounter for closed fracture
S42.91XA A Fracture of right shoulder girdle, part unspecified, initial encounter for closed fracture
S52.91XA A Unspecified fracture of right forearm, initial encounter for closed fracture
S42.92XA B Fracture of left shoulder girdle, part unspecified, initial encounter for closed fracture
S52.92XA B Unspecified fracture of left forearm, initial encounter for closed fracture

However, it is noted that unlike ICD–9–CM codes 828.0—Closed multiple fractures involving both lower limbs, lower with upper limb, and lower limb(s) with rib(s) and sternum, and 828.1—Open multiple fractures involving both lower limbs, lower with upper limb, and lower limb(s) with rib(s) and sternum, the IRF PPS ICD–10–CM translation provided no codes for the lower extremities as part of multiple fractures.

So that IRFs may appropriately count patients with multiple fractures that include lower extremity fractures under the presumptive methodology, we proposed to count IRF–PAIs that

contain 2 or more of the ICD–10–CM codes from the three major multiple trauma lists (in the specified code combinations) that are located on the CMS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Downloads/ICD-10-CM-DataFiles.zip.* These codes would need to be specifically combined so that (a) at least one lower extremity fracture is combined with an upper extremity fracture and/or a rib/sternum fracture or (b) fractures are present in both lower extremities.

In order for patients with multiple fractures to qualify as meeting the 60 percent rule requirement for IRFs under the presumptive methodology, the following codes could be used if combined as described above:

- List A: Major Multiple Trauma—Lower Extremity Fracture
- List B: Major Multiple Trauma—Upper Extremity Fracture
- List C: Major Multiple Trauma—Ribs and Sternum Fracture

We also proposed to remove ICD–10–CM diagnosis code T07—Unspecified multiple injuries from the presumptive methodology list and replace it with codes from the three major multiple trauma lists (in the specified code combinations), as described above. We believe that any patient who suffered multiple trauma and subsequently required admission into an IRF would have experienced an extensive medical examination to identify the scope of his or her injuries in the acute care setting. After a review of the acute care medical record, these injuries would be known to both the IRF pre-admission personnel and the admitting IRF physician, and would be able to be coded from the medical record in the most specific manner possible in the IRF setting.

We received 11 public comments on our proposed revisions to the presumptive methodology list for major multiple trauma, which are summarized below.

*Comment:* Commenters were generally supportive of our proposal to count IRF cases that contain two or more of the ICD–10–CM codes from three major multiple trauma lists in the specified combinations. However, one commenter suggested that CMS include ICD–10–CM codes on the major multiple trauma lists that represent diagnoses similar to previously accepted ICD–9–CM codes 819.0—Multiple closed fractures involving both upper limbs and limb with rib(s) and sternum and 819.1—Multiple open fractures involving both upper limbs and limb with rib(s) and sternum.

*Response:* We appreciate the commenters' support of our proposal to count IRF cases that contain two or more of the ICD–10–CM codes from three major multiple trauma lists in the specified combinations. Regarding the comment on upper extremity multiple trauma, in the FY 2015 IRF PPS final rule (79 FR 45872, 45905 through 45908), we finalized our translation of the diagnosis code lists from the ICD–9–CM codes used in the IRF PPS to ICD–10–CM codes. Under the IRF PPS, the GEMs translation provided the following ICD–10–CM combination codes (these are the same combination codes discussed above) as eligible codes for multiple trauma cases for ICD–9–CM codes 819.0 and 819.1:

S42.90XA A Fracture of unspecified shoulder girdle, part unspecified, initial encounter for closed fracture
S52.90XA A Unspecified fracture of unspecified forearm, initial encounter for closed fracture
S22.20XA B Unspecified fracture of sternum, initial encounter for closed fracture
S22.49XA C Multiple fractures of ribs, unspecified side, initial encounter for closed fracture
S42.91XA A Fracture of right shoulder girdle, part unspecified, initial encounter for closed fracture
S52.91XA A Unspecified fracture of right forearm, initial encounter for closed fracture
S42.92XA B Fracture of left shoulder girdle, part unspecified, initial encounter for closed fracture
S52.92XA B Unspecified fracture of left forearm, initial encounter for closed fracture

We have retained these combination codes on the ICD–10–CM presumptive methodology list so that IRFs may continue to count multiple major trauma involving upper extremity and rib/sternum injuries.

*Final Decision:* After carefully considering the comments that we received, we are finalizing our proposed revisions to the presumptive methodology list for major multiple trauma, effective for IRF discharges occurring on and after October 1, 2017. The lists for major multiple trauma: IRF List A—MMT-Lower Extremity Fracture; IRF List B—MMT-Upper Extremity Fracture; and IRF List C-Ribs and Sternum Fracture are available for download from the CMS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Downloads/ICD-10-CM-DataFiles.zip.*

*G. Further Consideration of Unspecified Codes and Arthritis Codes*

1. Unspecified Codes

In the FY 2014 IRF PPS final rule (78 FR 47860, 47884 through 47885), we stated that 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 the accuracy of the presumptive compliance method of calculating a facility's 60 percent rule compliance percentage. Thus, 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. As we stated in that final rule, generally, ''unspecified'' codes are used when there is a lack of information about location or severity of medical conditions in the medical record. We believe that specific diagnosis codes that narrowly identify anatomical sites where disease, injury, or condition exist should be used when coding patients' conditions on the IRF–PAI whenever such codes are available. Moreover, we believe that 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. 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 and document additional information from the patient's acute care hospital to determine and submit the appropriate, more specific code(s) to use.

In the proposed rule, we used the same approach in analyzing the ICD–10–CM diagnosis codes that we used in our analysis of ICD–9–CM diagnosis codes in the FY 2014 IRF PPS final rule. That is, we went through each ICD–10–CM code currently on the presumptive compliance methodology lists individually to determine whether the ICD–10–CM code is sufficiently specific to reliably identify a subset of conditions suitable for inclusion in the presumptive methodology compliance calculation. If we determined that a given ICD–10–CM code was not sufficiently specific, we ascertained whether more specific codes were available for use (that could count for the presumptive compliance methodology) to identify those members of the patient population with conditions that we believe it would be appropriate to include in the

presumptive methodology compliance calculation. For example, we would likely determine that an injury to an unspecified part of the body would not be sufficiently specific, but we sought to identify where there were codes available (that could count for the presumptive compliance methodology) to code that injury for specific locations on the body. In the FY 2018 IRF PPS proposed rule (80 FR 20711), we proposed to remove certain unspecified diagnosis codes that, on review, we believed to be inappropriate to include in the presumptive compliance list. However, in light of the comments we received, we are going to take a more cautious approach and give further consideration to the removal of the unspecified codes, though we continue to encourage IRFs to adhere to ICD–10–CM guidelines and use the most specific information available to describe a medical disease, condition, or injury.

In section X.G. of this final rule, we summarize and respond to the public comments we received on our proposed removal of the unspecified codes and arthritis codes that were re-introduced back onto the lists through the ICD–10–CM conversion process.

2. Arthritis Codes

In the FY 2014 IRF PPS final rule (78 FR 47887 through 47895), we finalized the removal of ICD–9–CM diagnosis codes for arthritis conditions from the from the ICD–9–CM Codes That Meet Presumptive Compliance Criteria list 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. The ICD–9–CM diagnosis codes that reflected these arthritis and arthropathy conditions did 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 (78 FR 47888) 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 (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 under § 412.29(b)(2)(x) through (xii) from the list of ICD–9–CM Codes That Meet Presumptive Compliance Criteria list.

Though we removed arthritis diagnosis codes from the ICD–9–CM Codes That Meet Presumptive Compliance Criteria list prior to the ICD–9–CM to ICD–10–CM conversion process, some ICD–10–CM arthritis codes are listed due to the straight translation. Though we had proposed to remove these codes in the FY 2018 IRF PPS proposed rule (80 FR 20711), consistent with our FY 2014 IRF PPS final rule rationale for removing ICD–9–CM arthritis diagnosis codes, we are going to take a more cautious approach and give further consideration to the removal of the remaining ICD–10–CM arthritis codes on the presumptive methodology list.

We received 10 public comments on our proposed removal of the unspecified codes and arthritis codes that were re-introduced back onto the lists through the ICD–10–CM conversion process, which are summarized below.

*Comment:* Several commenters expressed concerns about the proposed removal of unspecified codes from the presumptive methodology lists. These commenters stated that specific information may not be captured in the record in the acute care setting (for example, the emergency department), and the lack of this information would hinder the ability of the IRF to code the patient. Several commenters encouraged us not to remove codes from presumptive methodology simply because a code is ''unspecified,'' as that descriptor should have no bearing on the patient's current functional status or treatment for the type of condition that typically is treated in IRFs and meets the 60 percent rule.

*Response:* We recognize that, in rare instances, IRFs may not receive all of the information they need from the referring provider in order to code more specifically, and we want to move cautiously in this regard to ensure that IRFs have the information that they need to code more specifically. We agree with several of the comments that said that the ''unspecified'' descriptor, in and of itself, does not necessarily mean that the case fails to comply with the 60 percent rule criteria. In light of these comments, we have decided to take a more cautious approach and give further consideration to the removal of these unspecified codes. For now, then, we will retain the unspecified codes that were discussed in the FY 2018 IRF PPS proposed rule on the list of ICD–10–CM Codes That Meet Presumptive Compliance Criteria. In addition, we will continue to work together with the National Center for Health Statistics (NCHS), the American Hospital Association (AHA), and other organizations that provide guidance and education on the ICD–10 medical code data set to encourage providers to code to the highest level of specificity possible. For the IRF PPS in particular, we will continue holding National Provider Calls (as we have been doing for the IRF PPS since June 2014) to educate providers on coding to the greatest level of specificity possible in the IRF PPS. We will also continue to monitor the use of these codes and may propose adjustments to the presumptive methodology code lists in the future to ensure that the lists continue to reflect the conditions that meet the 60 percent rule criteria listed in § 412.29(b)(2).

*Comment:* While one commenter generally supported the CMS goal of encouraging better descriptive coding and documentation to demonstrate the appropriateness of a patient case under the presumptive methodology, the commenter strongly encouraged us not to remove the codes from counting under the presumptive methodology, but instead suggested that we monitor the coding practices of the service providers who refer patients to IRFs as the commenter indicated that the absence of specificity occurs earlier in the patient's hospitalization and negatively impacts IRFs.

*Response:* We acknowledge that as a post-acute care service provider, IRFs admit patients who are well along the continuum of care and that, rarely, documentation they receive from the acute care setting may be incomplete, making it more difficult to determine appropriate treatment for the patient and hampering the provider's efforts to complete their own medical records. In light of these comments and in an abundance of caution to ensure that IRFs receive the information they need to code more specifically, we will retain the unspecified codes that were re-introduced back onto the lists through the ICD–10–CM conversion process and continue to monitor the practices of service providers who refer patients to IRFs to ensure that the IRFs receive the appropriately detailed information from these providers.

*Comment:* One commenter suggested that CMS reconsider the removal of arthritis codes from the presumptive methodology lists. The commenter expressed concern that the removal of arthritis codes may impact access to care for certain populations with high incidence of these conditions.

*Response:* In light of these comments, to ensure that we do not affect access to care for patients with these conditions, we will give further consideration to the removal of these arthritis codes. For now, then, we will retain the arthritis

codes that were re-introduced back onto the lists through the ICD–10–CM conversion process and continue to analyze whether they are appropriate for inclusion on the list.

*Comment:* One commenter expressed concern that the proposed presumptive methodology revisions, if finalized, would put additional IRFs at risk for meeting the compliance standards and possibly burden IRFs (and CMS contractors) with additional medical record reviews.

*Response:* We do not agree that the proposed presumptive methodology changes would put any IRFs at risk for failing to meet the 60 percent rule requirements or would cause many of them (if any) to have to use the medical review methodology. First, as we indicated in the FY 2014 IRF PPS final rule (78 FR 47930), the proposed removal of unspecified diagnosis codes would not be expected to have any impact on IRFs' compliance with the 60 percent rule or on the amount of medical record reviews that would need to be completed for determining 60 percent rule compliance because IRFs would be able to choose another more specific code on the list to use instead of the unspecified code. As we did in the FY 2014 final rule, we were careful with the proposed changes for FY 2018 to ensure that more specific codes were available on the list in every instance for IRFs to use instead of an unspecified code. Second, in the FY 2015 IRF PPS final rule (79 FR 45903 through 45905), we implemented a new item on the IRF–PAI form to enable IRFs to indicate to us (and the Medicare Administrative Contractor to verify) whether or not a patient's arthritis condition meets the requirements in § 412.29(b)(2). Thus, removal of the arthritis diagnosis codes from the presumptive methodology list would similarly be expected to have no effect on the number of IRFs that are in compliance with the 60 percent rule requirements or the number of medical record reviews that would need to be completed for determining 60 percent rule compliance because the arthritis cases that count presumptively can be identified through this new verification process. Third, our analysis of the most current IRF–PAI data shows that IRFs' presumptive compliance percentages are almost always well above 60 percent. Thus, IRFs very rarely fail to meet the presumptive methodology or have to use the medical review methodology. However, as noted previously, we have decided to take a more cautious approach and give further consideration to the removal of the unspecified and arthritis codes. For now, then, we will retain the unspecified and arthritis codes that were re-introduced back onto the lists through the ICD–10–CM conversion process, continue to educate providers on the appropriate use of these codes, and continue to analyze whether they are appropriate for inclusion on the list.

*Comment:* Several commenters requested that CMS more clearly identify the code changes made to the presumptive compliance list and the IGC list by providing tables of the codes that are being added and the codes that are being removed, similar to the way that coding changes are presented in the IPPS setting and the way we presented presumptive methodology changes in the FY 2014 IRF PPS final rule. Other commenters suggested CMS employ a ''crosswalk'' or other mechanism for stakeholders to easily identify proposed changes from existing policy. Some commenters requested that we indicate the policy rationale behind each change on the lists. Another commenter expressed concern that the proposed changes to the code lists are supported with limited clinical or policy rationale. This commenter requested that for future changes to the presumptive methodology, CMS provide a comprehensive policy rationale, with supporting data, for each proposed coding change. Moreover, this commenter stated that it is difficult to determine the rationale behind the proposed changes, that is, whether they are for clinical reasons, policy reasons, due to the ICD–10–CM conversion, or changes related to the changes to the ICD–10 medical data codes set that are implemented annually.

*Response:* We appreciate the commenters' suggestions, and while we believe that all of the proposed changes are fully supported by the policy rationales discussed in the proposed rule, we agree that it would be helpful for us to further clarify the coding changes to the presumptive compliance list (and other presumptive methodology lists) by providing tables of codes that we are adding and codes that we are deleting. We will include this information in all future rulemaking. For this final rule, we have organized the changes in Table 1—ICD–10–CM Exclusion Codes Removed From IGC List. This list is available for download on the CMS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Downloads/ICD-10-CM-DataFiles.zip*.

In addition, we will take the commenters' suggestions into account for future refinements to the presumptive methodology code lists, including the suggestion that we include more supporting data for each proposed coding change, along with a comprehensive rationale for any future refinements.

*Final Decision:* After carefully considering the comments we received on the proposed removal of the unspecified codes and arthritis codes that were re-introduced back onto the lists through the ICD–10–CM conversion process, we are not finalizing these proposed changes to the presumptive compliance list. Instead, we have noted the commenter's concerns regarding issues of patient access to care, burden to providers, and potential absence of adequate information to support specificity of coding in the medical records of referring providers. Based on these concerns, we have decided to take a more cautious approach to these changes and not finalize the changes regarding removal of unspecified codes or arthritis codes. Instead, we will continue to educate providers and to analyze the use of these codes to determine their appropriateness for inclusion on the presumptive methodology list. We may propose additional changes to the presumptive methodology lists in the future, as needed, to ensure that the lists continue to reflect the conditions that meet the 60 percent rule criteria listed in 42 CFR 412.29(b)(2).

### *H. Further Consideration of ICD–10–CM Code G72.89—Other Specified Myopathies*

Through our monitoring of IRFs' use of the ICD–10–CM codes that currently count toward a facility's compliance percentage under the presumptive compliance method, we have discovered what we believe to be inconsistent use of one ICD–10–CM code (G72.89—Other Specified Myopathies) among IRFs. We included this ICD–10–CM code on the presumptive compliance code list based on our understanding that it is intended to represent a relatively narrow set of specified myopathies that are confirmed by the results of specific medical testing and identified as such in the patients' medical records. However, having reviewed certain IRFs' disproportionately higher use of the code, we have found that certain IRFs are using this code more broadly, including to represent patients with generalized weakness who do not meet the requirements in the 60 percent rule under § 412.29(b)(2). For the expanded use of this code by certain IRFs, we proposed to remove this code from the presumptive compliance list because we believed that we were unable to determine from the presence of this

code alone, without additional supporting information from the medical record, that patients coded with this code presumptively meet the 60 percent rule criteria.

We received 15 public comments on our proposal to remove ICD–10–CM code G72.89—Other specified myopathies from the presumptive compliance list, which are summarized below.

*Comment:* Several commenters supported our proposal to remove G72.89—Other specified myopathies from counting under the presumptive methodology and agreed that this code should not be coded for patients with generalized weakness or general debility.

*Response:* We appreciate the commenters' support for our proposal to remove G72.89—Other specified myopathies. However, as discussed below, we are not finalizing the removal of this code.

*Comment:* One commenter noted that among patients who are appropriately coded with G72.89—Other specified myopathies are those with significant medical comorbidities or those who have experienced prolonged hospitalization. Both of these instances may contribute to proximal weakness and loss of function that amount to ''other specified myopathies.'' The commenter stated that these types of patients are best served in an IRF. Several commenters stated that the removal of this code would have a significant impact on presumptive compliance because there is no more specific code on the presumptive compliance list under which these patients can be coded. Another commenter noted that if there is a problem with the overutilization of this code, it may be a matter of physician documentation and provider coding practices in which the code is inappropriately used to code for patients with generalized weakness and not for those who suffer from other specified myopathies. This commenter suggested that, instead of removing this code from the presumptive compliance list, we should address this concern through targeted coding audit reviews. Several commenters recommended that we provide education on the appropriate use of this code and conduct ongoing monitoring of the use of the code. In addition, one commenter noted that medical testing is not the only way for a physician to diagnose a myopathy.

*Response:* We continue to believe that the inappropriate use of G72.89—Other specified myopathies—does not allow us to determine, from the presence of the code alone without further information from the patient's medical record, that patients coded with this code presumptively meet the 60 percent rule criteria. However, we have decided to take a more cautious approach to ensure that we do not restrict access to IRF care for patients with myopathies, and are not finalizing removal of this code at this time. Our analysis indicates that many IRFs use this code appropriately, and that we are only unable to rely on this code alone for a particular subset of IRFs that are continuing to use the code for patients with generalized weakness and debility. Thus, we agree with many of the commenters that a more direct approach to addressing this issue may be to conduct targeted coding audit reviews (which we understand to mean targeted medical reviews) of claims containing this code, to provide education on the appropriate use of the code, and to conduct ongoing monitoring of the code. We have been and will continue doing these things. We note that we did not mean to imply that we believe that medical testing is the only way to determine whether a patient has an ''other specified myopathy,'' but was simply provided as one possible way of verifying this in the IRF medical record. We will consider re-proposing removal of this code in the future if our analysis indicates that the code continues to be used inappropriately.

*Final Decision:* After careful consideration of the comments we received regarding our proposal to remove code G72.89—Other specified myopathies from the presumptive methodology code list, we are not finalizing the removal of this code because we agree with the commenters' suggestions that a more effective way to deal with inappropriate utilization of this code is through focused medical reviews of claims containing this code, provider education on the appropriate use of this code, and ongoing monitoring of the use of this code. We note that we may again propose removal of this code from the presumptive methodology lists in the future, if we find that the code continues to be used inappropriately.

*I. Implementation of the Revisions to the Presumptive Methodology*

All revisions in the proposed rule were scheduled to take effective for IRF discharges occurring on or after October 1, 2017, unless otherwise stated. We believed that this was the most appropriate timing of the changes to the presumptive methodology because many of the changes (specifically, the restoration of the traumatic brain injury, hip fracture, and major multiple trauma codes) had been requested by IRFs, and they had also requested that these changes be made as soon as possible. However, we received 16 comments on the effective date for our proposed revisions to the presumptive methodology lists, which are summarized below.

*Comment:* Several commenters expressed concerns about the proposed effective date of October 1, 2017 for the revisions to the presumptive methodology that would remove ICD–10–CM codes from counting. Commenters generally stated that making the effective date of these changes on a date other than the start date of an IRF's compliance review period could potentially constitute ''impermissible retroactive rulemaking'' (because it would make IRFs have to go back to the start of the current compliance review period and reevaluate their admitting practices to ensure that the facility is in compliance with the 60 percent rule for the entire compliance review period), could create added confusion and burden among IRFs by making IRFs have to absorb potentially disruptive changes in the middle of a compliance review period, was inconsistent with the way these changes have been applied historically, and could affect IRFs differently depending on each IRF's particular cost reporting period (or compliance review period), potentially causing inequities among IRFs.

*Response:* We generally agree with the commenters that we should implement revisions to the presumptive methodology at the start of each IRF's compliance review period to ensure that implementation of the changes is equitable, minimizes the amount of confusion and burden among IRFs, is consistent with past implementation of similar changes, and affects all IRFs on a similar basis. As we are not finalizing any of the changes to the presumptive methodology in this final rule that would remove codes from counting under the presumptive methodology, we will keep these comments in mind for potential implementation of changes to the presumptive methodology codes in future rulemaking.

*Comment:* Several commenters suggested that we implement proposed changes that would increase the number of cases counting under the presumptive methodology (that is, the changes involving traumatic brain injury codes, hip fracture codes, and major multiple trauma codes) as soon as possible to ensure continued access to IRF services for patients with these conditions. The commenters suggested that we either

make these changes effective retroactively to October 1, 2015 (the applicable date when ICD–10–CM became the required medical code set for use on Medicare claims and IRF–PAI submissions for the IRF PPS), or for discharges on or after October 1, 2017, at the latest.

*Response:* We agree with the commenters that the immediacy of the need to ensure that patients with traumatic brain injuries, hip fractures, and major multiple traumas continue to have appropriate access to IRF services means that we need to ensure that these codes count toward meeting the 60 percent rule requirements under the presumptive methodology as soon as possible. As 60 percent rule determinations are always made prospectively, we disagree with the commenters and, consistent with past implementation, will implement these changes prospectively, effective for IRF discharges occurring on and after October 1, 2017, which represents the earliest possible prospective implementation time.

*Comment:* Several commenters stated that IRFs need adequate time to make appropriate adjustments to the changes in the code lists that would that would remove ICD–10–CM codes from counting, including time to educate and train staff and clinicians. For this reason, they said that we should delay the effective date of any such changes by at least a year to allow IRFs additional time to adjust to the changes.

*Response:* We are not finalizing any changes in this final rule that would remove ICD–10–CM codes from counting. However, we will take these comments into account for implementation of changes to the presumptive methodology in future rulemaking.

*Final Decision:* After carefully considering the comments we received on the effective date for our proposed revisions to the presumptive methodology lists, we are implementing the changes to the presumptive methodology that will increase the number of cases counting under the presumptive methodology (that is, the changes involving traumatic brain injury codes, hip fracture codes, and major multiple trauma codes) for all IRF discharges occurring on or after October 1, 2017. As previously discussed in sections X.G and X.H of this rule, we are not implementing any of the changes that would remove codes from counting under the presumptive methodology at this time, so we will take the comments on the effective date of these changes into consideration for possible future rulemaking on this issue.

*J. Summary of Comments Regarding the Criteria Used To Classify Facilities for Payment Under the IRF PPS*

Sections 1886(d)(1)(B) and 1886(d)(1)(B)(ii) of the Act give the Secretary discretion in defining a ''rehabilitation unit'' and a ''rehabilitation hospital'' for payment under the IRF PPS. In 1983, when Congress first authorized the Secretary to define IRFs for purposes of excluding them from the IPPS, we used some of the accreditation requirements that were used by the Joint Commission on Accreditation of Hospitals (which is now known as the Joint Commission) and other accrediting organizations to develop our definition of a rehabilitation hospital. We also used other criteria that we believed distinguished rehabilitation hospitals from other types of hospitals, including the requirement that the hospital must be primarily engaged in furnishing intensive rehabilitation services as demonstrated by patient medical records showing that, during the hospital's most recently completed 12-month cost reporting period, at least 75 percent of the hospital's inpatients were treated for one or more conditions specified in these regulations that typically require intensive inpatient rehabilitation (48 FR 39756). We included this requirement, commonly referred to as the 75 percent rule, as a defining feature of a rehabilitation hospital because we believed that examining the types of conditions for which the hospital's inpatients are treated, and the proportion of patients treated for conditions that typically require intensive inpatient rehabilitation, will help distinguish those hospitals in which the provisions of rehabilitation services is a primary, rather than a secondary, goal (48 FR 39756).

The original list of medical conditions used in evaluating this requirement were stroke, spinal cord injury, congenital deformity, amputation, major multiple trauma, fracture of femur (hip fracture), brain injury, and polyarthritis, including rheumatoid arthritis. This list of 8 medical conditions was partly based on the information contained in a document entitled, ''Sample Screening Criteria for Review of Admissions to Comprehensive Medical Rehabilitation Hospitals/Units,'' produced by the American Academy of Physical Medicine and Rehabilitation and the American Congress of Rehabilitation Medicine. On January 3, 1984, we published a final rule entitled ''Medicare Program: Prospective Payment for Medicare Inpatient Hospital Services'' (49 FR 234), that expanded the initial list of conditions to include neurological disorders (including multiple sclerosis, motor neuron diseases, polyneuropathy, muscular dystrophy, and Parkinson's disease) and burns, in response to public comment.

In the FY 2004 IRF PPS proposed rule, we provided additional background on how the definition of an IRF developed and evolved over time. In that proposed rule, we also discussed the need to use these requirements in distinguishing IRFs from other types of inpatient facilities and thereby maintaining compliance with sections 1886(d)(1)(B) and 1886(d)(1)(B)(ii) of the Act. In addition, we stated that making this distinction is also critical to fulfilling the requirements of section 1886(j)(1)(A), which requires Medicare to make payments to IRFs under a PPS specifically designed for the services they furnish.

In the May 7, 2004 final rule, we updated the list of conditions used to evaluate compliance with the ''75 percent rule'' from 10 conditions to 13, and implemented a new presumptive compliance methodology, as discussed previously in this proposed rule, to simplify the rule and to promote more consistent enforcement. The list of 13 conditions that were developed in the May 7, 2004 final rule, which is still the list that we use to evaluate compliance with the rule and which section 5005 of the Deficit Reduction Act of 2005, as amended by section 115(b) of MMSEA, subsequently required to be used, can be found in § 412.29(b)(2):

- Stroke.
- Spinal cord injury.
- Congenital deformity.
- Amputation.
- Major multiple trauma.
- Fracture of femur (hip fracture).
- Brain injury.
- Neurological disorders, including multiple sclerosis, motor neuron diseases, polyneuropathy, muscular dystrophy, and Parkinson's disease.
- Burns.
- Active, polyarticular rheumatoid arthritis, psoriatic arthritis, and seronegative arthropathies, under specified conditions (see § 412.29(b)(2)(x)).
- Systemic vasculidities with joint inflammation, under specified conditions (see § 412.29(b)(2)(xi)).
- Severe or advanced osteoarthritis (osteoarthritis or degenerative joint disease), under specified conditions (see § 412.29(b)(2)(xii)).
- Knee or hip joint replacement, or both, if the replacements are bilateral, if the patient is age 85 or older, or if the

patient has a body mass index (BMI) of at least 50.

Subsequent to the May 7, 2004 final rule, on June 16, 2005, the Government Accountability Office (GAO) issued a report entitled, ''More Specific Criteria Needed to Classify Inpatient Rehabilitation Facilities,'' which recommended that CMS describe more thoroughly the subgroups of patients within a condition that require IRF services, possibly using functional status or other factors in addition to condition. In this report, the GAO did not recommend that more conditions be added to the list of conditions in § 412.29(b)(2), in part because the experts convened for this study could not agree on conditions to add and in part because the GAO said that it believed that the rule should instead be ''refined to clarify which types of patients should be in IRFs as opposed to another setting.''

In addition, in September 2009, we issued a Report to Congress entitled ''Analysis of the Classification Criteria for Inpatient Rehabilitation Facilities.'' This report was required by section 115 of MMSEA, which also required the IRF compliance rate to be set no higher than 60 percent and required comorbidities to continue to be included in the compliance rate calculation. In conducting the analysis for this report, the contractor (Research Triangle Institute (RTI) International) solicited public comments and held a technical expert panel (TEP) to analyze the effects of, and potential refinements to, the 60 percent rule and the list of conditions that are used to evaluate compliance with the 60 percent rule. The report generally concluded the following:

- In considering changes to the 60 percent rule, CMS should establish policies that ensure the availability of IRF services to beneficiaries whose intensive rehabilitation needs cannot be adequately served in other settings.
- CMS should ensure that criteria for IRF classification focus on the intensity of service needs that justify the higher IRF payment rate.
- An IRF stay is not needed for all patients having a rehabilitation-type diagnosis.
- Patient characteristics, such as medical comorbidities, prognosis for improvement and cognitive deficits, are important to consider when identifying appropriate IRF patients.

Thus, to assist us in generating ideas and information for analyzing refinements and updates to the criteria used to classify facilities for payment under the IRF PPS, in the FY 2018 IRF PPS proposed rule (82 FR 20712), we specifically solicited public comments from stakeholders on the 60 percent rule, including but not limited to, the list of conditions in § 412.29(b)(2).

We received 28 comments in response to our solicitation, which are summarized below.

*Comment:* Most commenters suggested elimination of the 60 percent rule, indicating that the rule does not allow IRF care to be ''patient-centered''. Many of these commenters suggested that existing criteria, including the IRF coverage requirements and the requirements for IRF classification, such as the need to conduct preadmission screenings on all patients, provide close physician supervision, provide interdisciplinary care, etc., would suffice for defining IRF care and would be more patient-centered. Alternatively, commenters suggested that we lower the IRF compliance percentage from 60 percent to 50 percent. In addition, many commenters suggested that we add specific conditions to the list of conditions that meet the rule, including organ transplant, cardiac, pulmonology, and oncology conditions. Many commenters stated that elimination or relaxing of the 60 percent rule would allow IRFs to more easily participate in alternative payment models.

*Response:* We appreciate the commenters' suggestions, and will carefully consider these suggestions as we explore ways to modernize the Medicare program.

## XI. Subregulatory Process for Certain Updates to Presumptive Methodology Diagnosis Code Lists

We have not established a formal process for updating the code lists used for the presumptive compliance methodology to account for changes to the ICD–10 medical code data set or to alert providers to the effects of these changes on the presumptive methodology code lists. In the proposed rule, we proposed to establish such a formal process, to distinguish between non-substantive updates to the ICD–10–CM codes on the lists that would be applied through a subregulatory process and substantive revisions to the ICD–10–CM codes on the lists that would only be proposed and finalized through notice and comment rulemaking.

In the proposed rule, we proposed to establish a formal process of updating the lists of ICD–10–CM codes used in the presumptive compliance methodology using a subregulatory process to apply non-substantive changes to the lists of ICD–10–CM codes used in the presumptive compliance methodology in accordance with changes to the ICD–10 medical data codes set that are implemented annually by the ICD–10 Coordination and Maintenance Committee (information about the ICD–10 Coordination and Maintenance Committee can be found at *https://www.cdc.gov/nchs/icd/icd10_maintenance.htm*). We would continue our practice of using notice-and-comment rulemaking to propose and finalize substantive changes to the lists of ICD–10–CM codes used in the presumptive methodology.

The ICD–10 Coordination and Maintenance Committee is a federal interdepartmental committee that is chaired by representatives from the NCHS and by representatives from CMS. The committee typically meets bi-annually, and publishes updates to the ICD–10 medical code data sets in June of each year, which become effective October 1 of each year. Note that the ICD–10 Coordination and Maintenance Committee has the ability to make changes to the ICD–10 medical code data sets effective on April 1, but has not yet done so. In accordance with 45 CFR part 162, subpart J, we require Medicare providers to use the most current ICD–10 medical code data set in coding Medicare claims and IRF–PAIs.

To ensure that the lists of ICD–10–CM codes used in the presumptive compliance methodology are updated in accordance with changes to the ICD–10 medical code data set, we proposed to obtain the list of changes to the ICD–10 medical code data set from the ICD–10 Coordination and Maintenance Committee (at *https://www.cdc.gov/nchs/icd/icd10_maintenance.htm*) and, through a subregulatory process, apply all relevant changes to the lists of codes used in the presumptive compliance methodology. Any such changes would be limited to those specific changes that are necessary to maintain consistency with the most current ICD–10 medical code data set, which Medicare providers are generally required to use in accordance with 45 CFR part 162, subpart J. Our intent in applying these changes through the subregulatory process is to keep the same conditions on the presumptive methodology lists, but ensure that the codes used to identify those conditions are synchronized with the most current ICD–10 medical code data set.

We proposed to publish the updated lists of codes on the IRF PPS Web site which can be accessed at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Data-Files.html* (we note that we inadvertently included the incorrect link in the proposed rule (82 FR 20690, 20713); this is the correct link, which was accessible from the original link in the proposed rule)

before the effective date for these changes so that IRFs will be able to use the most current ICD–10 medical code data set to appropriately count cases toward meeting the 60 percent rule requirements under the presumptive compliance methodology.

For example, ICD–10–CM code M50.02—Cervical disc disorder with myelopathy, mid-cervical region—is one of the ICD–10–CM codes on the presumptive compliance methodology list that ''counts'' a patient as meeting the 60 percent rule requirements if the patient is coded with this diagnosis code. However, effective October 1, 2016, the ICD–10 Coordination and Maintenance Committee made M50.02 an ''invalid'' code, meaning that this code is no longer available for use within the ICD–10 medical code data set. In place of this code, the ICD–10 Coordination and Maintenance Committee added:

- M50.020—Cervical disc disorder with myelopathy, mid-cervical region, unspecified level (new code),
- M50.021—Cervical disc disorder at C4–C5 level with myelopathy (new code)
- M50.022—Cervical disc disorder at C5–C6 level with myelopathy (new code)
- M50.023—Cervical disc disorder at C6–C7 level with myelopathy (new code)

As we did not have a process for updating the ICD–10–CM codes in the presumptive compliance methodology prior to October 1, 2016, we were unable to reflect this change in the presumptive compliance methodology and therefore only counted patients that had M50.02 on their IRF–PAI submission and were not able to recognize codes M50.020, M50.021, M50.022, or M50.023 in the presumptive compliance methodology. Thus, an IRF that adopted the changes to the ICD–10 medical code data set on October 1, 2016, as required, and coded a patient with, for example, M5.023, would not have that patient counted as meeting the 60 percent rule requirements under the presumptive compliance methodology (unless the patient happened to have another ICD–10–CM code that would have counted under the presumptive compliance methodology). The update process that we proposed in the proposed rule would enable us to remove the invalid code M50.02 and add the new codes M50.020, M50.021, M50.022, and M50.023 to the lists of codes used in the presumptive compliance methodology prior to the effective date of the change (October 1, 2016) so that an IRF's appropriate use of the newly added code M50.023 would allow the patient to count as meeting the 60 percent rule requirements.

We note that, in the example above, we would not make any policy judgments in adopting the changes to the ICD–10 medical code data set through subregulatory means. Whether or not we believed, for example, that M50.020 might be too non-specific to include in the presumptive compliance methodology, we would nevertheless add it through this subregulatory process because we would treat M50.020, M50.021, M50.022, and M50.023 exactly the same as the M50.02 code that they replaced. We would simply replace the invalid code with the four new valid codes. If, hypothetically speaking, we were to decide at a later date that M50.020 is too non-specific and would therefore want to remove it from the presumptive compliance lists, we would consider that to be a substantive change that would necessitate notice and comment rulemaking. Any substantive changes to the lists of codes used in the presumptive compliance methodology would be promulgated through notice and comment rulemaking.

In the FY 2007 IRF PPS final rule (71 FR 48354 at 48360 through 48361), we implemented the same subregulatory updating process for the IRF tier comorbidities list (also a list of ICD–10–CM codes) that we proposed to implement for the lists of ICD–10–CM codes used in the presumptive compliance methodology. As we discussed in that final rule, we believe that the best way for us to convey information about changes to the ICD–10 medical code data set that affect the presumptive compliance lists and alert providers to non-substantive program changes that result is to update the lists using a subregulatory process and make the documents containing the program's lists of ICD–10–CM codes web-based, rather than publishing each non-substantive change to the ICD–10–CM codes in regulation. We believe that this would ensure providers have the most up-to-date information possible for their 60 percent compliance purposes. Therefore, we proposed that each year's updated lists of ICD–10–CM codes for presumptive compliance methodology will be available on the IRF PPS Web site (located at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Data-Files.html*) prior to the effective date of the changes to the ICD–10 medical code data set.

The current presumptive compliance lists are available for download from the IRF PPS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Criteria.html.* These lists reflect the substantive revisions outlined in this final rule, as well as adoption of the ICD–10 Coordination and Maintenance Committee's draft changes to the ICD–10 medical code data sets, effective October 1, 2017. The version of these lists that is finalized in conjunction with this final rule will constitute the baseline for any future updates to the presumptive methodology lists.

We received 13 public comments on the proposed subregulatory process for certain updates to the presumptive methodology ICD–10–CM code lists, which are summarized below.

*Comment:* Several commenters suggested that we more clearly define how we determine a ''substantive'' change versus a ''non-substantive'' change in regards to the proposed subregulatory process to update the presumptive methodology code lists. Another commenter stated that any change or modification to the presumptive methodology that would make it more restrictive, should be viewed as ''substantive'' and thus should not be performed outside of formal notice and comment procedures. However, this commenter believed that changes that make the presumptive methodology less restrictive would be best immediately implemented. Still, several other commenters stated that they supported the proposal to make non-substantive changes to the presumptive methodology lists in accordance with annual changes to the ICD–10–CM code set. This commenter stated that mirroring the ICD–10–CM code set updates without a timing delay (like that of a formal proposed rule schedule) would provide better synchronization with national coding standards.

*Response:* The proposed subregulatory process would only be used to make changes that are necessary to maintain consistency with the most current ICD–10 medical code data set, which Medicare providers are generally required to use in accordance with 45 CFR part 162, subpart J. Our intent in applying these changes through the subregulatory process is to keep the same conditions on the presumptive methodology lists, but ensure that the codes used to identify those conditions are synchronized with the most current ICD–10 medical code data set.

We note that we would not make any policy judgments in adopting the changes to the ICD–10 medical code data set through subregulatory means.

Any substantive changes to the lists of codes used in the presumptive compliance methodology would be promulgated through notice-and-comment rulemaking.

*Comment:* One commenter stated that since the ICD–10–CM medical data code set changes are finalized more than a year in advance of the implementation date, CMS has sufficient time to include these changes in annual rulemaking. The commenter stated that the changes that are necessary to maintain consistency with the most current ICD–10 medical data code set should not necessarily be considered ''non-substantive.''

*Response:* The commenter is incorrect that the updates to the ICD–10 medical code data set are finalized each year more than a year before the changes become effective. ICD–10 medical data code set changes are generally finalized in June of each year, and take effect on October 1 of that same year. For further discussion of the ICD–10 Coordination and Maintenance Committee and the process that the committee uses to update the ICD–10 medical code data set, please refer to the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19850 through 19852). Thus, we do not believe that we would have sufficient time to include these changes in the annual rulemaking.

*Comment:* Several commenters stated that if CMS finalizes this proposed sub-regulatory process, it should clearly delineate the changes in a manner that makes clear what diagnosis codes are being deleted or added.

*Response:* We appreciate these suggestions and will provide lists of which codes are being added and removed as part of this subregulatory process in conjunction with the IRF final rule or notice for each fiscal year.

*Final Decision:* After careful consideration of the comments we received on the proposed subregulatory process for adopting changes to the ICD–10–CM medical code data set for the presumptive methodology lists, we are finalizing this proposed subregulatory process, effective for discharges occurring on and after October 1, 2017. We are providing a list of the codes that indicates whether codes are being added, removed, or the code label revised for FY 2018 as a result of this subregulatory process on the CMS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Data-Files.html* in conjunction with this final rule.

## XII. Use of IRF–PAI Data To Determine Patient Body Mass Index (BMI) Greater Than 50 for Cases of Lower Extremity Single Joint Replacement

Previously, we had no information from the IRF–PAI that we could use to calculate the BMI for patients. Thus, we were not able to count lower-extremity joint replacement patients with BMI greater than 50 as meeting the 60 percent rule requirements using the presumptive compliance methodology. We could only identify these specific patients using the medical review methodology.

In the FY 2014 IRF PPS final rule (78 FR 47860, 47896 and 47899), we added Item 25A-Height and Item 26A-Weight to the IRF–PAI. This information can be used to calculate BMI and thereby provides the data necessary to presumptively identify and count lower extremity single joint replacement cases with a BMI greater than 50 in an IRF's 60 percent rule compliance percentage. In the proposed rule, we proposed to use the information recorded for Item 25A-Height and Item 26A-Weight on the IRF–PAI in the calculation of a patient BMI greater than 50 and to use that data to determine and presumptively count lower extremity single joint replacement cases toward an IRF's compliance percentage.

We received 2 public comments on the proposed plan to calculate BMI greater than 50 for cases of lower extremity single joint replacement, which are summarized below.

*Comment:* One commenter expressed support for this proposal as it would serve to identify a patient's BMI without the need for a separate medical review. Another commenter expressed concern about using the information recorded for Item 25A-Height and Item 26A-Weight on the IRF–PAI to calculate BMI greater than 50 for cases of lower extremity single joint replacement and thereby provide the data necessary to presumptively identify and count lower extremity single joint replacement cases with a BMI greater than 50 in an IRF's 60 percent rule compliance percentage. The commenter stated that this method would be inconsistent with other methods we use to determine presumptive compliance, that is, through ICD–10–CM diagnosis codes. The commenter suggested that the ICD–10–CM code Z68.43—Body mass index (BMI) 50–59.9, adult be included on the Presumptive Methodology list. Moreover, the commenter stated that using this code as an etiologic diagnosis or comorbid condition instead of using two items from the IRF–PAI that previously have been unrelated to the presumptive methodology would be more straightforward.

*Response:* We disagree with the commenter's statement that we only use ICD–10–CM codes in the presumptive compliance methodology. In fact, as indicated on page 8 of the specifications document entitled ''Determining IRF Compliance_specifications_081915.pdf'' (available for download from the IRF PPS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Criteria.html),* we already use a patient's age, as calculated as the number of complete years between the admission date and the patient's birth date, to count patients presumptively who are being treated in the IRF for lower-extremity joint replacement and are over the age of 85. Using the height and weight items on the IRF–PAI to compute a patient's BMI is consistent with this approach. As the height and weight information is required on the IRF–PAI, we believe that this information would be more reliable and less burdensome than depending on the IRF to code an additional etiologic code or comorbidity using ICD–10–CM code Z68.43—Body mass index (BMI) 50–59.9.

*Final Response:* After careful consideration of the comments we received, we are finalizing our proposal to use the information recorded for Item 25A-Height and Item 26A-Weight on the IRF–PAI to calculate BMI greater than 50 for cases of lower extremity single joint replacement and to use that data to determine and presumptively count lower extremity single joint replacement cases toward an IRF's presumptive compliance percentage, effective for all IRF discharges occurring on and after October 1, 2017.

## XIII. Revisions and Updates to the IRF Quality Reporting Program (QRP)

### *A. Background and Statutory Authority*

Section 3004(b) of the PPACA amended section 1886(j) of the Act by adding paragraph (7), requiring the Secretary to establish the IRF QRP. This program applies to freestanding IRFs, as well as IRF units affiliated with either acute care facilities or critical access hospitals. Beginning with the FY 2014 IRF QRP, the Secretary is required to reduce any annual update to the standard federal rate for discharges occurring during such fiscal year by 2 percentage points for any IRF that does not comply with the requirements established by the Secretary. Section 1886(j)(7) of the Act requires that for the FY 2014 IRF QRP, each IRF submit data on quality measures specified by the Secretary in a form and manner, and at

a time, specified by the Secretary. For more information on the statutory history of the IRF QRP, please refer to the FY 2015 IRF PPS final rule (79 FR 45908).

When we use the term ''FY [year] IRF QRP'', we are referring to the fiscal year for which the IRF QRP requirements applicable to that fiscal year must be met for a IRF to receive the full annual update when calculating the payment rates applicable to it for that fiscal year.

The Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) amended Title XVIII of the Act, in part, by adding a new section 1899B, entitled ''Standardized Post-Acute Care (PAC) Assessment Data for Quality, Payment and Discharge Planning,'' that enacts new data reporting requirements for certain post-acute care (PAC) providers, including IRFs. Specifically, sections 1899B(a)(1)(A)(ii) and (iii) of the Act require IRFs, long-term care hospitals (LTCHs), skilled nursing facilities (SNFs) and home health agencies (HHAs), under the provider type's respective quality reporting program (which, for IRFs, is found at section 1886(j)(7)), to report data on quality measures specified under section 1899B(c)(1), which in turn requires that the measures cover at least five domains, and data on resource use and other measures specified under section 1899B(d)(1), which in turn requires that the measures cover at least three domains. Section 1899B(a)(1)(A)(i) further requires each of these PAC providers to report under their respective quality reporting program standardized patient assessment data in accordance with section (b), which requires that the data be for at least the quality measures specified under section (c)(1) and that is for five specific categories: functional status; cognitive function and mental status; special services, treatments, and interventions; medical conditions and co-morbidities; and impairments. Section 1899B(a)(1)(B) requires that all of the data that must be reported in accordance with section 1899B(a)(1)(A) be standardized and interoperable to allow for the exchange of the information among PAC providers and other providers and the use of such data in order to enable access to longitudinal information and to facilitate coordinated care. For information on the IMPACT Act, please refer to the FY 2016 IRF PPS final rule (80 FR 47080 through 47083).

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

For a detailed discussion of the considerations we use for the selection of IRF QRP quality measures, such as alignment with the CMS Quality Strategy,[1] which incorporates the three broad aims of the National Quality Strategy,[2] please refer to the FY 2015 IRF PPS final rule (79 FR 45911) and the FY 2016 IRF PPS final rule (80 FR 47083 through 47084).

As part of our consideration for measures for use in the IRF QRP, we review and evaluate measures that have been implemented in other programs and take into account measures that have been endorsed by NQF for provider settings other than the IRF setting. We have previously adopted measures with the term ''Application of'' in the names of those measures. We have received questions pertaining to the term ''application'' and want to clarify that when we refer to a measure as an ''application of'' the measure, we mean that the measure will be used in the IRF setting, rather than the setting for which it was endorsed by the NQF. For example, in the FY 2016 IRF PPS final rule (80 FR 47096 through 47100), we adopted a measure entitled, Application of Percent of Residents Experiencing One or More Falls With Major Injury (Long Stay) (NQF #0674), which is currently endorsed for the nursing home setting, but not for the IRF setting. For such measures, we intend to seek NQF endorsement for the IRF setting, and if the NQF endorses one or more of them, we will update the title of the measure to remove the reference to ''application.''

We received several comments generally related to the proposed measures, the IMPACT Act, NQF endorsement, and training needs, which are summarized and discussed below.

*Comment:* Several commenters expressed support for the goals and objectives of the IMPACT Act, including the standardization of patient assessment data across PAC settings. One commenter noted that the collection of standardized patient assessment data in PAC settings will help ensure that PAC patients receive quality care in the appropriate setting. One commenter expressed support for the IMPACT Act quality measure domains and data elements. One commenter conveyed support for the continued additions and modifications to the IRF QRP as mandated by the IMPACT Act, stating that regulatory changes from the IRF QRP have not only required IRFs to focus more on care processes and data collection, but also promoted a shift in provider focus toward improved care quality, increased transparency, and enhanced provider accountability. A few commenters expressed appreciation for CMS' efforts to comply with the IMPACT Act, including CMS' efforts to maintain regular communication with stakeholders regarding the status of all aspects of the IMPACT Act implementation. However, one of the commenters indicated additional time may be necessary to fully implement changes outlined in the proposed rule.

*Response:* We appreciate the commenters' support for the goals and objectives of the IMPACT Act to standardize data across PAC settings. We believe that standardizing patient assessment data will allow for the exchange of data among PAC providers to facilitate care coordination and improve patient outcomes. We value feedback regarding appreciation for CMS' efforts to maintain regular communication with stakeholders regarding implementation of the IMPACT Act. We will continue to utilize different mechanisms to communicate with stakeholders including memos, emails, Medicare Learning Network (MLN) announcements, and notices on our IRF QRP Web site to communicate further regarding implementation of the IMPACT Act. We also appreciate the commenters' feedback regarding the need for sufficient time to implement required changes. We are cognizant that all quality reporting processes are on-going and take time to implement. We believe the rulemaking process takes these timing issues into account and permits sufficient time for providers to implement appropriate data collection and reporting processes.

*Comment:* A few commenters expressed concern about inconsistencies and insufficiencies in CMS training and support related to the collection of the quality measure data implemented in the IRF QRP. One commenter requested that CMS provide additional training materials and further clarification related to the collection of standardized patient assessment data, prior to the implementation of new quality measures.

*Response:* We appreciate commenter's feedback regarding the need for consistent training. We are committed to providing educational opportunities to

[1] *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.html*

[2] *http://www.ahrq.gov/workingforquality/nqs/nqs2011annlrpt.htm.*

ensure consistent collection of valid and reliable patient data. In order to ensure consistent data collection, we engage in multiple educational efforts regarding the coding of data elements. These include training events, updates to the manuals and training materials, and responses to Help Desk questions to promote understanding and proper coding of these data elements. As we further develop and modify any adopted quality measures or standardized patient assessment data elements, we will continue to engage in these training activities.

*Comment:* One commenter noted the role of the NQF-convened MAP and the role of this public-private partnership for meeting CMS goals. The commenter further noted that the NQF has improved transparency in measure selection. A few commenters expressed concern about quality measures that do not have NQF endorsement. One commenter stated that all quality measures should be NQF endorsed in order to demonstrate validity. One commenter expressed concern about quality measures specified to meet IMPACT Act requirements that do not have PAC setting-specific NQF endorsement. The commenter recommended that CMS delay or suspend the implementation of quality measures and standardized patient assessment data elements until the measures receive setting-specific NQF endorsement.

*Response:* We acknowledge that the NQF-convened MAP serves a critical function in evaluating measures under consideration and providing recommendations for measure implementation prior to rulemaking though MAP support is not a requirement for a measure to be proposed or finalized. However, as the MAP's role is to maintain transparency for the public and encourage public engagement throughout the measure development process, we value the MAP's input and take into consideration all input received.

We would like to clarify that the MAP recommended ''conditional support for rulemaking'' for the proposed measures for the IRF QRP. According to the MAP, the term ''conditional support for rulemaking'' is applied when a measure is fully developed and tested and meets MAP assessment criteria; however, should meet a condition specified by MAP before it can be supported for implementation. Measures that are conditionally supported are not expected to be resubmitted to MAP. In contrast, the MAP uses the phrase ''do not support'' when it does not support the measure at all.

For the proposed measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, the MAP Post-Acute Care/Long-Term Care (PAC/LTC) Workgroup met on December 14 and 15, 2016, and provided CMS a recommendation of ''support for rulemaking'' for use of the measure in the IRF QRP. The MAP Coordinating Committee met on January 24 and 25, 2017, and provided a recommendation of ''conditional support for rulemaking'' for use of the proposed measure in the IRF QRP. The MAP's conditions of support include as a part of measure implementation, that CMS provide guidance on the correct collection and calculation of the measure result. We intend to comply with all conditions recommended by the MAP and will engage in intensive training and guidance efforts to ensure appropriate calculation of the measure.

We have consistently used the MAP process to improve measures prior to rulemaking and implementation and to ensure continued enhancement of the IRF QRP. We believe that the measures have been fully and robustly developed, and believe they are appropriate for implementation and should not be delayed.

*Comment:* We received a few comments regarding standardization and interoperability of quality measures and patient assessment data elements. One commenter expressed concern about quality measures specified to meet IMPACT Act requirements that are not standardized and interoperable across PAC settings. The commenter recommended that CMS delay or suspend the implementation of quality measures and patient assessment data elements until the quality measures are standardized and interoperable across all PAC settings. Another commenter stated that the IRF–PAI, LTCH Care Data Set, MDS 3.0, and OASIS assessment instruments are not interoperable and not appropriate for measuring standardized patient assessment data across PAC settings. The commenter recommended that CMS develop a new uniform reporting tool that is interoperable across PAC settings, in order to align quality measures across PAC settings, further the objectives of the IMPACT Act, simplify reporting requirements, and reduce the financial and administrative burden of the IRF–PAI.

*Response:* The data elements currently included in IMPACT Act measures are standardized and have been mapped to electronic exchange content standard vocabularies (such as LOINC and SNOMED) to enable interoperability. We are engaging in efforts to further facilitate interoperability, including populating the Data Element Library (DEL) data base. The DEL includes information to support interoperability, including information on patient assessment data elements, the domain of the element, whether the data elements are standardized across patient assessment instruments and applicable health information technology content and exchange standards. Regarding the recommendation that CMS delay or suspend the implementation of quality measures and patient assessment data elements, we discuss below our decision to not finalize the majority of our proposals related to the reporting of standardized patient assessment data.

As for the request for a new uniform reporting tool, we recognize that data are currently collected by means of the commonly leveraged assessment instruments for each PAC setting; however, each assessment instrument has been developed to address patient care specific to that setting. Also, the use of setting-specific data elements and quality measures helps ensure that measures assess patient populations appropriately by setting and would preclude the development of a uniform assessment instrument that is utilized across PAC settings. Finally, data collected via assessment instruments are also used for other purposes, including for payment, survey, and certification.

*Comment:* One commenter noted the role of the IMPACT Act in standardizing data collection across PAC settings to facilitate meaningful comparisons between PAC settings and protect Medicare beneficiaries against underservice. One commenter expressed agreement with CMS that quality improvement is appropriate for all patients regardless of payer source and expressed concern, along with several other commenters, that data for assessment-based quality measures are collected on different patient populations across PAC settings, inhibiting cross-setting comparison and impacting data validity and reliability. One commenter expressed concern that quality measures with different patient populations in the denominator are misleading to consumers and providers and requested that CMS clearly identify which measures are comparable. One commenter recommended that quality measures and data collection implemented under the IMPACT Act apply to uniform Medicare populations. One commenter expressed concern that the definition for standardized patient assessment data may be misinterpreted to mean that measures developed using standardized patient assessment data are identical across PAC settings. The

commenter expressed further concern that IMPACT Act measures are developed by PAC setting rather than across PAC settings, resulting in measures that use standardized assessment data but have risk adjustment and covariates that are unique to each PAC setting, limiting comparability. Multiple commenters expressed concern that current and proposed quality measures are not comparable across PAC settings because the measures are not adequately standardized across settings. One commenter noted that measures are not comparable across PAC settings because measures are not consistently representative of unique patient populations by PAC setting. One commenter expressed concern that some measures are not only not comparable across PAC settings, but also not comparable over time within the same PAC setting.

*Response:* We appreciate comments regarding support for the IMPACT Act and quality improvement efforts for all patients regardless of payer source. While we acknowledge data for assessment-based quality measures are currently collected on different patient populations across PAC settings, primarily related to payer, we note that measures are developed and tested in their intended settings, ensuring greater reliability and validity.

Regarding the concern that quality measures with different patient population denominators are misleading, we seek to clarify the intent and use of quality measures through rulemaking, provider training and ongoing communication with stakeholders. Ongoing communication includes posting measure specifications and public reporting.

Additionally, we are working, in collaboration with our measure contractors, to standardize the measure methodology where feasible. For example, the patient assessment-based measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, was developed to be uniform across the PAC settings in terms of the measure definitions, measure calculations, and risk-adjustment. However, there is currently variation in the measure across settings primarily due to the data sources for each PAC setting. Refinement of measures is a significant part of the measure lifecycle which ensures that measures are reliable and valid. If significant refinements or modifications are made to measures, we will ensure these changes are clearly communicated to all stakeholders.

*Comment:* Several commenters expressed concern regarding the increasing burden of reporting data under the current IRF QRP. Several commenters expressed concern that increased administrative burden requires additional facility clinical staff for data collection, which may take time away from patient care. One commenter expressed concern about time and financial resources expended on staff training to ensure data reporting accuracy. One commenter expressed concern about an increased regulatory and financial burden for providers without evidence of increased care quality or cost reduction. A few commenters stated that the IRF–PAI has increased in length and now requires clinicians to spend additional time on patient assessments. One commenter recommended that CMS further harmonize measures to reduce burden and enable clinical staff to focus on patient care.

*Response:* We appreciate the commenters' concerns regarding perceived burden due to changes to the IRF QRP as a result of the IMPACT Act. Further, we appreciate the importance of avoiding undue burden on providers and will continue to evaluate and avoid any unnecessary burden associated with the implementation of the IRF QRP. We will continue to work with stakeholders to explore ways to minimize and decrease burden as our mutual goal is to focus on improving patient care. Finally, in response to stakeholders' concerns regarding burden, and as discussed further below, we have decided not to finalize a number of the proposed standardized patient assessment data elements.

*Comment:* Several commenters expressed concern about the frequency of modifications to assessment items and measure calculation methods. Two commenters expressed concern that the frequency of modifications result in inconsistent data, making provider performance monitoring more difficult. One of these commenters also expressed concern that the frequency of modifications could adversely impact data reliability and validity, citing provider struggles with inconsistent data collection specifications, training materials, and feedback. Several commenters conveyed concern that providers have not had sufficient time to adjust to the volume of new data items and the frequency of modifications to the IRF QRP, including time to augment work flow processes, update data infrastructures, and train staff for changes to data collection requirements. One commenter acknowledged that implementation timeframe requirements are imposed by the IMPACT Act, but expressed that timeframe requirements do not allow sufficient time for successful implementation. One commenter requested that CMS use discretion and allow for phased implementation. One commenter recommended that CMS delay or suspend the implementation of new and previously finalized quality measures and patient assessment data elements until CMS provides evidence that standardized patient assessment data can be feasibly collected, and improves quality of care for patients. The commenter further recommended delay of the quality measures until CMS provides full support for the measures including training materials, data-collection specifications, and responses to provider questions.

*Response:* We appreciate commenters' feedback regarding concerns about frequent changes to quality measures and the inability to consistently monitor performance related to changes in IRF QRP quality measures over time. We note that we have implemented modifications in data items and calculation methods for previously finalized measures primarily to improve quality measure reliability and validity and to increase standardization across PAC settings. These changes are part of the phased approach CMS adopted to meet the IMPACT Act requirements. We recognize that frequent changes are disruptive and strive to avoid unnecessary measure and manual revisions. While we aim to avoid unnecessary changes, we acknowledge that modifying measures is an important part of the measure lifecycle to ensure measures are scientifically sound. We will further our monitoring and data evaluation efforts in order to ensure we limit the frequent modifications.

We also appreciate the feedback regarding the need for sufficient time to implement required changes. We are cognizant that all quality reporting processes are on-going and can take time to implement. We strive to provide sufficient training and education and advance notice of changes to support providers in adapting to changes. Regarding the recommendation that CMS delay or suspend the implementation of new and previously finalized quality measures and patient assessment data elements, below we discuss our decision to not finalize the majority of our proposals related to the reporting of standardized patient assessment data. With regard to previously finalized measures and data items, we wish to clarify that we have provided trainings, manuals, and ongoing Help Desk support to facilitate successful and accurate implementation by facilities.

1. Measuring and Accounting for Social Risk Factors in the IRF QRP

In the FY 2018 IRF PPS proposed rule (82 FR 20715), we discussed accounting for social risk factors in the IRF QRP. We stated that we consider related factors that may affect measures in the IRF QRP. We understand that social risk factors such as income, education, race and ethnicity, employment, disability, community resources, and social support (certain factors of which are also sometimes referred to as socioeconomic status (SES) factors or socio-demographic status (SDS) factors) play a major role in health. One of our core objectives is to improve beneficiary outcomes, including reducing health disparities, and we want to ensure that all beneficiaries, including those with social risk factors, receive high quality care. In addition, we seek to ensure that the quality of care furnished by providers and suppliers is assessed as fairly as possible under our programs while ensuring that beneficiaries have adequate access to excellent care.

We have been reviewing reports prepared by the Office of the Assistant Secretary for Planning and Evaluation (ASPE [3]) and the National Academies of Sciences, Engineering, and Medicine on the issue of measuring and accounting for social risk factors in CMS' quality measurement and payment programs, and considering options on how to address the issue in these programs. On December 21, 2016, ASPE submitted a Report to Congress on a study it was required to conduct under section 2(d) of the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014. The study analyzed the effects of certain social risk factors of Medicare beneficiaries on quality measures and measures of resource use used in one or more of nine Medicare value-based purchasing programs.[4] The report also included considerations for strategies to account for social risk factors in these programs. In a January 10, 2017 report released by The National Academies of Sciences, Engineering, and Medicine, that body provided various potential methods for measuring and accounting for social risk factors, including stratified public reporting.[5]

As discussed in the FY 2017 IRF PPS proposed rule (81 FR 52056), the NQF undertook a 2-year trial period in which new measures, measures undergoing maintenance review and measures endorsed with the condition that they enter the trial period can be assessed to determine whether risk adjustment for selected social risk factors is appropriate for these measures. This trial entailed temporarily allowing inclusion of social risk factors in the risk-adjustment approach for these measures. The trial has concluded and NQF will issue recommendations on the future inclusion of social risk factors in risk adjustment for quality measures.

As we continue to consider the analyses and recommendations from these reports and await the results of the NQF trial on risk adjustment for quality measures, we are continuing to work with stakeholders in this process. As we previously communicated, we are concerned about holding providers to different standards for the outcomes of their patients with social risk factors because we do not want to mask potential disparities or minimize incentives to improve the outcomes for disadvantaged populations. Keeping this concern in mind, while we sought input on this topic previously, we continue to seek public comment on whether we should account for social risk factors in measures in the IRF QRP, and if so, what method or combination of methods would be most appropriate for accounting for social risk factors. Examples of methods include: confidential reporting to providers of measure rates stratified by social risk factors, public reporting of stratified measure rates, and potential risk adjustment of a particular measure as appropriate based on data and evidence.

In addition, in the FY 2018 IRF PPS proposed rule (82 FR 20715), we sought public comment on which social risk factors might be most appropriate for reporting stratified measure scores and/or potential risk adjustment of a particular measure. Examples of social risk factors include, but are not limited to, dual eligibility/low-income subsidy, race and ethnicity, and geographic area of residence. We sought comments on which of these factors, including current data sources where this information would be available, could be used alone or in combination, and whether other data should be collected to better capture the effects of social risk. We will take the commenters' input into consideration as we continue to assess the appropriateness and feasibility of accounting for social risk factors in the IRF QRP. We note that any such changes would be proposed through future notice and comment rulemaking.

We look forward to working with stakeholders as we consider the issue of accounting for social risk factors and reducing health disparities in CMS programs. Of note, implementing any of the above methods would be taken into consideration in the context of how this and other CMS programs operate (for example, data submission methods, availability of data, statistical considerations relating to reliability of data calculations, among others), so we sought comment on operational considerations. We are committed to ensuring that beneficiaries have access to and receive excellent care, and that the quality of care furnished by providers and suppliers is assessed fairly in CMS programs.

We received several comments in response to our request for public comment on accounting for social risk factors in the calculation of measures adopted for the IRF QRP, which are summarized below.

*Comment:* Some commenters expressed appreciation for the agency's efforts and ongoing consideration of this issue. Commenters were generally supportive of accounting for social risk factors for IRF QRP quality measures. Some commenters stated that social risk factors are beyond the control of the facility and were concerned that without risk adjustment, differences in quality scores may reflect differences in patient populations rather than differences in quality, which may be misleading to patients, payers, and policy makers. Commenters also recommended incorporating the results of the ASPE's Report to Congress into consideration of adopting risk-adjustment strategies.

A few commenters, while acknowledging the influence of social risk factors on health outcomes, cautioned against adjusting for them in quality measurement due to the potential for unintended consequences. Several commenters expressed concern that adjusting for social risk factors may mask potential disparities and create disincentives to improve outcomes for vulnerable populations. Another commenter believes that social risk factors may be too subjective to adequately quantify and monitor over time.

Regarding the methodology for risk adjustment, some commenters made specific recommendations regarding the type of risk adjustment to be used. Several commenters endorsed risk stratification as a means of enabling providers to compare themselves to their peers and identify opportunities for improvement. MedPAC noted that the stratification approach of peer

[3] *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[4] *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[5] National Academies of Sciences, Engineering, and Medicine. 2017. Accounting for social risk factors in Medicare payment. Washington, DC: The National Academies Press.

grouping of facilities would be straightforward to implement and would allow for shared social risk factors in a patient population to be considered without being dampened by other, non-social, individual patient characteristics. A few commenters drew attention to how adjustment should be conducted on a measure-specific basis, as different social risk factors affect different outcomes such as caregiver satisfaction and care delivery. Multiple commenters recommended further research into and testing of risk-adjustment methods.

One commenter expressed support for risk stratification, but only as a temporary solution while CMS continues to explore more robust risk adjustment factors. Another commenter suggested using multivariate regression analyses to determine the impact of various social risk factors on health outcomes and stated that the use of a composite measure framework will ensure that idiosyncrasies of patient populations are preserved.

In addition to expressing support for CMS's suggested categories of race/ethnicity, dual eligibility status, and geographical location, specific social risk factors suggested by commenters included: Availability of primary care and therapy services, access to food and medications, community resources, lack of personal resources, age, gender, comorbidities, education level, limited English proficiency, healthcare literacy, lack of adequate support system, living conditions including homelessness, and home access, unemployment, cognition, presence of pre-morbid assistance, and the presence and physical ability of a caregiver. While several commenters suggested the use of dual-eligibility status as an indicator, one commenter cautioned against its use because it takes neither community-based social risk factors associated with patient residence nor facility location into account. Another commenter suggested utilizing the Distressed Community Index compiled by the Economic Innovation Group.

A few commenters discussed confidential and public display of data adjusted for social risk factors. Many of these commenters advocated for initial confidential reporting of risk stratified performance to providers, and for the eventual public reporting of this information.

Other commenters recommended adjusting for social risk factors, specifically for resource use measures assessing potentially preventable readmissions, discharge to community, and Medicare spending per beneficiary. Several commenters recommended conducting additional testing and evaluating this on a measure by measure basis.

*Response:* As we have previously stated, we are concerned about holding providers to different standards for the outcomes of their patients with social risk factors, because we do not want to mask potential disparities. We believe that the path forward should incentivize improvements in health outcomes for disadvantaged populations while ensuring that beneficiaries have adequate access to excellent care. We will consider all suggestions as we continue to assess each measure and the overall program. We intend to explore options including but not limited to measure stratification by social risk factors in a consistent manner across programs, informed by considerations of stratification methods described in section IX.A.13 of the FY 2018 IPPS/LTCH PPS final rule. We appreciate the commenters for this important feedback and will continue to consider options to account for social risk factors that would allow us to view disparities and potentially incentivize improvement in care for patients and beneficiaries. We will also consider providing feedback to providers on outcomes for individuals with social risk factors in confidential reports.

*C. Collection of Standardized Patient Assessment Data Under the IRF QRP*

1. Definition of Standardized Patient Assessment Data

Section 1886(j)(7)(F)(ii) of the Act requires that for fiscal year 2019 (beginning October 1, 2018) and each subsequent year, IRFs report standardized patient assessment data required under section 1899B(b)(1) of the Act. For purposes of meeting this requirement, section 1886(j)(7)(F)(iii) of the Act requires an IRF to submit the standardized patient assessment data required under section 1899B(b)(1) of the Act using the standard instrument in a time, form, and manner specified by the Secretary.

Section 1899B(b)(1)(B) of the Act describes standardized patient assessment data as data required for at least the quality measures described in section 1899B(c)(1) of the Act and that is for the following categories:

- Functional status, such as mobility and self-care at admission to a PAC provider and before discharge from a PAC provider;
- Cognitive function, such as ability to express ideas and to understand and mental status, such as depression and dementia;
- Special services, treatments and interventions such as the need for ventilator use, dialysis, chemotherapy, central line placement and total parenteral nutrition (TPN);
- Medical conditions and co-morbidities such as diabetes, congestive heart failure and pressure ulcers;
- Impairments, such as incontinence and an impaired ability to hear, see or swallow; and
- Other categories deemed necessary and appropriate.

As required under section 1899B(b)(1)(A) of the Act, the standardized patient assessment data must be reported at least for IRF admissions and discharges, but the Secretary may require the data to be reported more frequently.

In this final rule, we define the standardized patient assessment data that IRFs must report to comply with section 1886(j)(7)(F)(ii) of the Act, as well as the requirements for the reporting of these data. The collection of standardized patient assessment data is critical to our efforts to drive improvement in healthcare quality across the four post-acute care (PAC) settings to which the IMPACT Act applies. We intend to use these data for a number of purposes, including facilitating their exchange and longitudinal use among healthcare providers to enable high quality care and outcomes through care coordination, as well as for quality measure calculations, and identifying comorbidities that might increase the medical complexity of a particular admission.

IRFs are currently required to report patient assessment data through the IRF–PAI by responding to an identical set of assessment questions using an identical set of response options (we refer to each solitary question/response option as a data element and we refer to a group of questions/responses as data elements), both of which incorporate an identical set of definitions and standards. The primary purpose of the identical questions and response options is to ensure that we collect a set of standardized patient assessment data elements across IRFs which can then be used for a number of purposes, including IRF payment and measure calculation for the IRF QRP.

LTCHs, skilled nursing facilities (SNFs), and home health associations (HHAs) are also required to report patient assessment data through their applicable PAC assessment instruments, and they do so by responding to identical assessment questions developed for their respective settings using an identical set of response

options (which incorporate an identical set of definitions and standards). Like the IRF–PAI, the questions and response options for each of these other PAC assessment instruments are standardized across the PAC provider type to which the PAC assessment instrument applies. However, the assessment questions and response options in the four PAC assessment instruments are not currently standardized with each other. As a result, questions and response options that appear on the IRF–PAI cannot be readily compared with questions and response options that appear, for example, on the MDS, the PAC assessment instrument used by SNFs. This is true even when the questions and response options are similar. This lack of standardization across the four PAC providers has limited our ability to compare one PAC provider type with another for purposes such as care coordination and quality improvement.

To achieve a level of standardization across SNFs, LTCHs, IRFs, and HHAs that enables us to make comparisons between them, we proposed to define ''standardized patient assessment data'' as patient assessment questions and response options that are identical in all four PAC assessment instruments, and to which identical standards and definitions apply.

Standardizing the questions and response options across the four PAC assessment instruments will also enable the data to be interoperable, allowing it to be shared electronically, or otherwise, between PAC provider types. It will enable the data to be comparable for various purposes, including the development of cross-setting quality measures, which may enhance provider and patient choice when selecting a post-acute care setting that will deliver the best outcome possible, and to inform payment models that take into account patient characteristics rather than setting, as described in the IMPACT Act.

We proposed to define ''standardized patient assessment data'' as patient assessment questions and response options that are identical in all four PAC assessment instruments, and to which identical standards and definitions apply. We solicited comments on this proposal.

We did not receive any specific comments on the proposed definition.

*Final Decision:* We are finalizing as proposed our proposed definition of standardized patient assessment data.

2. General Considerations Used for the Selection of Standardized Patient Assessment Data

As part of our effort to identify appropriate standardized patient assessment data for purposes of collecting under the IRF QRP, we sought input from the general public, stakeholder community, and subject matter experts on items that would enable person-centered, high quality health care, as well as access to longitudinal information to facilitate coordinated care and improved beneficiary outcomes.

To identify optimal data elements for standardization, our data element contractor organized teams of researchers for each category, and each team worked with a group of advisors made up of clinicians and academic researchers with expertise in PAC. Information-gathering activities were used to identify data elements, as well as key themes related to the categories described in section 1899B(b)(1)(B) of the Act. In January and February 2016, our data element contractor also conducted provider focus groups for each of the four PAC provider types, and a focus group for consumers that included current or former PAC patients and residents, caregivers, ombudsmen, and patient advocacy group representatives. The Development and Maintenance of Post-Acute Care Cross-Setting Standardized Patient Assessment Data Focus Group Summary Report is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Our data element contractor also assembled a 16-member TEP that met on April 7 and 8, 2016, and January 5 and 6, 2017, in Baltimore, Maryland, to provide expert input on data elements that are currently in each PAC assessment instrument, as well as data elements that could be standardized. The Development and Maintenance of Post-Acute Care Cross-Setting Standardized Patient Assessment Data TEP Summary Reports are available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

As part of the environmental scan, data elements currently in the four existing PAC assessment instruments were examined to see if any could be considered for proposal as standardized patient assessment data. Specifically, this evaluation included consideration of data elements in OASIS–C2 (effective January 2017); IRF–PAI, v1.4 (effective October 2016); LCDS, v3.00 (effective April 2016); and MDS 3.0, v1.14 (effective October 2016). Data elements in the standardized assessment instrument that we tested in the Post-Acute Care Payment Reform Demonstration (PAC PRD)—the Continuity Assessment Record and Evaluation (CARE) were also considered. A literature search was also conducted to determine whether additional data elements to propose as standardized patient assessment data could be identified.

We additionally held four Special Open Door Forums (SODFs) on October 27, 2015; May 12, 2016; September 15, 2016; and December 8, 2016, to present data elements we were considering and to solicit input. At each SODF, some stakeholders provided immediate input, and all were invited to submit additional comments via the CMS IMPACT Mailbox at *PACQualityInitiative@cms.hhs.gov.*

We also convened a meeting with federal agency subject matter experts (SMEs) on May 13, 2016. In addition, a public comment period was open from August 12, to September 12, 2016, to solicit comments on detailed candidate data element descriptions, data collection methods, and coding methods. The IMPACT Act Public Comment Summary Report containing the public comments (summarized and verbatim) and our responses is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We specifically sought to identify standardized patient assessment data that we could feasibly incorporate into the LTCH, IRF, SNF, and HHA assessment instruments and that have the following attributes: (1) Being supported by current science; (2) testing well in terms of their reliability and validity, consistent with findings from the Post-Acute Care Payment Reform Demonstration (PAC PRD); (3) the potential to be shared (for example, through interoperable means) among PAC and other provider types to facilitate efficient care coordination and improved beneficiary outcomes; (4) the potential to inform the development of quality, resource use and other measures, as well as future payment methodologies that could more directly take into account individual beneficiary health characteristics; and (5) the ability

to be used by practitioners to inform their clinical decision and care planning activities. We also applied the same considerations that we apply with quality measures, including the CMS Quality Strategy which is framed using the three broad aims of the National Quality Strategy.

*D. Policy for Retaining IRF QRP Measures and Application of That Policy to Standardized Patient Assessment Data*

In the CY 2013 Hospital Outpatient Prospective Payment System/Ambulatory Surgical Center (OPPS/ASC) Payment Systems and Quality Reporting Programs final rule (77 FR 68500 through 68507), we adopted a policy that allows any quality measure adopted for use in the IRF QRP to remain in effect until the measure is removed, suspended, or replaced. For further information on how measures are considered for removal, suspension, or replacement, please refer to the CY 2013 OPPS/ASC final rule (77 FR 68500). We proposed to apply this policy to the standardized patient assessment data that we adopt for the IRF QRP.

*Comment:* We received comments in support of our proposal to apply the existing policy for retaining IRF QRP quality measures to standardized patient assessment data.

*Response:* We appreciate the commenters' support.

*Final decision:* We are finalizing our proposal to apply the policy for retaining IRF QRP measures to standardized patient assessment data.

*E. Policy for Adopting Changes to IRF QRP Measures and Application of That Policy to the Standardized Patient Assessment Data That We Adopt for the IRF QRP*

In the CY 2013 OPPS/ASC final rule (77 FR 68500 through 68507), we adopted a subregulatory process to incorporate updates to IRF quality measure specifications that do not substantively change the nature of the measure. Under that policy, substantive changes to quality measures are proposed and finalized through rulemaking. For further information on what constitutes a substantive versus a non-substantive change and the subregulatory process we use to make non-substantive changes to measures, please refer to the CY 2013 OPPS/ASC final rule (77 FR 68500). We proposed that this policy would be applied to the standardized patient assessment data that we adopt for the IRF QRP.

*Comment:* One commenter supported our proposal to apply our current policy for updating measures to the standardized patient assessment data. One commenter supported the concept of non-substantive changes, but expressed concern that CMS did not provide examples specific to the standardized patient assessment data. The commenter recommended that CMS delay this proposal until it has engaged stakeholders to vet examples of non-substantive changes. One commenter had concerns about the subjectivity of what is considered substantive, and suggested that CMS consider increased burden and any change that makes it more difficult for IRFs to fulfill their data collection obligations. The commenter encouraged CMS to use the rulemaking process to give stakeholders an opportunity to comment and allow time for training and preparation.

*Response:* In the CY 2013 OPPS/ASC final rule (77 FR 68500), we listed examples of what we might generally regard as a non-substantive change to a quality measure in the IRF QRP, including but not limited to, updated diagnosis or procedure codes, medication updates for categories of medications, or a broadening of age ranges. We stated that we will continue to use rulemaking to adopt substantive updates. Examples of changes that we might generally consider to be substantive would include, but are not limited to: Those circumstances in which the changes are so significant that the measure is no longer the same measure; when a standard of performance assessed by a measure becomes more stringent (for example, changes in acceptable timing of medication; and NQF expansion of endorsement of a previously endorsed measure to a new setting, procedure/process, or test administration). We believe that many of these criteria would also apply to standardized patient assessment data. However, these and other changes would need to be evaluated on a case by-case basis to determine whether or not a change to a measure is in fact substantive.

*Final Decision:* After consideration of the public comments, we are finalizing our proposal to apply the policy for adopting changes to IRF QRP measures to the standardized patient assessment data that we adopt for the IRF QRP.

*F. Quality Measures Currently Adopted for the IRF QRP*

The IRF QRP currently has 18 currently adopted measures, as outlined in Table 7.

We received several comments about quality measures currently adopted for the IRF QRP, which are summarized and discussed below.

*Comment:* A few commenters expressed views regarding previously finalized readmission measures for the IRF QRP. A few commenters expressed concern over the performance categories used for public reporting, and one commenter opposed public reporting of the all-cause and PPR measures until an alternative approach for reporting could be developed.

Commenters recommended additional transparency regarding the statistical methods used for measure calculation and suggested that CMS make patient-level data available to providers for quality improvement efforts. Some commenters recommended ongoing testing and evaluation of the PPR definition, and one expressed concern over hospital DRG coding practices. We also received several comments suggesting that the PPR measures be adjusted for social risk factors.

*Response:* We refer commenters to the FY 2017 IRF PPS final rule (81 FR 52103 through 52111) for detailed responses that address concerns related to statistical methods used for calculating these measures, the PPR definition, and hospital coding practices, which were raised by these commenters. For the same reasons we expressed in that final rule, we continue to believe that the measure specifications are appropriate for these measures.

We appreciate the commenters' concerns over the performance categories used to publicly display the IRF QRP readmission measures and refer readers to section XIII.O of this final rule for responses to comments regarding this topic.

We refer readers to section XIII.B.1. of this final rule for responses to comments received related to social risk factors for the IRF QRP PPR measures.

*Comment:* A few commenters expressed views regarding Medicare Spending per Beneficiary—PAC IRF QRP, a measure previously finalized in the FY 2017 IRF PPS final rule (81 FR 52087 through 52095). Commenters addressed the risk-adjustment approach, accounting for social risk factors, NQF endorsement, and unintended consequences related to implementation of the measure. One commenter expressed concern that the measure was not NQF-endorsed. Several commenters encouraged CMS to utilize claims and patient assessment data to incorporate functional status into the risk-adjustment. Another commenter believed that the measure was confusing, and that patients and providers might incorrectly interpret it as a measure of quality rather than efficiency. The commenter expressed concern that PAC providers'

performance on this measure would focus on costs per patient, without fully accounting for patient outcomes, and that efficiency should not be based solely on the MSPB–PAC measures. This commenter also noted that this measure may result in limiting access to certain patients.

*Response:* We addressed these issues in the FY 2017 IRF PPS final rule (81 FR 52087 through 52095), and we refer the reader to that detailed discussion. We continue to believe that the measure specifications, including the risk-adjustment, are appropriate for this measure. With regard to comments related to accounting for social risk factors, we refer readers to section XIII.B.1 of this rule.

*Comment:* We received comments related to the Discharge to Community-PAC IRF QRP measure, a measure previously finalized in the FY 2017 IRF PPS final rule. Comments included suggestions to adjust for sociodemographic and socioeconomic risk factors, to exclude patients who died in the observation window following return to a community setting, to distinguish between a patient's return to home in the community versus home in a custodial nursing facility, and to assess reliability and validity of the claims discharge status code used to calculate the measure.

*Response:* We previously responded to comments on these topics in the FY 2017 IRF PPS final rule (81 FR 52095 through 52103); we refer readers to the FY 2017 IRF PPS final rule for a detailed response on these issues. In the FY 2018 IRF PPS proposed rule (82 FR 20721), we sought comment on the exclusion of baseline nursing facility residents as a potential future modification of the Discharge to Community-PAC IRF QRP measure. We refer readers to section XIII.I of this rule for a discussion of this issue. With regard to comments related to social risk factors, we refer readers to section XIII.B.1 of this final rule.

TABLE 7—QUALITY MEASURES CURRENTLY ADOPTED FOR THE IRF QRP

| Short name | Measure name and data source |
|---|---|
| **IRF–PAI** | |
| Pressure Ulcers | Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678). |
| Patient Influenza Vaccine | Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680). |
| Application of Falls | Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674).* |
| Application of Functional Assessment. | Application of Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631).* |
| Change in Self-Care | IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (NQF #2633).** |
| Change in Mobility | IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634).** |
| Discharge Self-Care Score | IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (NQF #2635).** |
| Discharge Mobility Score | IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (NQF #2636).** |
| DRR | Drug Regimen Review Conducted with Follow-Up for Identified Issues–PAC IRF QRP.* |
| **NHSN** | |
| CAUTI | National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138). |
| MRSA | NHSN Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure (NQF #1716). |
| CDI | NHSN Facility-wide Inpatient Hospital-Onset Clostridium difficile Infection (CDI) Outcome Measure (NQF #1717). |
| HCP Influenza Vaccine | Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431). |
| **Claims-based** | |
| All-Cause Readmissions | All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from IRFs (NQF #2502). |
| MSPB | Medicare Spending per Beneficiary (MSPB)–PAC IRF QRP.* |
| DTC | Discharge to Community–PAC IRF QRP.* |
| Potentially Preventable Readmissions (PPR) 30 day. | Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP.* |
| PPR Within Stay | Potentially Preventable Within Stay Readmission Measure for IRFs.* |

* Not currently NQF-endorsed for the IRF setting.
** In satisfaction of section 1899B(c)(1) of the Act quality measure domain: functional status, cognitive function, and changes in function and cognitive function domain.

### *G. IRF QRP Quality Measures Beginning With the FY 2020 IRF QRP*

In the FY 2018 IRF PPS Proposed Rule (82 FR 20718 through 20720), we proposed that beginning with the FY 2020 IRF QRP, in addition to the quality measures we are retaining under our policy described in section XIII.F. of this final rule, we will remove the current pressure ulcer measure entitled Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) and replace it with a modified version of the measure entitled Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury. We also proposed to characterize the data elements described below as standardized patient assessment data under section

1899B(b)(1)(B) of the Act that must be reported by IRFs under the IRF QRP through the IRF–PAI.

1. Replacing the Current Pressure Ulcer Quality Measure, Percent of Residents or Patients With Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), With a Modified Pressure Ulcer Measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury

a. Measure Background

In the FY 2018 IRF PPS proposed rule (82 FR 20717 through 20720), we proposed to remove the current pressure ulcer measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), from the IRF QRP measure set and to replace it with a modified version of that measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, beginning with the FY 2020 IRF QRP. The change in the measure name is to reduce confusion about the new modified measure. The modified version differs from the current version of the measure because it includes new or worsened unstageable pressure ulcers, including deep tissue injuries (DTIs), in the measure numerator. The proposed modified version of the measure also contains updated specifications intended to eliminate redundancies in the assessment items needed for its calculation and to reduce the potential for underestimating the frequency of pressure ulcers. The modified version of the measure would satisfy the IMPACT Act domain of skin integrity and changes in skin integrity.

b. Measure Importance

As described in the FY 2012 IRF PPS final rule (76 FR 47876 through 47878), pressure ulcers are high-cost adverse events and are an important measure of quality. For information on the history and rationale for the relevance, importance, and applicability of having a pressure ulcer measure in the IRF QRP, we refer readers to the FY 2012 IRF PPS final rule (76 FR 47876 through 47878) and the FY 2014 IRF PPS final rule (78 FR 47911 through 47912).

We proposed to adopt a modified version of the current pressure ulcer measure because unstageable pressure ulcers, including DTIs, are similar to Stage 2, Stage 3, and Stage 4 pressure ulcers in that they represent poor outcomes, are a serious medical condition that can result in death and disability, are debilitating and painful, and are often an avoidable outcome of medical care.[6] [7] [8] [9] [10] [11] Studies show that most pressure ulcers can be avoided and can also be healed in acute, post-acute, and long-term care settings with appropriate medical care.[12] Furthermore, some studies indicate that DTIs, if managed using appropriate care, can be resolved without deteriorating into a worsened pressure ulcer.[13] [14]

While there are few studies that provide information regarding the incidence of unstageable pressure ulcers in PAC settings, an analysis conducted by a contractor suggests the incidence of unstageable pressure ulcers varies according to the type of unstageable pressure ulcer and setting.[15] This analysis examined the national incidence of new unstageable pressure ulcers in IRFs at discharge compared with admission using IRF discharges from January through December 2015. The contractor found a national incidence of 0.14 percent of new unstageable pressure ulcers due to slough and/or eschar, 0.02 percent of new unstageable pressure ulcers due to non-removable dressing/device, and 0.26 percent of new DTIs. In addition, an international study spanning the time period 2006 to 2009 provides some evidence to suggest that the proportion of pressure ulcers identified as DTI has increased over time.[16] The study found DTIs increased by three fold, to 9 percent of all observed ulcers in 2009, and that DTIs were more prevalent than either Stage 3 or 4 ulcers. During the same time period, the proportion of Stage 1 and 2 ulcers decreased, and the proportion of Stage 3 and 4 ulcers remained constant.

The inclusion of unstageable pressure ulcers, including DTIs, in the numerator of this measure is expected to increase measure scores and variability in measure scores, thereby improving the ability to discriminate among poor- and high-performing IRFs. In the currently implemented pressure ulcer measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), analysis using data from Quarter 4 2016 reveals that the IRF mean score is 0.64 percent and the 25th and 75th percentiles are 0 percent and 0.95 percent, respectively. In the proposed measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, during the same timeframe, the IRF mean score is 1.46 percent and the 25th and 75th percentiles are 0 percent and 2.27 percent, respectively.

c. Stakeholder Feedback

Our measure development contractor sought input from subject matter experts, including Technical Expert Panels (TEPs), over the course of several years on various skin integrity topics and specifically those associated with the inclusion of unstageable pressure ulcers, including DTIs. Most recently, on July 18, 2016, a TEP convened by our measure development contractor provided input on the technical specifications of this quality measure, including the feasibility of implementing the proposed measure's updates across PAC settings. The TEP supported the updates to the measure across PAC settings, including the inclusion in the numerator of unstageable pressure ulcers due to slough and/or eschar that are new or worsened, new unstageable pressure ulcers due to a non-removable dressing or device, and new DTIs. The TEP also supported the use of different data elements for measure calculation. The TEP recommended supplying additional guidance to providers regarding each type of unstageable pressure ulcer. This support was in agreement with earlier TEP meetings, held on June 13 and

[6] Casey, G. (2013). ''Pressure ulcers reflect quality of nursing care.'' Nurs NZ 19(10): 20–24.

[7] Gorzoni, M.L. and S.L. Pires (2011). ''Deaths in nursing homes.'' Rev Assoc Med Bras 57(3): 327–331.

[8] Thomas, J.M., et al. (2013). ''Systematic review: health-related characteristics of elderly hospitalized adults and nursing home residents associated with short-term mortality.'' J Am Geriatr Soc 61(6): 902–911.

[9] White-Chu, E.F., et al. (2011). ''Pressure ulcers in long-term care.'' Clin Geriatr Med 27(2): 241–258.

[10] Bates-Jensen BM. Quality indicators for prevention and management of pressure ulcers in vulnerable elders. Ann Int Med. 2001;135 (8 Part 2), 744–51.

[11] Bennet, G, Dealy, C Posnett, J (2004). The cost of pressure ulcers in the UK, Age and Aging, 33(3):230–235.

[12] Black, Joyce M., et al. ''Pressure ulcers: avoidable or unavoidable? Results of the national pressure ulcer advisory panel consensus conference.'' Ostomy-Wound Management 57.2 (2011): 24.

[13] Sullivan, R. (2013). A Two-year Retrospective Review of Suspected Deep Tissue Injury Evolution in Adult Acute Care Patients. Ostomy Wound Management 59(9).

[14] Posthauer, ME, Zulkowski, K. (2005). Special to OWM: The NPUAP Dual Mission Conference: Reaching Consensus on Staging and Deep Tissue Injury. Ostomy Wound Management 51(4) *http://www.o-wm.com/content/the-npuap-dual-mission-conference-reaching-consensus-staging-and-deep-tissue-injury.*

[15] Final Specifications for IRF QRP Quality Measures and Standardized Patient Assessment Data Elements, available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.*

[16] VanGilder, C, MacFarlane, GD, Harrison, P, Lachenbruch, C, Meyer, S (2010). The Demographics of Suspected Deep Tissue Injury in the United States: An Analysis of the International Pressure Ulcer Prevalence Survey 2006–2009. Advances in Skin & Wound Care. 23(6): 254–261.

November 15, 2013, which had recommended that we update the specifications for the pressure ulcer measure to include unstageable pressure ulcers in the numerator.[17] [18] Exploratory data analysis conducted by our measure development contractor suggests that the addition of unstageable pressure ulcers, including DTIs, will increase the observed incidence and variation in the rate of new or worsened pressure ulcers at the facility level, which may improve the ability of the proposed quality measure to discriminate between poor- and high-performing facilities.

We solicited stakeholder feedback on this proposed measure by means of a public comment period held from October 17 through November 17, 2016. In general, we received considerable support for the proposed measure. A few commenters supported all of the changes to the current pressure ulcer measure that resulted in the proposed measure, with one commenter noting the significance of the work to align the pressure ulcer quality measure specifications across the PAC settings.

Many commenters supported the inclusion of unstageable pressure ulcers due to slough/eschar, non-removable dressing/device, and DTIs in the quality measure. Other commenters did not support the inclusion of DTIs in the quality measure because they stated that there is no universally accepted definition for this type of skin injury.

Some commenters provided feedback on the data elements used to calculate the proposed quality measure. We believe that these data elements will promote facilitation of cross-setting quality comparison as mandated by the IMPACT Act, alignment between quality measures and payment, reduction in redundancies in assessment items, and prevention of inappropriate underestimation of pressure ulcers. The currently implemented pressure ulcer measure is calculated using retrospective data elements that assess the number of new or worsened pressure ulcers at each stage, while the proposed measure is calculated using the number of unhealed pressure ulcers at each stage after subtracting the number that were present upon admission. Some commenters did not support the data elements that would be used to calculate the proposed measure and requested further testing of these data elements. Other commenters supported the use of these data elements, stating that these data elements simplified the measure calculation process.

The public comment summary report for the proposed measure is available on the CMS Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.* This summary includes further detail about our responses to various concerns and ideas stakeholders raised.

The NQF-convened Measures Application Partnership (MAP) Post-Acute Care/Long-Term Care (PAC/LTC) Workgroup met on December 14 and 15, 2016, and the MAP Coordinating Committee met on January 24 and 25, 2017, and provided input to CMS about this proposed measure. The MAP provided a recommendation of ''conditional support for rulemaking'' for use of the proposed measure in the IRF QRP. The MAP's conditions of support include that, as a part of measure implementation, we provide guidance on the correct collection and calculation of the measure result, as well as guidance on public reporting Web sites explaining the impact of the specification changes on the measure result. The MAP's conditions also specify that we continue analyzing the proposed measure in order to investigate unexpected results reported in public comment. We intend to fulfill these conditions by offering additional training opportunities and educational materials in advance of public reporting, and by continuing to monitor and analyze the proposed measure. More information about the MAP's recommendations for this measure is available at *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=84452.*

We reviewed the NQF's consensus endorsed measures and were unable to identify any NQF-endorsed pressure ulcer quality measures for PAC settings that are inclusive of unstageable pressure ulcers. There are related measures, but after careful review, we determined these measures are not applicable for use in IRFs based on the populations addressed or other aspects of the specifications. We are unaware of any other such quality measures that have been endorsed or adopted by another consensus organization for the IRF setting. Therefore, based on the evidence discussed above, we proposed to adopt the quality measure entitled, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, for the IRF QRP beginning with the FY 2020 IRF QRP. We plan to submit the proposed measure to the NQF for endorsement consideration as soon as feasible.

d. Data Collection

The data for this quality measure will be collected using the IRF–PAI, which is currently submitted by IRFs through the Quality Improvement and Evaluation System (QIES) Assessment Submission and Processing (ASAP) System. The proposed standardized patient assessment admission and discharge data applicable to this measure that must be reported by IRFs for patients discharged on or after October 1, 2018 are described in section XII.K of this final rule. While the inclusion of unstageable wounds in the proposed measure results in a measure calculation methodology that is different from the methodology used to calculate the current pressure ulcer measure, the data elements needed to calculate the proposed measure are already included on the IRF–PAI. In addition, our proposal to eliminate duplicative data elements that are used in the calculation of the current pressure ulcer measure will result in an overall reduced reporting burden for IRFs for the proposed measure. To view the updated IRF–PAI, with the changes, we refer the reader to *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-PAI-and-IRF-QRP-Manual.html.* For more information on IRF–PAI submission using the QIES ASAP System, we refer readers to *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/IRFPAI.html* and *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/index.html.*

For technical information about this measure, including information about the measure calculation and the standardized patient assessment data elements used to calculate this measure, we refer readers to the document titled, Final Specifications for IRF QRP Quality Measures and Standardized Patient

[17] Schwartz, M., Nguyen, K.H., Swinson Evans, T.M., Ignaczak, M.K., Thaker, S., and Bernard, S.L.: Development of a Cross-Setting Quality Measure for Pressure Ulcers: OY2 Information Gathering, Final Report. Centers for Medicare & Medicaid Services, November 2013. Available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Development-of-a-Cross-Setting-Quality-Measure-for-Pressure-Ulcers-Information-Gathering-Final-Report.pdf.*

[18] Schwartz, M., Ignaczak, M.K., Swinson Evans, T.M., Thaker, S., and Smith, L.: The Development of a Cross- Setting Pressure Ulcer Quality Measure: Summary Report on November 15, 2013, Technical Expert Panel Follow- Up Webinar. Centers for Medicare & Medicaid Services, January 2014. Available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Development-of-a-Cross-Setting-Pressure-Ulcer-Quality-Measure-Summary-Report-on-November-15-2013-Technical-Expert-Pa.pdf.*

Assessment Data Elements, available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.*

We proposed that IRFs would begin reporting the pressure ulcer measure Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury with data collection beginning October 1, 2018.

We invited public comment on our proposal to replace the current pressure ulcer measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), with a modified version of that measure, entitled Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, for the IRF QRP beginning with the FY 2020 IRF QRP.

We received several comments about this proposal, which are summarized below.

*Comment:* Many commenters supported the proposed replacement of the current pressure ulcer measure, the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), with a modified version of that measure, entitled Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury. Commenters appreciated that the implementation of this modified measure will reduce burden for providers by eliminating redundancies in the assessment items needed for its calculation, as well as reduce the potential for underestimating the frequency of pressure ulcers. Commenters recognized that the proposed measure will meet the requirements of the IMPACT Act for the Skin Integrity and Changes in Skin Integrity domain.

*Response:* We appreciate the commenters' support to replace the current pressure ulcer measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), with a modified version of the measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury to fulfill the requirements of the IMPACT Act. We agree that this proposal will limit regulatory burden and promote high quality care, as the commenters describe.

*Comment:* Several commenters raised questions about the rationale for adopting the proposed measure. One commenter inquired how the proposed measure is a more appropriate way to identify skin changes.

*Response:* The proposed measure includes new or worsened unstageable pressure ulcers, including deep tissue injuries (DTIs), in the measure numerator. These types of pressure ulcers are important to include in the measure because they represent poor outcomes, are often an avoidable outcome of medical care, are debilitating and painful, and can result in death and/or disability. The decision to include unstageable pressure ulcers, including DTIs was supported by TEPs held in 2013 and 2016, and closes a gap in quality reporting. Therefore, we believe that the proposed measure offers an improved measure of quality when compared to the current pressure ulcer measure.

*Comment:* Several commenters requested that additional testing analyses be conducted prior to the implementation of this measure. These commenters indicated that the purpose of this additional testing should be to verify that the specifications of this measure reflect actual differences in the care practices and the quality of care provided by IRFs, rather than differences in compliance. Specifically, some commenters expressed concerns that the variation in measure scores between facilities could reflect differences in the interpretation of definitions for unstageable pressure ulcers or DTIs, rather than actual differences in quality or care practices. These commenters noted that a measure should not be changed to create performance variation, but rather to be consistent with current science or to provide clarity and consistent data collection.

One commenter pointed out the difference in scores between the current and proposed measures, and questioned whether the proposed measure can be considered valid since it produces different scores. One commenter indicated concern that the proposed measure may quickly become ''topped-out'' since the rate of patients with new or worsened pressure ulcers is low.

Some commenters stated that analysis related to development of the proposed measure has not been made publicly available. A few other commenters suggested that the specifications of the proposed measure are based on data from SNFs, rather than IRFs. Another commenter suggested that CMS conduct an independent medical record review to support the data elements used in calculation of the measure.

*Response:* We have performed testing to compare the performance of the proposed measure with the existing pressure ulcer/injury measure. Current findings indicate that the measure is both valid and reliable in the SNF, LTCH, and IRF settings. One of the differences between the current and proposed pressure ulcer measures is that the proposed measure is calculated using the M0300 data element. Reliability and validity of the M0300 data element used to calculate this quality measure have been tested in several ways. Rigorous testing on both reliability and validity of the data elements in the MDS 3.0 provides evidence for the data elements used in the SNF, LTCH, and IRF settings.[19] The MDS 3.0 pilot test showed good reliability, and the results are applicable to the IRF–PAI as well as the LTCH CARE Data Set because the data elements tested are the same as those used in the IRF–PAI and LTCH CARE Data Set. Across pressure ulcer data elements, average gold-standard to gold-standard kappa statistic was 0.905. The average gold-standard to facility-nurse kappa statistic was 0.937. These kappa scores indicate ''almost perfect'' agreement using the Landis and Koch standard for strength of agreement.[20] Analyses conducted by the measure development contractor indicate that there is a high level of alignment between the M0300 data element and the M0800 data element, suggesting that the data elements assess an equivalent concept. Using the M0300 data elements improves accuracy by establishing a standardized calculation method.

A second main difference between the current and proposed pressure ulcer measures is that the proposed measure includes unstageable pressure ulcers, including DTIs, in the numerator of the quality measure, resulting in increased scores in all settings, compared with the previously implemented pressure ulcer measure. This is due to the fact that the proposed measure includes unstageable pressure ulcers, including DTIs, while the current measure does not, as well as the fact some pressure ulcers captured as new or worsened in the M0300 data element were not reported in the M0800 data element. By including pressure ulcers that were not included in the numerator of the current pressure ulcer measure, the scores on the proposed measure are higher and the risk of the measure being ''topped-out'' are lower.

To assess the construct validity of this measure, or the degree to which the measure construct measures what it claims or purports to be measuring, our

[19] Saliba, D., & Buchanan, J. (2008, April). Development and validation of a revised nursing home assessment tool: MDS 3.0. Contract No. 500–00–0027/Task Order #2. Santa Monica, CA: Rand Corporation. Retrieved from *http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf.*

[20] Landis, R., & Koch, G. (1977, March). The measurement of observer agreement for categorical data. Biometrics 33(1), 159–174.

measure contractor sought input from TEPs over the course of several years. Most recently, on July 18, 2016, a TEP supported the inclusion in the numerator of unstageable pressure ulcers due to slough and/or eschar that are new or worsened, new unstageable pressure ulcers/injuries due to a non-removable dressing or device, and new DTIs. The measure testing activities were presented to TEP members for their input on the reliability, validity, and feasibility of this measure change. The TEP members supported the measure construct.

The proposed measure also increased the variability of measures scores between providers, as noted by some commenters. In the currently implemented pressure ulcer measure, analysis using 2016 data from Quarter 4 reveals that the IRF mean score is 0.64 percent and the 25th and 75th percentiles are 0 percent and 0.95 percent, respectively. In the proposed measure, during the same timeframe, the IRF mean score is 1.46 percent and the 25th and 75th percentiles are 0 percent and 2.27 percent, respectively. We would like to clarify that the goal of the proposed measure is not to create performance variation where none exists, but rather to better measure existing performance variation. This increased variability of scores between facilities will improve the ability of the measure to distinguish between high- and low-performing facilities. In addition to the analyses presented in this rule and the measure specifications,[21] we presented analyses supporting this measure in a letter submitted to the NQF MAP Coordinating Committee as part of their review of this measure. These analyses were included in MAP public comments and are publicly available.[22]

We will continue to perform reliability and validity testing in compliance with NQF guidelines and the Blueprint for the CMS Measures Management System to ensure that that the measure demonstrates scientific acceptability (including reliability and validity) and meets the goals of the QRP. Finally, as with all measure development and implementation, we will provide training and guidance prior to implementation of the measure to promote consistency in the interpretation of the measure.

*Comment:* Several commenters requested further training and guidance in completing the M0300 data element that will be used to calculate the proposed quality measure. Some commenters requested comprehensive guidance on completing the ''present on admission'' data element. A few comments indicated a belief that the data element used to calculate this measure would be new, and one included incorrect information about the M0300 data element. Some commenters supported the proposed measure calculation approach, which will not count pressure ulcers that were present at the time of admission at the same stage, but stated that this would add complexity in coding and would require further training. Some commenters stated that the modified measure may be difficult for providers to capture because they are requested to report on a different data element, and some stated that this may decrease the accuracy of documentation. One commenter stated that there may be misinterpretations of how to code the assessment data element, or operational or documentation issues that affect a facility's documentation of pressure ulcers that are present on admission. Some commenters indicated that the definition of pressure ulcers included in the measure is too subjective. One commenter requested that the proposed measure be delayed until the assessment items have been collected for 12 to 24 months. One commenter stated that the MAP's conditions of support for this measure have not been met.

*Response:* The measure will be calculated using data reported on the M0300 data element collected at discharge, which only requires IRFs to report the number of pressure ulcers for each stage (including stages 2, 3, and 4, unstageable due to slough and/or eschar, unstageable due to non-removable dressing/device, and DTIs), and of those, the number that were present on admission.

The M0300 data element currently exists on the IRF–PAI, and the current IRF–PAI Manual, as well as prior versions of the Manual, include guidance about how to complete the M0300 data element, including the assessment and coding of pressure ulcers that are present on admission. We will provide further training, education, and guidance prior to implementation of the proposed measure. The IRF–PAI Manual will be updated with additional examples to further address the coding of unstageable pressure ulcers, and to provide further clarification on the coding of pressure ulcers/injuries that are ''present on admission.'' The IRF–PAI Manual can be found at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-PAI-and-IRF–QRP-Manual.html.* We believe that these additional training opportunities, combined with ongoing monitoring and analysis of the measure, fulfill the conditions of support outlined by the MAP.

*Comment:* We received several comments regarding the inclusion of unstageable pressure ulcers in the proposed measure. One commenter supported the modification of this measure. Other commenters did not support the inclusion of unstageable pressure ulcers in the quality measure as proposed, and encouraged further testing. Some commenters stated that there is a lack of clear definition of pressure ulcers included in this measure, and that those definitions may be too subjective to get reliable data. Commenters also requested that we provide training opportunities and educational materials prior to the implementation of this measure.

*Response:* We appreciate the support we have received regarding the inclusion of unstageable pressure ulcers, including DTIs, in the proposed quality measure. We believe that the inclusion of unstageable pressure ulcers in the measure will result in a fuller picture of quality to patients and families, and lead to further quality improvement efforts that will advance patient safety by reducing the rate of facility-acquired pressure ulcers at any stage.

We would like to clarify that the definitions of pressure ulcers are adapted from the National Pressure Ulcer Advisory Panel (NPUAP) and are standardized across all PAC settings. These definitions are universally accepted, objective, and considered to be the gold-standard definition by national and international stakeholders such as the NPUAP, European Pressure Ulcer Advisory Panel (EPUAP), Wound, Ostomy and Continence Nurses Society (WOCN), amongst others. As a result, the use of these universally accepted definitions of pressure ulcers furthers our commitment to ensuring that all quality measures implemented in the QRP meet the testing goals of the QRP.

To provide greater clarity about the definitions of different types of unstageable pressure ulcers and how to code them on the IRF–PAI, we are currently engaged in multiple educational efforts. These include training events, updates to the manuals and training materials, and responses to Help Desk questions to promote

[21] Final Specifications for IRF QRP Quality Measures and Standardized Patient Assessment Data Elements, available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.*

[22] *http://public.qualityforum.org/MAP/MAP%20Coordinating%20Committee/CMS%20Public%20Comment%2012-22.pdf.*

understanding and proper coding of these data elements. We will continue to engage in these training activities prior to implementation of the proposed measure.

*Comment:* We received few comments regarding the inclusion of DTIs specifically. Some commenters did not support the inclusion of DTIs in the measure. Commenters stated that there is not a universally accepted definition of DTIs, and that DTIs are commonly misdiagnosed, which could lead to surveillance bias. One commenter stated that it is often difficult to determine the presence of a DTI at admission and many are not identifiable until a week or two after admission.

*Response:* We appreciate the comments regarding the inclusion of DTIs in the proposed quality measure. DTIs are often an avoidable outcome of medical care, are debilitating and painful, and can result in death and/or disability, similar to Stage 2, Stage 3 and Stage 4 pressure ulcers. While some DTIs may worsen, studies indicate that many DTIs, if managed using appropriate care, can be resolved without deteriorating into a worsened pressure ulcer. Therefore, we believe that the inclusion of DTIs in the proposed quality measure is essential to be able to accurately reflect the number of these types of pressure injuries and to provide the appropriate patient care. Further, we believe that it is important to do a thorough assessment on every patient in each PAC setting, including a thorough skin assessment documenting the presence of any pressure ulcers or injuries of any kind, including DTIs. We agree that it is important to conduct thorough and consistent assessments to avoid the possibility of surveillance bias.

When considering the addition of DTIs to the measure numerator, we convened cross-setting TEPs in June and November 2013, and obtained input from clinicians, experts, and other stakeholders. An additional cross-setting TEP convened by our measure development contractor in July 2016 also supported the recommendation to include unstageable pressure ulcers, including DTIs, in the numerator of the quality measure. Given DTIs' potential impact on mortality, morbidity, and quality of life, it may be detrimental to the quality of care to exclude DTIs from a pressure ulcer quality measure.

*Comment:* Several commenters recommended that CMS attain NQF endorsement of the Changes in Skin Integrity Post- Acute Care: Pressure Ulcer/Injury measure prior to implementation.

*Response:* While this measure is not currently NQF-endorsed, we recognize that the NQF endorsement process is an important part of measure development and we plan to submit this measure for NQF endorsement consideration as soon as feasible.

*Comment:* We received several comments regarding the use of the term ''pressure injury.'' Some comments received were in support of adapting the NPUAP terminology. Other commenters stated that the proposed measure does not align with the NPUAP standard. One commenter requested that staging definitions be updated to match the NPUAP standard, and that the category of pressure ulcers that are unstageable due to non-removable dressing/device be removed.

*Response:* We appreciate the feedback regarding the terminology used in the Changes in Skin Integrity Post- Acute Care: Pressure Ulcer/Injury measure. The terminology and definitions developed by the NPUAP for the care of pressure ulcers are often used to inform the PAC patient and resident assessment instruments and corresponding assessment manuals. The pressure ulcer definitions used in the IRF–PAI Training Manual have been adapted from those recommended by the NPUAP 2007 Pressure Ulcer Stages.

Considering the recent updates made by the NPUAP to their Pressure Ulcer Staging System, we intend to continue the adaptation of NPUAP terminology for coding the patient and resident assessment instruments. The updated NPUAP guidance was discussed by a TEP in December 2016, and the TEP recommended we maintain current guidance for staging pressure ulcers, despite some differences from NPUAP staging definitions.

We are aware of the array of terms used to describe alterations in skin integrity due to pressure. Some of these terms include: pressure ulcer, pressure injury, pressure sore, decubitus ulcer, and bed sore. However, for purposes of the proposed measure, a skin condition should be coded on the IRF–PAI as a pressure ulcer if the primary cause of the skin condition is related to pressure. For example, if the medical record reflects the presence of a Stage 2 pressure injury, it should be coded on the assessment as a Stage 2 pressure ulcer.

*Comment:* We received some comments related to burden associated with this pressure ulcer measure. One commenter supported CMS's efforts to implement this measure as it may reduce the burden of collecting assessment data. Other commenters noted that there have been multiple changes to the current pressure ulcer quality measure over the years, and indicated that those changes, in addition to the current proposal, place a burden on providers by requiring further training or education. One commenter noted a burden on software developers. Commenters recommended that CMS suspend or delay implementing the proposed measure.

*Response:* While we avoid making unnecessary changes to measures, modifying measures is an important part of the measure lifecycle to ensure measures that are reliable, valid, and scientifically sound. We do not believe that the reporting of the proposed measure will impose a new burden on IRFs because the measure is calculated using data elements that are currently included in IRF–PAI. Further, our proposal to remove duplicative data elements will result in an overall reduced reporting burden for providers for the proposed measure.

*Comment:* One commenter noted that there is a difference in the denominator across settings in terms of which payer sources (Medicare Part A or Medicare Advantage) are included in the measure. Commenters recommended that we ensure that common denominators are used when displaying this measure for quality comparison purposes. Another commenter requested clarification on measure specification differences between IRFs and other PAC settings. Some commenters stated that there is an IMPACT Act mandate to implement ''interoperable measures'' across PAC settings.

*Response:* We recognize that data is currently collected from different payer sources for each PAC setting. We believe that quality care is best assessed through the collection of data from all patients, and strive to include the largest possible patient population in the measure denominator. For this reason, we do not seek to limit the denominator in each setting based on the data currently available in other settings (that is, limiting every setting denominator to Medicare Part A patients). Regarding the concern that different patient population denominators are misleading to consumers and providers, we seek to clarify the intent and use of this quality measure through rulemaking, provider training, and ongoing communication with stakeholders. Ongoing communication includes the posting of measure specifications and communication accompanying public reporting. Further, we will take into consideration the expansion of the SNF QRP to include all payer sources through future rulemaking.

The Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury measure is harmonized across all PAC settings and uses standardized patient assessment data as required by the IMPACT Act. Further, we would like to clarify that the M0300 data element used to calculate this measure is standardized across all PAC settings, enabling interoperability. This standardization and interoperability of patient assessment data elements allow for the exchange of information among PAC providers and other providers to whom this data is applicable. We refer readers to the measure specifications, which describe the specifications for the measure in PAC settings, Final Specifications for IRF QRP Quality Measures and Standardized Patient Assessment Data Elements, available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.*

*Comment:* A few commenters noted that IRF performance scores on the proposed measure are likely to differ from performance scores on the currently implemented pressure ulcer measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678). The commenters recommended development of educational materials for the public to explain the perceived shifts in performance. One commenter stated that changes to the measure can make it difficult for IRFs to review and improve their performance. One commenter expressed concern that, since this measure will be publicly reported, it may impact case-mix development or provider reimbursement.

*Response:* We appreciate commenters' concerns about differences in performance scores between the two measures, and the possibility of misinterpretation. While the proposed measure will not be directly comparable to the existing measure, it is expected to provide an improved measure of quality moving forward since it will more accurately capture the number of new and worsened pressure ulcers and include unstageable pressure ulcers. Further information and training will be provided to providers as well as consumers regarding how to interpret scores on the proposed measure, to avoid any possible confusion between the proposed measure and the existing measure. We would like to clarify for the IRF QRP, APU determination is not predicated on performance results for the measures.

*Comment:* We received one comment recommending the addition of morbid obesity as a risk adjustor for this quality measure.

*Response:* The proposed quality measure would be risk adjusted for functional mobility admission performance, bowel continence, diabetes mellitus or peripheral vascular disease/peripheral arterial disease, and low body mass index in each of the four settings. This risk adjustment methodology is described further in the Specifications for IRF QRP Quality Measures and Standardized Patient Assessment Data Elements, available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.* As with our measure modification and evaluation processes, we will continue to analyze this measure, specifically assessing the addition of variables to the risk adjustment model, and testing the inclusion of other risk factors as additional risk adjustors. This continued refinement of the risk adjustment models will ensure that the measure remains valid and reliable to inform quality improvement within and across each PAC setting, and to fulfill the public reporting goals of quality reporting programs.

*Comment:* Some commenters requested that CMS maintain the M0900 data element, which captures healed pressure ulcers, on the IRF–PAI. The commenters stated that IRFs heal many pressure ulcers and it is clinically valuable to monitor these positive outcomes. One commenter requested that CMS add three additional items to address healed unstageable pressure ulcers due to slough or eschar, healed unstageable pressure ulcers/injuries due to non-removable dressing or device, and healed DTIs. This commenter recommended that CMS consider developing a pressure ulcer quality measure that tracks the rate of healed pressure ulcers in addition to the rate of new or worsened wounds.

*Response:* We appreciate the suggestion for additional quality of care measures. We are responsible for continuously evaluating existing quality reporting programs and identifying potential new measures. We will take this suggestion into consideration as we continue our evaluation and refinement of skin integrity quality measures for PAC settings.

*Comment:* One commenter indicated that IRFs should not be required to report late stage pressure ulcers because these pressure ulcers are rare events during IRF stays.

*Response:* We agree that new or worsened stage 3 or 4 pressure ulcers are rare events in IRFs. Pressure ulcers interfere with activities of daily living and functional gains made during rehabilitation, predispose patients to osteomyelitis and septicemia, and are strongly associated with longer hospital stays, longer IRF stays, and mortality.[23] [24] [25]Analysis conducted by our measure development contractor examined the national incidence of new or worsened Stage 2, 3, or 4 pressure ulcers in IRFs at discharge compared with admission using discharges from January through December 2015. In IRFs, we found a national incidence of 0.56 percent of new or worsened Stage 2 pressure ulcers, 0.09 percent of new or worsened Stage 3 pressure ulcers, and 0.01 percent of new or worsened Stage 4 pressure ulcers. This indicates that, while the rates of stage 3 or stage 4 pressure ulcers are low, there are still some stage 3 or 4 pressure ulcers developing in IRFs. Overall, we believe it is important to continue to collect information on these types of pressure ulcers because of the serious nature of this medical condition.

*Final Decision:* After consideration of the public comments we received, we are finalizing our proposal to remove the current pressure ulcer measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), from the IRF QRP and to replace it with a modified version of that measure, entitled Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, for the IRF QRP with an implementation date of October 1, 2018.

### *H. Removal of the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge From IRFs From the IRF QRP*

In the FY 2018 IRF PPS proposed rule (82 FR 20720), we proposed to remove the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from IRFs (NQF #2502) beginning with the FY 2019 IRF QRP.

In the FY 2016 IRF PPS final rule (80 FR 47087 through 47089), we adopted the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from IRFs (NQF #2502) for the IRF QRP.

[23] Bates-Jensen BM. Quality indicators for prevention and management of pressure ulcers in vulnerable elders. Ann Int Med. 2001;135 (8 Part 2), 744–51.

[24] Park-Lee E, Caffrey C. Pressure ulcers among nursing home residents: United States, 2004 (NCHS Data Brief No. 14). Hyattsville, MD: National Center for Health Statistics, 2009. Available from *http://www.cdc.gov/nchs/data/databriefs/db14.htm.*

[25] Wang, H., et al. (2014). ''Impact of pressure ulcers on outcomes in inpatient rehabilitation facilities.'' Am J Phys Med Rehabil 93(3): 207–216.

This measure assesses all-cause unplanned hospital readmissions from IRFs. In the FY 2017 IRF PPS final rule (81 FR 52103 through 52108), we adopted the Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP to fulfill IMPACT Act requirements. We also adopted the Potentially Preventable Within Stay Readmission Measure for IRFs (81 FR 52108 through 52111) for the IRF QRP. In response to the FY 2017 IRF PPS proposed rule, we received public comments expressing concern over the multiplicity of readmission measures and the overlap between the All-Cause Readmission and Potentially Preventable Readmission (PPR) 30-Day Post-Discharge measures (see 81 FR 52106; 81 FR 52109 through 52111). Commenters also commented that multiple readmission measures would create confusion and require additional effort by providers to track and improve performance.

We retained the All-Cause Readmission measure because it would allow us to monitor trends in both all-cause and PPR rates. In particular, we could compare facility performance on the All-Cause Readmission and PPR 30-Day Post-Discharge measures. However, upon further consideration of the public comments, we believe that removing the All-Cause Readmission measure and retaining the PPR 30-Day Post-Discharge measure in the IRF QRP would prevent duplication, because potentially preventable readmissions are a subset of all-cause readmissions. Although there is no data collection burden associated with these claims-based measures, we recognize that having 3 hospital readmission measures in the IRF QRP may create confusion. We also agree with commenters who preferred the PPR measures, which identify a subset of all-cause readmissions, because we believe the PPR measures will be more actionable for quality improvement.

Accordingly, we proposed to remove the All-Cause Readmission measure beginning with the FY 2019 IRF QRP. We proposed that public reporting of this measure would end by October 2018 when public reporting of the PPR 30-Day Post-Discharge and PPR Within Stay measures begins by October 2018. We refer readers to section XIII.O of this final rule for more information regarding public reporting for the PPR 30-Day Post Discharge and PPR Within Stay measures. We refer readers to the PPR 30-Day Post-Discharge and PPR Within Stay measure specifications available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/Downloads/Measure-Specifications-for-FY17-IRF-QRP-Final-Rule.pdf.*

We invited public comment on our proposal to remove the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from IRFs (NQF #2502) from the IRF QRP, beginning with the FY 2019 IRF QRP. We received several comments, which are summarized below.

*Comment:* Several commenters, including MedPAC, supported the proposed removal of the All-Cause Readmission measure from the IRF QRP. The commenters supported the PPR measures over the All-Cause Readmission measure, which hold providers accountable for a subset of all-cause readmissions that are considered potentially preventable.

Some commenters were concerned that three hospital readmission measures in the IRF QRP is burdensome and supported the removal of the All-Cause Readmission measure because they consider it confusing and duplicative of the PPR 30-Day Post-Discharge measure. Commenters expressed concern that a lack of patient-level data makes it difficult to track and improve performance. Some commenters suggested that CMS evaluate PAC readmission measures adopted for other quality reporting programs to ensure that they create consistent incentives across the system.

*Response:* We appreciate the support for the proposed removal of the All-Cause Readmission measure from the IRF QRP. We note commenters' concerns regarding the availability of patient-level data for tracking and improving performance, and are exploring the feasibility of making additional data available to IRFs. We appreciate commenters' concern over consistent incentives and will continue to monitor PAC readmission measures to ensure they align incentives across the system.

*Final Decision:* After consideration of the public comments, we are finalizing our proposal to remove the All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from IRFs from the IRF QRP, beginning with the FY 2019 IRF QRP.

*I. IRF QRP Quality Measures under Consideration for Future Years*

We invited public comment on the importance, relevance, appropriateness, and applicability of each of the quality measures listed in Table 8 for future years in the IRF QRP.

We solicited public comments on the use of survey-based experience of care measures for the IRF QRP. We are currently developing an experience of care survey for IRFs, and survey-based measures will be developed from this survey. These survey-based measures may be considered for inclusion in the IRF QRP through future notice-and-comment rulemaking. This survey was developed using a rigorous survey development methodology that included a public request for measures (refer to Request for Information To Aid in the Design and Development of a Survey Regarding Patient and Family Member Experiences With Care Received in Inpatient Rehabilitation Facilities, at 80 FR 72726 through 72727); focus groups and interviews with patients, family members, and caregivers; input from a TEP of IRF providers, researchers, and patient advocates; and cognitive interviewing. The survey has also been field tested. The survey explores experience of care across five main areas: (1) Beginning stay at the rehabilitation hospital/unit; (2) interactions with staff; (3) experience during the rehabilitation hospital/unit stay; (4) preparing for leaving the rehabilitation hospital/unit; and (5) overall rehabilitation hospital/unit rating. We are specifically interested in comments regarding survey implementation and logistics, use of the survey-based measures in the IRF QRP, and general feedback. We are also considering a measure focused on pain that relies on the collection of patient-reported pain data.

We received several comments on measures under considerations for future years, which are summarized below.

*Comment:* In the FY 2018 IRF PPS proposed rule (82 FR 20720 through 20721), we requested stakeholder feedback on the use of an experience of care survey in the IRF setting. CMS received several comments about the IRF survey currently in development. Some commenters raised the importance of including questions about experience with various types of rehabilitative therapy and the ability of the IRF to help meet patients' goals. Other commenters were concerned with response rates and burden. The commenters suggested ways to increase response rate and lessen burden, such as with electronic or mobile survey administration options and reducing the number of survey questions. Several commenters wanted more information about the survey to be made public and for CMS to ensure that stakeholder feedback is taken into account as the survey is finalized. One commenter questioned about subdividing survey respondents into diagnosis groups to allow for a more granular level of analysis.

*Response:* We appreciate the comments about the IRF Experience of Care Survey. We will take those comments into consideration as we finish developing the survey and related survey-based measures.

*Comment:* We received several comments about the Application of Percent of Residents Who Self-Report Moderate to Severe Pain (Short Stay) (NQF #0676) measure. Many commenters did not support this measure's inclusion in the IRF QRP because of the intensive nature of therapy in IRFs may cause patients to experience some degree of pain and discomfort. Commenters expressed concern that inquiring about pain does not provide enough information about whether the pain was treated or the patient's quality of life improved as a result of pain management, and suggested a measure that assessed whether staff responded to and helped manage pain instead. Many commenters had concerns about opioid over-prescription as a result of inquiring about pain, citing CMS's Opioid Misuse Strategy 2016, which can be found at *https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/Downloads/CMS-Opioid-Misuse-Strategy-2016.pdf.* Some commenters supported a measure related to pain, as it could prevent participation in rehabilitation and daily activities, and one commenter suggested an additional measure to capture this issue for non-verbal patients. One commenter supported that the measure could be collected as a patient reported outcome.

*Response:* We appreciate the comments pertaining to the Application of Percent of Residents Who Self-Report Moderate to Severe Pain (Short Stay) (NQF #0676) measure under consideration for future implementation in the IRF QRP. We note that appropriately assessing pain as an outcome is important, and will take into consideration the commenters' recommendations.

*Comment:* We received several other comments with recommendations for future measures. One commenter suggested CMS align any future measures across all post-acute care settings. One commenter suggested measures assessing patient and family goals and introducing palliative care, and recommended expanding measures related to mobility and self-care. One commenter suggested including more immunization measures such as a pneumococcal quality measure.

*Response:* We appreciate the commenters' recommendations and will take all their suggestions into consideration.

1. IMPACT Act Measure—Possible Future Update To Measure Specifications

In the FY 2017 IRF PPS final rule (81 FR 52095 through 52103), we finalized the Discharge to Community-PAC IRF QRP measure, which assesses successful discharge to the community from an IRF setting, with successful discharge to the community including no unplanned rehospitalizations and no death in the 31 days following discharge from the IRF. We received public comments (see 81 FR 52098 through 52099), recommending exclusion of baseline nursing facility residents from the measure, as these residents did not live in the community prior to their IRF stay. At that time, we highlighted that using Medicare FFS claims alone, we were unable to accurately identify baseline nursing facility residents. We stated that potential future modifications of the measure could include assessment of the feasibility and impact of excluding baseline nursing facility residents from the measure through the addition of patient assessment-based data. In response to these public comments, we are considering a future modification of the Discharge to Community-PAC IRF QRP measure, which would exclude baseline nursing facility residents from the measure. We invited public comment on the possible exclusion of baseline nursing facility residents from the Discharge to Community-PAC IRF QRP measure in future years of the IRF QRP.

We received several comments on this potential future modification, which are summarized below.

*Comment:* Multiple commenters expressed support for excluding baseline nursing facility residents from the discharge to community measure as a potential future measure modification. Commenters stated that this exclusion would result in the measure more accurately portraying quality of care provided by IRFs, while controlling for factors outside of IRF control. One commenter emphasized that the proposed exclusion be applied across all PAC settings for cross-setting measure standardization and quality comparisons. One commenter supported this exclusion, and suggested that CMS try to address needs of long-term nursing facility residents in quality reporting programs via other strategies and not wholly exclude them from a nursing facility's accountability. One commenter stated that we are considering excluding patients admitted to IRF from a skilled nursing facility setting.

*Response:* We appreciate the support for the potential exclusion of baseline nursing facility residents as a future measure modification. We will consider these views and determine whether to propose to exclude baseline nursing facility residents from the Discharge to Community-PAC IRF QRP measure in future years of the IRF QRP. We would like to clarify that we are only considering exclusion of baseline long-term nursing facility residents from the measure. We are not considering exclusion of patients admitted to IRF from a SNF setting.

2. IMPACT Act Implementation Update

As a result of the input and suggestions provided by technical experts at the TEPs held by our measure developer, and through public comment, we engaged in additional development work, including performing additional testing, for two measures that would satisfy the domain of accurately communicating the existence of and providing for the transfer of health information and care preferences in section 1899B(c)(1)(E) of the Act. The measures under development are: (1) Transfer of Information at Post-Acute Care Admission, Start or Resumption of Care from other Providers/Settings; and (2) Transfer of Information at Post-Acute Care Discharge, and End of Care to other Providers/Settings. We intend to specify these measures under section 1899B(c)(1)(E) of the Act no later than October 1, 2018, and we intend to propose to adopt them for the FY 2021 IRF QRP, with data collection beginning on or about October 1, 2019.

We received several comments on this implementation update, which are summarized below.

*Comment:* A few commenters supported continued work on the two transfer of information measures. Some commenters suggested that CMS be cautious in its development of the Transfer of Information measure set and only propose and adopt measures that receive NQF endorsement. These commenters cited concerns about the measure development, citing the 2016 MAP PAC/LTC meeting. One commenter noted that care is often fragmented, disorganized, and guided by factors that are not related to the quality of care or patient outcomes and that decision-makers often lack adequate information to make the best decisions during care transition planning. The commenter, noting the importance of including the patient and family members in decision-making about the most appropriate location for the patient's post-acute care,

recommended that CMS adopt a more direct approach for engaging the patient. The commenter believes that patient and family member insight and feedback on quality of care will ensure that the transfer of patient health information and care preferences are accurately communicated. One commenter emphasized that the measures should include both the receipt of information and the transmittal of information needed to coordinate care. Another commenter encourages more conversation about the measure and recommended types of information to be included to meet the measure criteria. The commenter supports balancing the burden of reporting with the utility of the measure and believes that limiting the information collected may not lead to improvements in the quality of care transitions.

*Response:* We appreciate the comments and feedback on the Transfer of Health Information measures that are currently under development. As we continue to develop these measures, we will take the commenters' concerns into account. We agree with the comment that patient engagement in decisions about their care at transitions is a priority in ensuring patient-centered care. We will also consider the feedback pertaining to the importance of having the two measures, the types of information to be included in the measure numerators, balancing burden with the measure utility, patient and family engagement and involvement in decision-making about care, and the transfer of patient goals and care preferences. We intend to re-submit these measures, once fully specified and tested, for review to the MAP PAC/LTC Workgroup. Further, we plan to submit the measures to the NQF for consideration for endorsement when the measures are ready to be reviewed.

TABLE 8—IRF QRP QUALITY MEASURES UNDER CONSIDERATION FOR FUTURE YEARS

| NQS priority | Patient- and caregiver-centered care |
|---|---|
| Measures | Experience of Care.<br>Application of Percent of Residents Who Self-Report Moderate to Severe Pain (Short Stay) (NQF #0676). |
| NQS priority | Communication and care coordination |
| Measure | Modification of the Discharge to Community-Post Acute Care Inpatient Rehabilitation Facility Quality Reporting Program measure. |

*J. Standardized Patient Assessment Data Reporting for the IRF QRP*

1. Standardized Patient Assessment Data Reporting for the FY 2019 IRF QRP

Section 1886(j)(7)(F)(ii) of the Act requires that for fiscal year 2019 and each subsequent year, IRFs report standardized patient assessment data required under section 1899B(b)(1) of the Act. As we describe in more detail in section XII.G.1 of this final rule, we are finalizing that the current pressure ulcer measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), will be removed and replaced with the proposed pressure ulcer measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, beginning with the FY 2020 IRF QRP. The current pressure ulcer measure will remain in the IRF QRP until that time. Accordingly, for the requirement that IRFs report standardized patient assessment data for the FY 2019 IRF QRP, we proposed in the FY 2018 IRF PPS proposed rule (82 FR 20721 through 20722) that the data elements used to calculate the current pressure ulcer measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) meet the definition of standardized patient assessment data for medical conditions and co-morbidities under section 1899B(b)(1)(B)(iv) of the Act, and that the successful reporting of that data under section 1886(j)(7)(F)(i) of the Act for admissions as well as discharges occurring during fourth quarter CY 2017 would also satisfy the requirement to report standardized patient assessment data for the FY 2019 IRF QRP.

The collection of assessment data pertaining to skin integrity, specifically pressure related wounds, is important for multiple reasons. Clinical decision support, care planning, and quality improvement all depend on reliable assessment data collection. Pressure related wounds represent poor outcomes, are a serious medical condition that can result in death and disability, are debilitating, painful and are often an avoidable outcome of medical care.[26] [27] [28] [29] [30] [31] Pressure related wounds are considered healthcare acquired conditions.

As we previously noted, the data elements needed to calculate the current pressure ulcer measure are already included on the IRF–PAI and reported for IRFs, and exhibit validity and reliability for use across PAC providers. Item reliability for these data elements was also tested for the nursing home setting during implementation of MDS 3.0. Testing results are from the RAND Development and Validation of MDS 3.0 project.[32] The RAND pilot test of the MDS 3.0 data elements showed good reliability and is also applicable to both the IRF–PAI and the LTCH CARE Data Set because the data elements tested are the same. Across the pressure ulcer data elements, the average gold-standard nurse to gold-standard nurse kappa statistic was 0.905. The average gold-standard nurse to facility-nurse kappa statistic was 0.937. Data elements used to risk adjust this quality measure were also tested under this same pilot test, and the gold-standard to gold-standard kappa statistic, or percent agreement (where kappa statistic is not available), ranged from 0.91 to 0.99 for these data elements. These kappa scores indicate ''almost perfect'' agreement using the

[26] Casey, G. (2013). ''Pressure ulcers reflect quality of nursing care.'' Nurs N Z 19(10): 20–24.

[27] Gorzoni, M.L. and S.L. Pires (2011). ''Deaths in nursing homes.'' Rev Assoc Med Bras 57(3): 327–331.

[28] Thomas, J.M., et al. (2013). ''Systematic review: health-related characteristics of elderly hospitalized adults and nursing home residents associated with short-term mortality.'' J Am Geriatr Soc 61(6): 902–911.

[29] White-Chu, E.F., et al. (2011). ''Pressure ulcers in long-term care.'' Clin Geriatr Med 27(2): 241–258.

[30] Bates-Jensen BM. Quality indicators for prevention and management of pressure ulcers in vulnerable elders. Ann Int Med. 2001;135 (8 Part 2), 744–51.

[31] Bennet, G, Dealy, C Posnett, J (2004). The cost of pressure ulcers in the UK, Age and Aging, 33(3):230–235.

[32] Saliba, D., & Buchanan, J. (2008, April). Development and validation of a revised nursing home assessment tool: MDS 3.0. Contract No. 500–00–0027/Task Order #2. Santa Monica, CA: Rand Corporation. Retrieved from *http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf.*

Landis and Koch standard for strength of agreement.[33]

The data elements used to calculate the current pressure ulcer measure received public comment on several occasions, including when that measure was proposed in the FY 2012 IRF PPS (76 FR 47876) and IPPS/LTCH PPS proposed rules (76 FR 51754). Further, they were discussed in the past by TEPs held by our measure development contractor on June 13 and November 15, 2013, and recently by a TEP on July 18, 2016. TEP members supported the measure and its cross-setting use in PAC. The report, ''*Technical Expert Panel Summary Report: Refinement of the Percent of Patients or Residents with Pressure Ulcers that are New or Worsened (Short-Stay) (NQF #0678) Quality Measure for Skilled Nursing Facilities (SNFs), Inpatient Rehabilitation Facilities (IRFs), Long-Term Care Hospitals (LTCHs), and Home Health Agencies (HHAs)* is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/July-2016-Pressure-Ulcer-TEP-Report_revised.pdf.* We solicited stakeholder feedback on our proposal and received several comments, which are summarized below.

*Comment:* Several comments supported reporting the data elements already implemented in the IRF QRP to fulfill the requirement to report standardized patient assessment data for the FY 2019 IRF QRP. Specifically, many commenters supported the use of data elements used in calculation of the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) to fulfill this requirement.

*Response:* We appreciate the commenters' support of the proposal.

*Final decision:* After consideration of the public comments received, we are finalizing that the data elements currently reported by IRFs to calculate the current measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), meet the definition of standardized patient assessment data with respect to medical conditions and co-morbidities under section 1899B(b)(1)(B)(iv) of the Act, and that the successful reporting of that data under section 1886(j)(7)(F)(i) of the Act will also satisfy the requirement to report standardized patient assessment data under section 1886(j)(7)(F)(ii) of the Act.

2. Standardized Patient Assessment Data Reporting Beginning With the FY 2020 IRF QRP

In the FY 2018 IRF PPS proposed rule (82 FR 20722 through 20739), we described our proposals for the reporting of standardized patient assessment data by IRFs beginning with the FY 2020 IRF QRP. For FY 2020, this would apply to all Medicare Part A and MA patients discharged between October 1, 2018 and December 31, 2018. IRFs would be required to report these data on admission and discharge, with the exception of three data elements (Brief Interview of Mental Status (BIMS), Hearing, and Vision) that would be collected on admission only. Following the initial reporting year for the FY 2020 IRF QRP, subsequent years for the IRF QRP would be based on a full calendar year of such data reporting.

In selecting the data elements proposed in the FY 2018 IRF PPS proposed rule, we carefully weighed the balance of burden in assessment-based data collection and aimed to minimize additional burden through the utilization of existing data in the assessment instruments. We also noted that the patient assessment instruments are considered part of the medical record and sought the inclusion of data elements relevant to patient care. We also took into consideration the following factors for each data element: Overall clinical relevance; ability to support clinical decisions, care planning, and interoperable exchange to facilitate care coordination during transitions in care; and the ability to capture medical complexity and risk factors that can inform both payment and quality. Additionally, the data elements had to have strong scientific reliability and validity; be meaningful enough to inform longitudinal analysis by providers; had to have received general consensus agreement for its usability; and had to have the ability to collect such data once but support multiple uses. Further, to inform the final set of data elements for proposal, we took into account technical and clinical subject matter expert review, public comment, and consensus input in which such principles were applied. We also took into account the consensus work and empirical findings from the PAC PRD. We acknowledge that during the development process that led to these proposals, some providers expressed concern that changes to the IRF–PAI to accommodate standardized patient assessment data reporting would lead to an overall increased reporting burden. However, we noted that there is no additional data collection burden for standardized data already collected and submitted on the quality measures.

We received several comments related to the reporting of the standardized patient assessment data, which are summarized below.

*Comment:* Many commenters expressed significant concerns with respect to our standardized patient assessment data proposals. Several commenters stated that the new standardized patient assessment data reporting requirements will impose significant burden on providers, given the volume of new standardized patient assessment data elements that were proposed to be added to the IRF–PAI. Several commenters noted that the addition of the proposed standardized patient assessment data elements would require hiring more staff, retraining staff on revised questions or coding guidance, and reconfiguring internal databases and EHRs. Other commenters expressed concerns about the gradual but significant past and future expansion of the IRF–PAI through the addition of standardized patient assessment data elements and quality measures, noting the challenge of coping with ongoing additions and changes, especially for small or rural providers. Several commenters stated that clinicians already record comorbidities as ICD–10 diagnosis codes, and recommended that CMS investigate how to utilize patient information that is already reported (for example, claims) rather than adding new assessment items to the IRF–PAI.

Several commenters expressed concern related to the implementation timeline in the proposed rule, which would require IRFs to begin collecting the proposed standardized patient assessment data elements in the timeframe stated in the proposed rule. Several commenters noted that CMS had not yet provided sufficient specifications or educational materials to support implementation of the new patient assessments in the proposed timeline.

Several commenters recommended CMS to delay the reporting of new standardized patient assessment data elements by at least one year, and to carefully assess whether all of the proposed standardized patient assessment data elements are necessary under the IMPACT Act. Commenters suggested ways to delay the proposals for standardized patient assessment data elements in the categories of Cognitive Function and Mental Status; Special Services, Treatments, and Interventions; and Impairments, including allowing

[33] Landis, R., & Koch, G. (1977, March). The measurement of observer agreement for categorical data. Biometrics 33(1), 159–174.

voluntary or limited reporting for a period of time before making comprehensive reporting mandatory, and delaying the beginning of mandatory data collection for a period of time. Some commenters recommended that during the delay, CMS re-evaluate whether it can require the reporting of standardized patient assessment data in a less burdensome manner.

*Response:* We understand the concerns raised by commenters that the finalization of our standardized patient assessment data proposals would require IRFs to spend a significant amount of resources preparing to report the data, including updating relevant protocols and systems and training appropriate staff. We also recognize that we can meet our obligation to require the reporting of standardized patient assessment data for the categories described in section 1899B(b)(1)(B) of the Act while simultaneously being responsive to these concerns. Therefore, after consideration of the public comments we received on these issues, we have decided that at this time, we will not finalize the standardized patient assessment data elements we proposed for three of the five categories under section 1899B(b)(1)(B) of the Act: Cognitive Function and Mental Status; Special Services, Treatments, and Interventions; and Impairments. Although we believe that the proposed standardized patient assessment data elements would promote transparency around quality of care and price as we continue to explore reforms to the PAC payment system, the data elements that we proposed for each of these categories would have imposed a new reporting burden on IRFs. We agree that it would be useful to evaluate further how to best identify the standardized patient assessment data that would satisfy each of these categories; would be most appropriate for our intended purposes including payment and measure standardization; and can be reported by IRFs in the least burdensome manner. As part of this effort, we intend to conduct a national field test that allows for stakeholder feedback and to consider how to maximize the time IRFs have to prepare for the reporting of standardized patient assessment data in these categories. We intend to make new proposals for the categories described in sections 1899B(b)(1)(B)(ii), (iii) and (v) of the Act no later than in the FY 2020 IRF PPS proposed rule.

In this final rule, we are finalizing the standardized patient assessment data elements that we proposed to adopt for the IMPACT Act categories of Functional Status and Medical Conditions and Co-Morbidities. Unlike the standardized patient assessment data that we are not finalizing, the standardized patient assessment data that we proposed for these categories are already required to calculate the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (NQF #0678) quality measure, the Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury quality measure (which we are finalizing in this final rule), and the Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631) measure (which we finalized in the FY 2016 IRF PPS final rule). As a result, we do not believe that finalizing these proposals creates a new reporting burden for IRFs or otherwise necessitates a delay.

*Comment:* Several commenters expressed support for the adoption of standardized patient assessment data elements. Several commenters expressed support for standardizing the definitions as well as the implementation of the data collection effort. Several commenters also supported CMS' goal of standardizing the questions and responses across all PAC settings to help ''enable the data to be interoperable, allowing it to be shared electronically, or otherwise between PAC provider types.'' Several commenters stated that streamlining requirements across Medicare's quality reporting programs will reduce the administrative burden of quality reporting for these facilities as well as the physicians and other clinicians who contribute to that reporting. Another commenter noted full support of the IMPACT Act's goals and objectives and appreciated CMS' efforts to regularly communicate with stakeholders through various national provider calls, convening of stakeholders, and meetings with individual organizations. Another commenter recognized the value of and need for a unified patient assessment system for PAC as part of a potential unified payment system for PAC.

*Response:* We appreciate the support of these proposals, but note that for the reasons previously explained, we have decided at this time to not finalize the proposals for three of the five categories under section 1899B(b)(1)(B) of the Act: Cognitive Function and Mental Status; Special Services, Treatments, and Interventions; and Impairments.

*Comment:* Several commenters stated that there is insufficient evidence demonstrating the reliability and validity of the proposed standardized patient assessment data elements. Some commenters stated that the expanded standardized patient assessment data reporting requirements have not yet been adequately tested to ensure they collect accurate and useful data in this setting. A few commenters stated that only five of the proposed 23 standardized patient assessment data elements are currently reported in the IRF–PAI and the other 18 are currently used in other post-acute setting patient assessment instruments, mainly the Minimum Data Set (MDS) 3.0 used in skilled nursing facilities (SNFs). Other commenters stated that CMS' conclusion that the collection of these standardized patient assessment data elements in the IRF setting would be feasible and the standardized patient assessment data elements would result in valid and reliable data was based on the current use of these data elements in the MDS and the testing of these data elements in the PAC PRD. A few commenters stated that several of the proposed standardized patient assessment data elements that had not been adequately tested were deemed close enough to an item that had been tested in the PAC PRD or in other PAC settings and thus appropriate for implementation.

*Response:* Our standardized patient assessment data elements were selected based on a rigorous multi-stage process described in the FY 2018 IRF PPS Proposed Rule (82 FR 20716 through 20717). In addition, we believe that the PAC PRD testing of many of these data elements provides good evidence from a large, national sample of patients and residents in PAC settings to support the use of these standardized patient assessment data elements in and across PAC settings. However, as previously explained, we have decided at this time to not finalize the proposals for three of the five categories under section 1899B(b)(1)(B) of the Act: Cognitive Function and Mental Status; Special Services, Treatments, and Interventions; and Impairments. Prior to making new proposals for these categories, we intend to conduct extensive testing to ensure that the standardized patient assessment data elements we select are reliable, valid and appropriate for their intended use.

*Comment:* MedPAC suggested that CMS should be mindful that some data elements, when used for risk-adjustment, may be susceptible to provider manipulation. MedPAC is concerned about the proposed elements such as oxygen therapy, intravenous medications, and nutritional approaches that may induce service use. MedPAC supports the inclusion of these care items when they are tied to a medical

necessity, such as in previous MedPAC work, where patients were counted as using oxygen services only if they have diagnoses that typically require the use of oxygen. MedPAC encouraged CMS to take a similar approach in measuring use of services that are especially discretionary. For some data elements, the commenters suggested that CMS may want to consider requiring a physician signature to attest that the reported service was reasonable and necessary and including a statement adjacent to the signature line warning that filling a false claim is subject to treble damages under the False Claims Act.

*Response:* We acknowledge the feedback from MedPAC, and agree with the importance of data integrity within patient assessment instruments. We will explore the suggestions made by MedPAC.

A full discussion of the standardized patient assessment data elements that we proposed to adopt for the categories described in sections 1899B(b)(1)(B)(ii), (iii) and (v) of the Act can be found in the FY 2018 IRF PPS proposed rule (82 FR 20723 through 20739). In light of our decision to not finalize our proposals with respect to these categories, we are not going to address in this final rule the specific technical comments that we received on these proposed standardized patient assessment data elements. However, we appreciate the many technical comments we did receive specific to each of these data elements, and we will take them into consideration as we develop new proposals for these categories. Below we discuss the comments we received specific to the standardized patient assessment data we proposed to adopt, and are finalizing in this final rule, for the categories of Functional Status and Medical Conditions and Co-Morbidities.

a. Standardized Patient Assessment Data by Category

(1) Functional Status Data

We proposed that the data elements currently reported by IRFs to calculate the proposed measure, Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631), would also meet the definition of standardized patient assessment data for functional status under section 1899B(b)(1)(B)(i) of the Act, and that the successful reporting of that data under section 1886(j)(7)(F)(i) of the Act would also satisfy the requirement to report standardized patient assessment data under section 1886(j)(7)(F)(ii) of the Act.

These patient assessment data for functional status are from the CARE Item Set. The development of the CARE Item Set and a description and rationale for each item is described in a report entitled ''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.'' [34] Reliability and validity testing were conducted as part of CMS' Post-Acute Care Payment Reform Demonstration, and we concluded that the functional status items have acceptable reliability and validity. A description of the testing methodology and results are available in several reports, including the report entitled ''The Development and Testing of the Continuity Assessment Record And Evaluation (CARE) Item Set: Final Report On Reliability Testing: Volume 2 of 3'' [35] and the report entitled ''The Development and Testing of The Continuity Assessment Record And Evaluation (CARE) Item Set: Final Report on Care Item Set and Current Assessment Comparisons: Volume 3 of 3.'' [36] The reports are available on CMS' Post-Acute Care Quality Initiatives Web page at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/CARE-Item-Set-and-B-CARE.html.*

For more information about this quality measure, we refer readers to the FY 2016 IRF PPS final rule (80 FR 47100 through 47111). We invited public comment on this proposal.

We received several comments on this proposal, which are summarized below.

*Comment:* Several commenters, including MedPAC, supported the collection of standardized patient assessment data across PAC settings. Some commenters specifically addressed support for CMS's proposal that data elements submitted to CMS to calculate the measure, Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631), would also satisfy the requirement to report standardized patient assessment data under section 1899B(b)(1)(B)(i) of the Act addressing functional status, such as mobility and self-care at admission to a PAC provider and before discharge from a PAC provider.

*Response:* We appreciate the commenters' support.

*Comment:* One commenter did not support the proposed standardized patient assessment data elements for functional status, stating that the items were burdensome for providers, do not relate to all patients, are often too granular, and are duplicative of existing items related to functional status. Some commenters noted that the proposed standardized functional assessment data are used to calculate the cross-setting process measure, Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631), and recommended that CMS consider proposing data elements from outcomes-based functional status quality measures in PAC settings in the future. Another commenter noted that the proposed standardized data are not intended to capture all significant impacts of IRF interventions and encouraged CMS to consider instrumental activities of daily living as a measurement construct in the future, because instrumental activities of daily living performance is critical to maintain safety and avoid readmissions.

*Response:* We appreciate the commenters' concerns about the duplication of the functional data elements, relevance to the IRF population, and value of cross-setting application in post-acute settings. With regard to burden, we would like to clarify that the proposal to use data elements from the quality measure Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631) means that no new data elements will be added to the IRF–PAI to satisfy the requirement to report standardized patient assessment data under section 1899B(b)(1)(B)(i) of the Act addressing functional status. Therefore, this proposal does not add burden as the proposed data elements are currently reported on the IRF–PAI. We note that the three self-care items and nine mobility items are daily activities that are relevant for the majority of patients, and that gateway questions allow IRFs to skip walking items for patients who do not walk and to skip wheelchair items if the person does not mobilize using a wheelchair. For more information about this previously finalized quality measure, we refer readers to the FY 2016 IRF PPS final rule (80 FR47100 through 47111).

[34] Barbara Gage et al., ''The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report on the Development of the CARE Item Set'' (RTI International, 2012).

[35] Ibid.

[36] Ibid.

We appreciate the suggestions for future enhancements, such as including data elements related to instrumental activities of daily living and outcome-based measures on the IRF–PAI, and will take this suggestion into consideration.

*Comment:* One commenter cautioned CMS that collection of functional status data across PAC settings may be affected by the education level and professional expertise of the individual completing the assessment. Two commenters recommended revisions to section GG of the IRF–PAI training manual with one requesting clarification guidance about coding 09, Not Applicable and two commenters requesting clarification about coding 10, Activity not attempted due to environmental limitations. Another commenter requested clarification on the use of the ''Activity was not attempted'' codes on the IRF–PAI when setting goals. The commenter believed that use of the codes 07, Patient refused, 09, Not applicable, 10, Not attempted due to environmental limitations and 88, Not attempted due to medical or safety concerns for setting goals is inconsistent with IRF practices and clinical guidelines. Additionally, one commenter noted that the proposed changes to the existing standardized patient assessment data elements will be costly for providers as they retrain staff and modify items in documentation systems, both electronic and paper. The commenters suggested that these changes be submitted for review by the NQF.

One commenter requested clarification about the coding of self-care and mobility goals questioning if all goals are expected to be completed as part of the use of the data elements from the measure Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631).

*Response:* We appreciate the commenters' concerns related to the collection of standardized patient assessment data. We agree with the importance of comprehensive training for all PAC settings. We provide training materials through the CMS webinars, open door forums, and help desk support. We update training manuals based on feedback from providers, including help desk questions and public comments. We welcome ongoing input from stakeholders on key implementation and training considerations, which can be submitted via email at *PACQualityInitiative@cms.hhs.gov.*

The standardized patient assessment data element proposal proposed the use of data elements that are also used to calculate the adopted function process quality measure, Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631). This quality measure collects on the admission and discharge performance self-care and mobility items and requires only one goal to be reported for each IRF patient stay. Therefore, at least one goal is expected to be completed as part of the data elements for this adopted quality measure. For more information about this quality measure we refer the reader to our Quality Measure User's Manual, available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.* We would like to clarify that our proposal to adopt the standardized patient assessment data elements for functional status includes the admission and discharge performance data elements; it does not include the discharge goal data elements. We note that at least one self-care or mobility goal is required for the quality measure, as described above.

With regard to NQF review, we follow the NQF process of annual maintenance and endorsement maintenance for NQF-endorsed measures, including updating measure specifications each year to address any changes to the measure.

*Final Decision:* After consideration of the public comments we received, we are finalizing that the data elements currently reported by IRFs to calculate the measure, Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631), also meet the definition of standardized patient assessment data for functional status under section 1899B(b)(1)(B)(i) of the Act, and that the successful reporting of that data under section 1886(j)(7)(F)(i) of the Act will also satisfy the requirement to report standardized patient assessment data under section 1886(j)(7)(F)(ii) of the Act.

(2) Medical Condition and Comorbidity Data

We proposed that the data elements needed to calculate the current measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), and the proposed measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, meet the definition of standardized patient assessment data for medical conditions and co-morbidities under section 1899B(b)(1)(B)(iv) of the Act, and that the successful reporting of that data under section 1886(j)(7)(F)(i) of the Act would also satisfy the requirement to report standardized patient assessment data under section 1886(j)(7)(F)(ii) of the Act.

''Medical conditions and comorbidities'' and the conditions addressed in the standardized patient assessment data elements used in the calculation and risk adjustment of these measures, that is, the presence of pressure ulcers, diabetes, incontinence, peripheral vascular disease or peripheral arterial disease, mobility, as well as low body mass index, are all health-related conditions that indicate medical complexity that can be indicative of underlying disease severity and other comorbidities.

Specifically, the data elements used in the measure are important for care planning and provide information pertaining to medical complexity. Pressure ulcers are serious wounds representing poor healthcare outcomes, and can result in sepsis and death. Assessing skin condition, care planning for pressure ulcer prevention and healing, and informing providers about their presence in patient transitions of care is a customary and best practice. Venous and arterial disease and diabetes are associated with low blood flow which may increase the risk of tissue damage. These diseases are indicators of factors that may place individuals at risk for pressure ulcer development and are therefore important for care planning. Low BMI, which may be an indicator of underlying disease severity, may be associated with loss of fat and muscle, resulting in potential risk for pressure ulcers. Bowel incontinence, and the possible maceration to the skin associated, can lead to higher risk for pressure ulcers. In addition, the bacteria associated with bowel incontinence can complicate current wounds and cause local infection. Mobility is an indicator of impairment or reduction in mobility and movement which is a major risk factor for the development of pressure ulcers. Taken separately and together, these data elements are important for care planning, transitions in services and identifying medical complexities.

In sections XII.G.1 and XII.J.1 of this final rule, we discuss our rationale for proposing that the data elements used in the measures meet the definition of standardized patient assessment data. In summary, we believe that the collection of such assessment data is important for multiple reasons, including clinical decision support, care planning, and quality improvement, and that the data elements assessing pressure ulcers and

the data elements used to risk adjust showed good reliability. We solicited stakeholder feedback on the quality measure, and the data elements from which it is derived, by means of a public comment period and TEPs, as described in section XII.G.1 of this final rule. We received several comments on our proposal, which are summarized below.

*Comment:* We received support for the reporting of data elements already implemented in the IRF QRP to satisfy the requirement to report standardized patient assessment data. One commenter recommended the collection of additional data elements under the category of Medical conditions and co-morbidities.

*Response:* We appreciate the comments in support of the proposal, and agree that these data elements currently reported by IRFs meet the definition of standardized patient assessment data and satisfy the requirement to report standardized patient assessment data. In our ongoing work to identify clinically useful data elements appropriate for standardization, we are evaluating and testing additional data elements in the category of Medical Conditions and Co-morbidities that may address some of the commenter's concerns.

*Final decision:* After consideration of the public comments we received, we are finalizing that the data elements currently reported by IRFs to calculate the current measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), and the proposed measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, meet the definition of standardized patient assessment data for medical conditions and co-morbidities under section 1899B(b)(1)(B)(iv) of the Act, and that the successful reporting of that data under section 1886(j)(7)(F)(i) of the Act will also satisfy the requirement to report standardized patient assessment data under section 1886(j)(7)(F)(ii) of the Act.

For comments related to the pressure ulcer quality measure, we refer readers to section XII.G.1. of this final rule.

*K. Form, Manner, and Timing of Data Submission Under the IRF QRP*

1. Start Date for Standardized Patient Assessment Data Reporting by New IRFs

In the IRF PPS FY 2016 final rule (80 FR 47123 through 47124), we adopted timing for new IRFs to begin reporting quality data under the IRF QRP beginning with the FY 2017 IRF QRP. We proposed that the new IRFs will be required to begin reporting standardized patient assessment data on the same schedule.

We did not receive any comments about the timing for new IRFs to begin reporting standardized patient assessment data.

*Final decision:* We are finalizing our proposal that new IRFs will begin reporting standardized patient assessment data on the same schedule as the one established for quality data under the IRF QRP.

2. Mechanism for Reporting Standardized Patient Assessment Data Beginning With the FY 2019 IRF QRP

Under our current policy, IRFs report data by completing applicable sections of the IRF–PAI, and submitting the IRF–PAI to CMS through the QIES, ASAP system. For more information on IRF QRP reporting through the QIES ASAP system, refer to the ''Related Links'' section at the bottom of *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Software.html.* We proposed that the standardized patient assessment data elements would utilize the same mechanism, since they are either already included on, or would be added to, the IRF–PAI. Details regarding the IRF–PAI to the proposed standardized assessment data are available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-PAI-and-IRF-QRP-Manual.html.*

We did not receive any public comments on this proposal.

*Final decision:* We are finalizing our proposal that IRFs must report standardized patient assessment data by completing applicable sections of the IRF–PAI, and submitting the IRF–PAI to CMS through the QIES ASAP system.

3. Schedule for Reporting Standardized Patient Assessment Data Beginning With the FY 2019 IRF QRP

Starting with the FY 2019 IRF QRP, we proposed to apply our current schedule for the reporting of measure data to the reporting of standardized patient assessment data. Under that policy, except for the first program year for which a measure is adopted, IRFs must report data on measures for IRF Medicare patients who are discharged during the 12-month calendar year (CY) period that apply to the program year. For the first program year for which a measure is adopted, IRFs are only required to report data on IRF Medicare patients who are discharged on or after October 1 of the last quarter of the calendar year that applies to that program year. For example, for the FY 2018 IRF QRP, data on measures adopted for earlier program years must be reported for all IRF Medicare patients who are discharged during CY 2016. However, data on new measures adopted for the first time for the FY 2018 IRF QRP must only be reported for IRF Medicare patients who are discharged during the last calendar year quarter of 2016.

Tables 9 and 10 illustrate this policy using the FY 2019 and FY 2020 IRF QRP as examples.

TABLE 9—SUMMARY ILLUSTRATION OF INITIAL REPORTING CYCLE FOR NEWLY ADOPTED MEASURE AND STANDARDIZED PATIENT ASSESSMENT DATA REPORTING USING CY Q4 DATA *^

| Proposed data collection/submission quarterly reporting period * | Proposed data submission quarterly deadlines *^ for the FY 2019 IRF QRP * * |
|---|---|
| Q4: CY 2017 10/1/2017–12/31/2017 | CY 2017 Q4 Deadline: May 15, 2018. |

* We note that the submission of IRF–PAI data must also adhere to the IRF PPS deadlines.

* * The term ''FY 2019 IRF QRP'' means the fiscal year for which the IRF QRP requirements applicable to that fiscal year must be met in order for an IRF to receive the full annual update when calculating the payment rates applicable to it for that fiscal year.

^ Applies to data reporting using the IRF PAI and data reporting using the National Health Safety Network.

TABLE 10—SUMMARY ILLUSTRATION OF CALENDAR YEAR QUARTERLY REPORTING CYCLES FOR MEASURE AND STANDARDIZED PATIENT ASSESSMENT DATA REPORTING *^

| Proposed data collection/submission quarterly reporting period * | Proposed data submission quarterly deadlines *^ for the FY 2020 IRF QRP * * |
|---|---|
| Q1: CY 2018 1/1/2018–3/31/2018 | CY 2018 Q1 Deadline: August 15, 2018. |
| Q2: CY 2018 4/1/2018–6/30/2018 | CY 2018 Q2 Deadline: November 15, 2018. |
| Q3: CY 2018 7/1/2018–9/30/2018 | CY 2018 Q3 Deadline: February 15, 2019. |
| Q4: CY 2018 10/1/2018–12/31/2018 | CY 2018 Q4 Deadline: May 15, 2019. |

* We note that the submission of IRF–PAI data must also adhere to the IRF PPS deadlines.
* * The term ''FY 2020 IRF QRP'' means the fiscal year for which the IRF QRP requirements applicable to that fiscal year must be met in order for an IRF to receive the full annual update when calculating the payment rates applicable to it for that fiscal year.
^ Applies to data reporting using the IRF PAI and data reporting using the National Health Safety Network.

We proposed to extend our current policy governing the schedule for reporting quality measure data to the reporting of standardized patient assessment data beginning with the FY 2019 IRF QRP. We sought public comment on our proposal.

We did not receive any public comments on this proposal.

*Final decision:* We are finalizing our proposal to extend our current policy governing the schedule for reporting quality measure data to the reporting of standardized patient assessment data beginning with the FY 2019 IRF QRP.

4. Schedule for Reporting the Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury Measure Beginning With the FY 2020 IRF QRP

As discussed in section XIII.G. of this final rule, we are adopting the Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury measure beginning with the FY 2020 IRF QRP. In the FY 2018 IRF PPS proposed rule (82 FR 20740), we proposed that IRFs would report data on that measure using the IRF–PAI that is submitted through the QIES ASAP system. IRFs would be required to report these data on admission and discharge for all Medicare Part A and MA patients discharged between October 1, 2018 and December 31, 2018. More information on IRF reporting using the QIES ASAP system is located at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/Technical-Information.html.*

Under our current policy, IRFs would only be required to submit data on the proposed measure for the fourth quarter of CY 2018 for purposes of the FY 2020 IRF QRP. Starting in CY 2019, IRFs would be required to submit data for the entire calendar year beginning with the FY 2021 IRF QRP.

We did not receive any public comments on this proposal.

*Final decision:* We are finalizing our proposal to require IRFs to report data on the Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury measure using the IRF–PAI that is submitted through the QIES ASAP system beginning with the FY 2020 IRF QRP.

5. Input Sought for Data Reporting Related to Assessment Based Measures

Through various means of public input, including that through previous rules, public comment on measures and the Measures Application Partnership, we received input suggesting that we expand the quality measures to include all patients regardless of payer status so as to ensure representation of the quality of the services provided on the population as a whole, rather than a subset limited to Medicare. For IRFs, the Medicare population comprises approximately 60 percent of the IRF population served. We agree that collecting quality data on all patients in the IRF setting supports CMS' mission to ensure quality care for all individuals, including Medicare beneficiaries. We also appreciate that collecting quality data on all patients regardless of payer source may create additional burden. However, we also note that the effort to separate out Medicare beneficiaries from other patients has clinical and work flow implications with an associated burden, and we further appreciate that it is common practice for IRFs to collect IRF-PAI data on all patients, regardless of payer source. Accurate representation of quality provided in IRFs is best conveyed using data on all IRF patients, regardless of payer. Thus, we sought, and continue to seek, input on whether we should require quality data reporting on all IRF patients, regardless of payer, where feasible—noting that Part A claims data are limited to only Medicare beneficiaries.

We received several comments about the request for input on data reporting related to the IRF QRP, which are summarized below.

*Comment:* Several commenters supported expanding the IRF QRP to include all patients regardless of payer. MedPAC was supportive of the effort to ensure quality care for all patients, but sensitive to the issue of burden, and cautioned CMS that any future payment adjustments related to performance should be based only on Medicare beneficiary outcomes. However, many commenters noted that this would not be overly burdensome, as most of their organizations' members currently complete the IRF–PAI on all patients, regardless of payer status. One commenter recommended that CMS continue to align the patient assessment instruments across PAC settings to apply quality measures and patient assessment data to a uniform Medicare population at a minimum, and account for payer status in public reporting. One commenter questioned how CMS would use data collected from other payers, and whether the use of the data would outweigh any additional reporting burden. One commenter supported collecting the IRF–PAI on all patients, with the concern that collecting on only a subset of patients could be interpreted as providing different levels of care based on payer.

*Response:* We appreciate the feedback received on this topic and agree that it is import to ensure quality of care for all patients while accounting for burden. We will take into consideration the commenters' concerns, questions, and recommendations as we further assess expanding the IRF QRP to include all patients regardless of payer.

*L. Application of the IRF QRP Submission Requirements and Payment Impact to the Standardized Patient Assessment Data Beginning With the FY 2019 IRF QRP*

We proposed to revise § 412.634(b) to require IRFs to report both data on measures and standardized patient assessment data under the IRF QRP, in a form and manner, and at a time specified by CMS.

We did not receive any comments on this proposal.

*Final decision:* We are finalizing our proposal and revising § 412.634(b) to

require IRFs to report both data on measures and standardized patient assessment data under the IRF QRP, in a form and manner, and at a time specified by CMS.

*M. Application of the IRF QRP Exception and Extension Requirements to the Submission of Standardized Patient Assessment Data Beginning With the FY 2019 IRF QRP*

In the FY 2017 IRF PPS final rule (81 FR 52124), we codified the requirements pertaining to data submission exception and extension for the IRF QRP at § 412.634(c). We proposed to revise § 412.634(c) to extend these policies to the submission of standardized patient assessment data beginning with the FY 2019 IRF QRP.

We received one comment about this proposal, which is summarized below.

*Comment:* A commenter supported applying the existing exception and extension policies for IRF QRP to the reporting of standardized patient assessment data.

*Response:* We appreciate the commenter's support.

*Final decision:* We are finalizing our proposal and revising § 412.634(c) to apply the existing exception and extension policies for the IRF QRP to the submission of standardized patient assessment data beginning with the FY 2019 IRF QRP.

*N. Application of the IRF QRP Data Completion Thresholds to the Submission of Standardized Patient Assessment Data Beginning With the FY 2019 IRF QRP*

In the FY 2015 IRF PPS final rule (79 FR 45921 through 45923), we finalized IRF QRP thresholds for completeness of IRF data submissions. To ensure that IRFs are meeting an acceptable standard for completeness of submitted data, we finalized the policy that, beginning with the FY 2016 IRF QRP, IRFs must meet or exceed two separate data completeness thresholds: One threshold set at 95 percent for completion of measures data collected using the IRF–PAI submitted through the QIES and a second threshold set at 100 percent for measures data collected and submitted using the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN). The term ''measures'' refers to quality measures, resource use, and other measures.

For a detailed discussion of the finalized IRF QRP data completion requirements, please refer to the FY 2015 IRF PPS final rule (79 FR 45921 through 45923). In the FY 2017 IRF PPS final rule, (81 FR 52124), we codified the IRF QRP Data Completion Thresholds at § 412.634. We noted that § 412.634(f)(1) requires that IRFs meet or exceed the reporting threshold set at 95 percent for completion of measure data collected using the IRF–PAI. However, some assessment data will not invoke a response and in those circumstances are not ''missing'' nor is the data incomplete. For example, in the case of a patient who does not have any of the medical conditions in a check-all-that-apply listing, the absence of a response indicates that the condition is not present, and it would be incorrect to consider the absence of such data as missing in a threshold determination. In the FY 2018 IRF PPS proposed rule (82 FR 20740), we proposed to extend our current IRF QRP data completion requirements to the reporting of standardized patient assessment data.

We also proposed to revise § 412.634(f)(1) and (2) to include the submission of standardized patient assessment data that is collected using the IRF–PAI.

As we noted in the FY 2015 IRF PPS final rule (79 FR 45921 through 45923), the threshold of 95 percent is based on the need for complete records, which allows appropriate analysis of measure data for the purposes of updating measure specifications as they undergo measure maintenance reviews with the NQF. Additionally, complete data is needed to understand the validity and reliability of data items, including risk-adjustment models. Our data suggests that the majority of current IRF providers are in compliance with or exceed this threshold related to the measure data, and we believe it is feasible for the standardized patient assessment data as well.

We invited public comment on our proposal to revise § 412.634(f)(1) and (2) to add standardized patient assessment data for the 95 percent completeness threshold for data collected via IRF–PAI. We received several comments, which are summarized below.

*Comment:* Several commenters opposed the proposal to apply the 95 percent data completion requirement for IRF quality measures to the standardized patient assessment data, suggesting that the IRF QRP requirements are higher than other PAC settings. Many commenters noted that CMS has proposed an 80 percent completion threshold for standardized patient assessment data in the LTCH and SNF QRPs, and recommended that CMS avoid perpetuating discrepant standards across PAC settings. Commenters recommended that CMS adopt an 80 percent threshold for standardized patient assessment data, in line with other PAC QRPs. A commenter believed that IRF thresholds were historically higher than the SNF thresholds because of the relative length of the assessment instruments in the settings, but noted that the IRF–PAI has increased by several pages in the past three rulemaking cycles, making it similar in length to the SNF MDS instrument. Commenters recommended that CMS work with stakeholders to develop a more appropriate threshold, consistent with the requirements for other PAC QRPs.

One commenter suggested that the IRF QRP completion threshold should be lower in the first reporting year for which new items are required. One commenter suggested a grace period for the first three months of data collection on new measures to account for when IRFs are still training staff and adapting to new requirements. Alternatively, another commenter suggested that penalties for data completion threshold should be based on at least 12 months of data. One commenter stated that the availability of a ''dash'' response option on the IRF–PAI without sufficient guidance increases the risk that an IRF will fall short of the threshold. These commenters suggested that the dash counts against the completion threshold, raising concern that the rapid increase in items for which dashes are an available response option is unnecessarily increasing the risk that an IRF will fall short of the 95 percent threshold.

*Response:* While we maintain that providers should be submitting complete and accurate data, and that our data compliance checks suggest that the majority of current IRF providers are in compliance with, or exceed, the 95 percent data completion threshold for the assessment-based quality measure data, we also appreciate the concerns the commenters have expressed regarding the inconsistent reporting threshold for IRFs in comparison with other post-acute care quality reporting programs, the concerns expressed about the increased assessment data reporting required on the additional measures (and the proposed standardized patient assessment data elements) that have been implemented into the IRF QRP as the program has evolved, and the increased potential of falling short of achieving the threshold because the reporting requirements have increased. We also appreciate the concerns pertaining to an increase in assessment data elements are compounded because many response options include the use of a dash. However this assessment response option was intentional so as to enable the assessor to indicate if they

did not assess or know the status of the information at the time of the assessment rather than forcing a response.

We appreciate the suggestion regarding CMS working with stakeholders to consider additional approaches related to threshold determinations, and further appreciate the suggestions related to a grace period in the first quarter of data reporting on new data submission, and only assessing on a year of data submission, or lowering the threshold in the first year of reporting. Although IRFs have largely been successful in their data reporting and achieving the threshold, we also appreciate the confusion that may exist with two thresholds. We also appreciate the importance of consistency across programs and agree that the IRF QRP has evolved to include additional measures and data reporting. Taken together, we believe that while we would agree that working with stakeholders on new approaches to fair and consistent thresholds would be informative and useful, we also believe that our current policy, as commented on, requires revision due to the growth of the program. We are also mindful of the burden placed on providers in tracking threshold compliance. Therefore, while we anticipate continued levels of reporting success, we appreciate the concerns raised that the completion of at least 95 percent of all required assessments and will take these concerns under considerations for future rulemaking.

Regarding the suggestion that we not consider the initial quarter of data reporting by IRFs on new data that is required, we have analyzed the first quarter of data reporting on new measures submitted by IRFs and found that most IRFs were successful in their data submission and therefore do not believe that the first quarter of reporting should be waived at this time. While we appreciate that the suggestion regarding lowering the threshold for the first year of data reporting will address the concerns provided by commenters, we believe that addressing the concerns by reducing the overall threshold to a level that is consistent with the other programs, and maintained until we are able to further evaluate the data, would resolve the immediate concerns regarding our current policy pertaining to the fairness given the amount of data elements that must be coded 100 percent of the time on at least 95 percent of all assessments, which will likely expand as the program expands, as described. We believe that we should take such input into consideration. We are also sensitive to the level of tracking that would be necessary by IRFs and the potential this could have for increasing administrative burden and that such activities might detract from direct care services.

*Final Decision:* We are finalizing our policy to revise § 412.634(f)(1) and (2) to apply the IRF QRP data completion thresholds to the submission of standardized patient assessment data beginning with the FY 2019 IRF QRP.

*O. Policies Regarding Public Display of Measure Data for the IRF QRP*

Section 1886(j)(7)(E) of the Act requires the Secretary to establish procedures for making the IRF QRP data available to the public after ensuring that an IRF has the opportunity to review its data prior to public display. Measure data is currently displayed on the Inpatient Rehabilitation Facility Compare Web site, which is an interactive web tool that assists individuals by providing information on IRF quality of care, including those who need to select an IRF. For more information on IRF Compare, we refer readers to *https://www.medicare.gov/inpatientrehabilitationfacilitycompare/.* Additionally, for a more detailed discussion about the provider's confidential review process prior to public display of quality measures, we refer readers to the FY 2017 IRF PPS final rule (81 FR 52128 through 52131).

We also finalized the process we use to publish a list of IRFs that successfully meet the reporting requirements for the applicable IRF QRP year on the IRF QRP Web site in the FY 2017 IRF PPS final rule (81 FR 52125). The list of compliant IRFs is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Data-Submission-Deadlines.html.*

In the FY 2017 IRF PPS final rule (81 FR 52055 through 52141), we finalized the public display of measure data on the IRF Compare Web site in CY 2017 for the following four quality measures pending the availability of data: (1) NHSN Facility-wide Inpatient Hospital-onset MRSA Bacteremia Outcome Measure (NQF #1716); (2) NHSN Facility-wide Inpatient Hospital-onset CDI Outcome Measure (NQF #1717); (3) Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431); and (4) Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (NQF #0680).

In the FY 2017 IRF PPS final rule (81 FR 52126), we stated that ''pending the availability of data'', the public display of NHSN Facility-wide Inpatient Hospital-onset MRSA Bacteremia Outcome Measure (NQF #1716) and NHSN Facility-wide Inpatient Hospital-onset CDI Outcome Measure (NQF #1717) would initially be based on data collected from January 1, 2015, through December 31, 2015 and will be displayed based on four rolling quarters. We would like to clarify that the initial public display of data for these two quality measures (MRSA and CDI) will be based on data collected from January 1, 2016 through December 31, 2016 (CY 2016), as the CY 2015 data is not available for display using the Standardized Infection Ratio (SIR) metric, but rather this data (CY 2015) was used by the CDC to calculate the ''predicted'' number of infections (the number of infections that would be expected to occur based on previously reported data) for each IRF, so that subsequent data could be used to calculate the SIR for each of these quality measures.

The SIR is a summary statistic that compares the ''predicted'' number of infections to the ''observed'' or actual number of infections for a given IRF. This process or ''rebaselining'' of data occurs periodically when the CDC determines that referent period of data or ''baseline'' is no longer meaningful due to changes in the quality measure protocols or changes in provider populations. When the CDC uses a specific year's data to inform newly calculated ''predicted'' number of infections, we are unable to use that specific year of data to calculate the SIR, and for this reason, we are unable to display the MRSA and CDI performance data using the CY 2015 IRF NHSN data, and will use the CY 2016 data to inform the SIR calculations when we publicly display the SIRs for these measures in fall 2017. The Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) and Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (NQF #0680) will be based on the influenza vaccination season from October 1, 2015, through March 31, 2016 and will be updated annually. We refer readers to the FY 2017 IRF PPS final rule (81 FR 52126 through 52128) for details on the calculations and display of these quality measures. In the FY 2018 IRF PPS proposed rule, pending the availability of data, we proposed to publicly report data in CY 2018 for the following two assessment-based measures: (1) Application of Percent of Long-Term Care Hospital (LTCH) Patients With an Admission and Discharge Functional Assessment and a Care Plan That

Addresses Function (NQF #2631); and (2) Application of Percent of Residents Experiencing One or More Falls with Major Injury (NQF #0674). Data collection for these two assessment-based measures began on October 1, 2016. We proposed to display data for the assessment-based measures based on four rolling quarters of data and would initially use discharges from January 1, 2017, through December 31, 2017. In addition, we proposed to publicly report four claims-based measures: (1) Medicare Spending Per Beneficiary—PAC IRF QRP; (2) Discharge to Community—PAC IRF QRP; (3) Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP; and (4) Potentially Preventable Within Stay Readmission Measure for IRFs.

These measures were adopted for the IRF QRP in the FY 2017 IRF PPS final rule (81 FR 52130 through 52131) to be based on data from 2 consecutive calendar years. As previously adopted, confidential feedback reports for these four claims-based measures will be based on calendar years 2015 and 2016 and data collected for discharges beginning January 1, 2015, through December 31, 2016. However, our current proposal revises the dates for public reporting and we proposed to transition from calendar year to fiscal year to make these measure data publicly available by October 2018. Thus, we proposed for public reporting beginning in CY 2018 for four claims-based measures based on fiscal years 2016 and 2017 and data collected from discharges beginning October 1, 2015, through September 30, 2017.

We proposed to remove the following claims-based measure: ''All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from Inpatient Rehabilitation Facilities'' from the IRF QRP and public reporting by October 2018. We refer readers to section XIII.H. of this final rule for additional information regarding the removal of this measure from quality reporting and public display. We also proposed to remove the following assessment-based measure ''Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678)'' and to replace it with a modified version of the measure entitled ''Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury'' from the IRF QRP and public reporting by October 2020. We refer readers to section XIII.G. of this final rule for additional information regarding the proposed replacement of this measure from quality reporting and public display.

For the assessment-based measures, Application of Percent of LTCH Patients With an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631); and Application of Percent of Residents Experiencing One or More Falls with Major Injury (NQF #0674), to ensure the statistical reliability of the measures, we also proposed to assign IRFs with fewer than 20 eligible cases during a performance period to a separate category: ''The number of cases/patient stays is too small to report.'' If an IRF had fewer than 20 eligible cases, the IRF's performance would not be publicly reported for the measure for that performance period.

For the claims-based measures, Discharge to Community—PAC IRF QRP; Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP; and Potentially Preventable Within Stay Readmission Measure for IRFs, to ensure the statistical reliability of the measures, we also proposed to assign IRFs with fewer than 25 eligible cases during a performance period to a separate category: ''The number of cases/patient stays is too small to report.'' If an IRF had fewer than 25 eligible cases, the IRF's performance would not be publicly reported for the measure for that performance period. For Medicare Spending Per Beneficiary—PAC IRF QRP, to ensure the statistical reliability of the measure, we proposed to assign IRFs with fewer than 20 eligible cases during a performance period to a separate category: ''The number of cases/patient stays is too small to report.'' If an IRF had fewer than 20 eligible cases, the IRF's performance would not be publicly reported for the measure for that performance period.

TABLE 11—PREVIOUSLY FINALIZED AND MEASURES FOR CY 2018 PUBLIC DISPLAY AND CONFIDENTIAL FEEDBACK REPORTS

| |
|---|
| Previously Finalized Measures: |
| Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #678). |
| National Healthcare Safety Network Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138). |
| NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus Bacteremia Outcome Measure (NQF #1716). |
| NHSN Facility-wide Inpatient Hospital-onset Clostridium difficile Infection Outcome Measure (NQF #1717). |
| Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431). |
| Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (NQF #0680). |
| Proposed Measures: |
| Application of Percent of Long-Term Care Hospital (LTCH) Patients With an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631). |
| Application of Percent of Residents Experiencing One or More Falls with Major Injury (NQF #0674). |
| Medicare Spending Per Beneficiary—PAC IRF QRP. |
| Discharge to Community—PAC IRF QRP. |
| Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP. |
| Potentially Preventable Within Stay Readmission Measure for IRFs. |

We invited public comment on the proposal for the public display of the two assessment-based measures and four claims-based measures, the removal of the All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from IRFs from the IRF QRP and from public display, and the replacement of ''Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678)'' with a modified version of the measure entitled ''Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury'' as described above.

We received several comments on our proposals related to public display, which are summarized below.

*Comment:* A few commenters supported public display of quality measures. One commenter expressed support for publicly displaying measures as long as they are sufficiently risk adjusted, and specifically supported the following measures: Medicare Spending Per Beneficiary—PAC IRF QRP, Discharge to Community—PAC

IRF QRP, Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP, and Potentially Preventable Within Stay Readmission Measure for IRFs. One commenter specifically supported public reporting for the Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) and Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (NQF #0680).

*Response:* We acknowledge the support for finalized, risk adjusted measures that will be posted for public display, and agree that displaying IRF QRP data on the IRF Compare Web site is important for patients and families.

*Comment:* Several commenters requested that CMS provide IRFs with patient-level feedback reports for the claims-based measures. The commenters expressed concern that IRFs cannot examine their performance and identify opportunities for modifications to their patient care practices and procedures to improve quality without patient-level data. A few of these commenters added that the claims-level data are updated infrequently, which also affects IRFs' ability to use the data to improve quality of care.

*Response:* We acknowledge the commenters' request and agree that the reporting of patient-level feedback reports would be useful for providers. We are taking this recommendation into consideration and are actively exploring approaches to providing patient-level data for the claims-based measures. Regarding the timeliness of claims data for quality improvement, we addressed this issue in the FY 2017 IRF PPS final rule (81 FR 52129 through 52131), and we refer the reader to that detailed discussion.

*Comment:* Several commenters expressed concern that measure changes on IRF Compare may be confusing to providers and difficult to use. One commenter stated that the proposed change to the pressure ulcer measure would fundamentally change the values reported on IRF Compare and that modifications to the way items are collected on the IRF–PAI will also influence measures that are being reported. The commenter requested that a clear methodology for adding, modifying, and removing measures be made available to providers so they are able to manage their data accordingly.

*Response:* We acknowledge the concerns regarding updates to measures and underlying items, and the resulting performance results displayed on IRF Compare. We would like to clarify that the proposed modifications to the pressure ulcer measure will not result in changes to how the quality measure performance results are publicly displayed. We plan to provide IRFs with detailed instructions and outreach training regarding measure changes and how to obtain and interpret confidential feedback reports that give providers their quality measure information before it is posted on IRF Compare. Additionally, we will work to provide documentation, education, and notification to the public prior to any measure change that will be displayed on IRF Compare.

*Comment:* A few commenters expressed concern that the measures employ different time frames for collecting data that result in provider performance based on different patient populations which could lead to misinterpretation of quality. As a result, a few commenters recommended delaying the public display of the IRF QRP data on IRF Compare until the measure reporting periods align.

*Response:* We acknowledge the concern expressed from the commenters that the measures use different time frames for collecting data that result in provider performance based on different patient populations, which could lead to misinterpretation of quality. We align the reporting periods and deadlines across PAC settings where alignment of the reporting period for consistency is appropriate.

*Comment:* One commenter recommended removal of the measure performance categories from IRF Compare, and requested that CMS provide the statistical methodologies used to calculate provider performance available to stakeholders. The commenter believed that this transparency would allow providers to analyze and replicate the IRF QRP data in order to validate measures on public display.

*Response:* We appreciate the commenter's concerns over the performance categories used to publicly display the IRF QRP readmission measures. The methods used to construct and assign performance categories are based on a robust statistical approach. Further, the approach used for displaying these measures is consistent with those used for public reporting of readmission measures in other quality reporting programs. For the currently publicly displayed NQF-endorsed All-Cause Readmission measure, information regarding the consideration of the statistical approach used and creation of the comparative performance categories is detailed in the NQF submission materials available at *http://www.qualityforum.org/ProjectTemplateDownload.aspx?SubmissionID=2502* (see section 2b of the IRF MSF Measure Testing document). Also, we plan to publish additional technical documentation regarding the methods used for categorizing provider performance for the claims-based measure that will be publicly displayed in 2018. We will continue to evaluate reporting methods for public display of the claims-based measures.

*Comment:* The commenter expressed concern regarding CMS's current approach to publicly report readmissions data and stated that the proposed rule does not provide clear details on how this data would be displayed for Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP and Potentially Preventable Within Stay Readmission Measure for IRFs. The commenter recommended that CMS work with stakeholders in the development of a meaningful approach to publicly report readmissions quality data. The commenter further recommended not using performance categories if the PPR measures are publicly reported.

*Response:* We acknowledge the commenter's concerns regarding the public display of the readmission measures. We continue to encourage stakeholders to provide input regarding approaches to publicly report readmissions quality data through the public mailbox or through future technical expert panels and other opportunities. With regard to the commenter's recommendation not to use performance categories when the readmission measures are publicly reported, please refer to the detailed response above regarding the approach for public display for all claims-based measures.

*Comment:* A commenter recommended not finalizing the proposal to publicly report the claims-based resource use measure, Medicare Spending Per Beneficiary-PAC IRF QRP. The commenter stated that this measure does not relate to quality of care in IRFs, is not an intuitive measure for consumers, and may be confused with other measures such as the Medical Loss Ratio (MLR) reported by private insurance plans. The commenter further stated that the measure should be available to researchers and others with an understanding of the measure's nuances, but is not ready to be made available for the public.

*Response:* We appreciate the commenter's concerns and will take their suggestions into consideration. Section 1899B(g)(1) of the Act requires

the Secretary to provide for public reporting of provider performance on resource use and other measures under section 1899B(d)(1) of the Act which includes total estimated Medicare spending per beneficiary. Confidential feedback reports will be available to IRFs prior to the public display of this measure and measure specifications are available to providers, researchers, and other stakeholders on the IRF QRP Web site: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.* We will also perform provider outreach and training. In regard to the commenter's concerns about public interpretation, before we display a measure on IRF Compare we perform consumer testing to understand if the information is meaningful to the consumer and if they understand the measure as we intend on displaying it. We also continue to receive and review public comment on an ongoing basis submitted by users regarding IRF Compare and take these into consideration when revising the Web site.

*Comment:* One commenter supported the removal of the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge (NQF #2502) and replacing it with Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, for public display.

*Response:* We appreciate the support for the removal of the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge (NQF #2502), and implementation of Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury on IRF Compare. We want to clarify that the Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP and the Potentially Preventable Within Stay Readmission Measure for IRFs will replace the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge (NQF #2502). Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury will replace the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) measure.

*Comment:* One commenter expressed concern about the proposed minimum patient thresholds and recommended CMS provide rationale for proposed limits and use a threshold of 30 cases for all measures.

*Response:* We appreciate the comment regarding the minimum patient threshold. Each measure has specifically applied minimum patient thresholds in public reporting so that there is enough volume of cases reported to protect individual privacy and provide meaningful results with a representative sample size. As we continue to monitor and evaluate measure performance, we will consider revising the minimum patient thresholds.

*Comment:* A few commenters expressed concern about the claims-based measures reporting periods. One commenter stated that the claims-based measure reported on IRF Compare is one to two years behind the other IRF–PAI and CDC NHSN measures. Another commenter stated the claims-based All-Cause measure is delayed three to four years (January 1, 2013 through December 31, 2014), and that this delay affects how actionable the data is for providers and how meaningful the data is to stakeholders and consumers.

*Response:* We acknowledge the commenters' concerns and suggestions to provide claims-based measure reports in a timelier manner. The All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from IRFs (NQF #2502) is based on two consecutive years of data to ensure a sufficient sample size to reliably assess IRF performance. As discussed in section XIII.H of this final rule, we are finalizing the removal of the All-Cause Readmission measure beginning with the FY 2019 IRF QRP and will replace it with the Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP and Potentially Preventable Within Stay Readmission Measure for IRFs, which will use more timely claims data and will initially include data from October 1, 2015 through September 30, 2017. The measures are as current as possible given the time for the claims submission process and the run-off period.

*Comment:* Some commenters expressed concern about the usefulness of the CAUTI, MRSA, and CDI quality measures due to the measures reported low incidence rate for CAUTI and expected low incidence rates for MRSA and CDI. A few commenters recommended publicly reporting data that is relevant and variable across IRFs or focus on one Hospital Acquired Infection (HAI) measure instead of all three CDC NHSN infection measures; CAUTI, MRSA, and CDI.

*Response:* We appreciate commenters' concern about the usefulness of the HAI measures given the low incidence rates in IRFs. The HAI measures currently on IRF Compare and those being proposed for public reporting support the goals of the National Quality Strategy, the CMS Quality Strategy, the HHS HAI Action Plan (*https://health.gov/hcq/prevent-hai-action-plan.asp*), and the Hospital Acquired Condition (HAC) Reduction Program. It is both a CMS and an HHS priority to ensure the delivery of high quality, patient-centered, and safe care across all care settings.

All of the HAI measures are fully endorsed by NQF for the IRF setting. The CAUTI measure is highly relevant to IRFs because urinary catheters are commonly used in the IRF setting. Healthcare-associated MRSA infections occur frequently in patients whose treatment involves the use of invasive devices, such as catheters. Older adults and patients in health care settings are most vulnerable to MRSA infections, as these patients may have weakened immune systems. CDIs are increasing in all health care facilities, and the IRF population is highly vulnerable to CDI. Readers can refer to additional information regarding the clinical significance of the MRSA and CDI measures in FY 2015 IRF PPS final rule (79 FR 45911 through 45913).

Even if the incidence rates may be low for these measures in IRFs, we have observed variability among facilities. We believe it is important to report data on HAIs acquired during the IRF stay because these infections are associated with increased cost, hospital length of stay, morbidity, and mortality. However, we appreciate the feedback and will continue to monitor IRF performance across all quality measures and reassess reporting certain measures in our QRPs.

*Comment:* One commenter suggested CMS include the total number of pressure ulcers and the observed rate of pressure ulcers for the measure Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) in the Provider Preview reports to support IRFs in validating their information.

*Response:* We appreciate the commenter's recommendation and will take it into consideration as we continue to make refinements to IRF Compare.

*Comment:* A commenter expressed concern regarding providers' ability to review CDC NHSN measure results prior to public display on IRF Compare due to timing and system issues.

*Response:* We acknowledge the commenter's concerns and are working closely with CDC to ensure provider access to timely and appropriate reports with accurate data prior to public display. In response to the various CDC NHSN systems issues providers experienced in late 2016 and early 2017, we have suppressed public display of the CDC NHSN CAUTI and CLABSI measure results on IRF Compare until such time as we are certain we can post accurate data. We would like to assure providers that they will be given the

opportunity to review any corrected data for a full 30 days, prior to the public posting of that data. We will notify providers when we are ready to add CAUTI and CLABSI measure results back to IRF Compare through normal channels of communications such as listserv notices, IRF QRP Web site postings, etc. Furthermore, given the systems issues that have arisen to date, we are considering any potential effect on provider compliance, and factoring this into our analysis.

*Comment:* One commenter expressed concern that the measures on the IRF Compare are not discernable and relevant to the general public, and questioned whether differences in quality that are displayed are clinically meaningful and distinguishable between high- and low-quality providers.

*Response:* We appreciate the commenter's feedback. We respectfully disagree that there is not enough variability to distinguish between high- and low-quality providers. Most of the measures are NQF-endorsed and go through a rigorous vetting process including analysis of data regarding variability, validity, and reliability. Reporting these measures encourages providers to strive for the highest quality of care. The measures currently on IRF Compare or proposed for public reporting support the goals of the National Quality Strategy, the CMS Quality Strategy, the HHS HAI Action Plan, and the HAC Reduction Program. It is both a CMS and an HHS priority to ensure the delivery of high quality, patient-centered, and safe care across all care settings.

*Comment:* A few commenters recommended CMS delay the public display of quality measures until at least a full twelve months of data has been collected and providers are able to review and correct the information on these measures. In addition, one commenter suggested CMS could use case-mix index, length of stay efficiency, Functional Improvement Measure (FIM) change, and discharge FIM in public reporting because the data is easily available to CMS and provides a good source of comparison between IRF providers.

*Response:* We acknowledge commenters' suggestions and note that the recommendations align with the current process for public display of quality measures. That is, data for the quality measures in the IRF QRP is collected for at least twelve months before it is available in confidential feedback reports. In addition, providers have the ability to review and correct their data prior to public display using Review and Correct reports. Subsequently, the Provider Preview reports will be available after the data correction deadline has passed for the last quarter of the reporting period. IRF Compare currently provides additional facility-level information on the medical conditions treated in the IRF over the last year. The quality of patient care that IRFs provide to patients can vary from facility to facility. IRF Compare reports information on over 1,100 facilities across the nation and allows consumers to obtain information on the quality of care each facility provides. They can compare IRFs based on important indicators of quality. The information can assist them to make more informed decisions. In regard to comparison data, we will take the commenter's suggestions into consideration for future updates to IRF Compare.

*Final Decision:* After consideration of the public comments we received, we are finalizing our proposals as proposed to begin publicly reporting in CY 2018 the following two assessment-based measures pending the availability of the data: ''Application of Percent of Long-Term Care Hospital (LTCH) Patients With an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function'' (NQF #2631), and ''Application of Percent of Residents Experiencing One or More Falls with Major Injury'' (NQF #0674), as well as the following four claims-based measures: ''Medicare Spending Per Beneficiary—PAC IRF QRP'', ''Discharge to Community—PAC IRF QRP'', ''Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP'', and ''Potentially Preventable Within Stay Readmission Measure for IRFs''. We are finalizing our proposals to remove the claims-based measure ''All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from IRFs'' from the IRF QRP and from public display by October 2018. We are also finalizing our proposals to remove the assessment-based measure ''Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay)'' (NQF #0678) and replace it with a modified version of the measure entitled ''Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury'' from the IRF QRP and public reporting by October 2020.

*P. Mechanism for Providing Feedback Reports to IRFs*

Section 1899B(f) of the Act requires the Secretary to provide confidential feedback reports to PAC providers on their performance on the measures specified under sections 1899B(c)(1) and (d)(1) of the Act, beginning 1 year after the specified application date that applies to such measures and PAC providers. In the FY 2017 IRF PPS final rule (81 FR 52131), we finalized processes to provide IRFs the opportunity to review their data and information using confidential feedback reports that will enable IRFs to review their performance on the measures required under the IRF QRP. Information on how to obtain these and other reports available to the IRF can be found at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Public-Reporting.html.* We did not propose any changes to this policy.

We received one comment on this topic, which is summarized below.

*Comment:* One commenter recommended an alternative mechanism, QualityNet, for providing confidential feedback reports to post-acute care providers, including IRFs.

*Response:* We appreciate the commenter's suggestion and will take this into consideration in future public reporting development for the IRF QRP and other post-acute care QRPs.

*Q. Method for Applying the Reduction to the FY 2018 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 section 1886(j)(7)(A)(i) of the Act, we proposed to apply a 2-percentage point reduction to the applicable FY 2018 market basket increase factor in calculating a proposed adjusted FY 2018 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.

We invited public comment on the proposed method for applying the reduction to the FY 2018 IRF increase factor for IRFs that fail to meet the quality reporting requirements. We did not receive any comments on this proposal.

*Final Decision:* We are finalizing our proposed method for applying the

reduction to the FY 2018 IRF increase factor for IRFs that fail to meet the quality reporting requirements.

Table 12 shows the calculation of the adjusted FY 2018 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 for the applicable reporting period(s).

TABLE 12—CALCULATIONS TO DETERMINE THE ADJUSTED FY 2018 STANDARD PAYMENT CONVERSION FACTOR FOR IRFS THAT FAILED TO MEET THE QUALITY REPORTING REQUIREMENT

| Explanation for adjustment | Calculations |
|---|---|
| Standard Payment Conversion Factor for FY 2017 | $15,708 |
| Increase Factor for FY 2018 (1.0 percent), as required by section 1886(j)(3)(C)(iii) of the Act, and further reduced by 2 percentage points for IRFs that failed to meet the quality reporting requirement | × 0.9900 |
| Budget Neutrality Factor for the Wage Index and Labor-Related Share | × 1.0007 |
| Budget Neutrality Factor for the Revisions to the CMG Relative Weights | × 0.9976 |
| Adjusted FY 2018 Standard Payment Conversion Factor | = $15,524 |

**XIV. Miscellaneous Comments**

*Comment:* Commenters suggested that CMS be more transparent about the methodology used to update the facility-level adjustments and the implementation schedule of these updates.

Additionally, the commenters suggested that we establish a three-year minimum interval or percentage change threshold in the methodology used to update these factors.

*Response:* As we did not propose any changes to the facility-level adjustments, these comments are outside the scope of the proposed rule. We reiterate our belief that it is better for the overall efficiency of the IRF PPS to update the facility-level 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), rather than to specify an exact period or threshold for updating the adjustment factors. 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 stated that CMS should not remove G72.81—Critical illness myopathy from the presumptive compliance list.

*Response:* We did not propose to remove G72.81—Critical illness myopathy from the presumptive compliance list and are not doing so in this final rule.

*Comment:* Two commenters recommended that CMS include the applicable 7th character for ''subsequent encounter'' for diagnosis codes on the presumptive compliance list. The commenters stated that IRF providers should follow all official ICD–10–CM coding values, regardless of payer. These commenters stated that including the subsequent encounter 7th character would eliminate the need for IRFs to keep up with multiple sets of coding rules.

*Response:* We appreciate the feedback from the commenters regarding the use of the 7th character for subsequent encounter for the presumptive methodology. We will consider the commenters' suggestion to consider the 7th character ''D''—subsequent encounter for certain injury codes on the list in future rulemaking.

*Comment:* One commenter requested the removal of the following codes as exclusions from the IGC list:

- S06.2X—(subcategory) Diffuse traumatic brain injury,
- S06.309A Unspecified focal traumatic brain injury, with loss of consciousness of unspecified duration, initial encounter.
- S06.309D Unspecified focal traumatic brain injury, with loss of consciousness of unspecified duration, subsequent encounter.
- S06.309S Unspecified focal traumatic brain injury, with loss of consciousness of unspecified duration, sequel.

*Response:* These codes were not listed as code exclusions on the proposed IGC lists, nor are they listed as code exclusions on the IGC lists that we are finalizing in this final rule. In addition, the codes S06.2X0A—Diffuse traumatic brain injury without loss of consciousness, initial encounter and S06.2X0S—Diffuse traumatic brain injury without loss of consciousness, sequela were listed on the proposed presumptive compliance list and are listed on the presumptive compliance list that we are finalizing in this final rule. If the commenter intended to refer to the code exclusion S06.9X9A—Unspecified intracranial injury with loss of consciousness of unspecified duration, initial encounter, which we are retaining as an excluded code under ''IGC Brain Dysfunction—0002.22 Traumatic, Closed Injury'' on the IGC lists that we are finalizing in this final rule, then we refer readers to section X.E. of this final rule for a discussion of code S06.9X9A.

*Comment:* One commenter stated that the proposed rule did not address the inclusion of recreational therapy in the case mix of therapies which are traditionally offered for selection by rehabilitation physicians for inclusion in the therapies order as medically necessary for patients of IRFs. The commenter encouraged us to include recreational therapy as one of covered therapy services (speech-language therapy, occupational therapy, physical therapy, and prosthetics/orthotics) in IRFs.

*Response:* As we did not propose any changes to the IRF coverage requirements in § 412.622(a)(3), (4), and (5) that would affect any of the requirements described in chapter 1, section 110 of the Medicare Benefit Policy Manual (Pub. L. 100–02), this comment is outside the scope of the proposed rule. As recreational therapy is generally less expensive for an IRF to provide than physical therapy, occupational therapy, or speech-language therapy, we believe that it would, in practice, replace many of these important core therapy services if it were included in the list of therapies that may be used to demonstrate the intensity of therapy provided in an IRF. We do not believe that recreational therapy services should replace the provision of any of the four core skilled therapy services (physical therapy, occupational therapy, speech-language therapy, and prosthetics/orthotics). Thus, we believe it should be left to each individual IRF to determine whether offering recreational therapy is the best way to achieve the desired patient care outcomes. As we have stated previously in the FY 2014 IRF PPS final rule (78 FR 47921), recreational therapy is a covered service in IRFs when the medical necessity is

well-documented by the rehabilitation physician in the medical record and is ordered by the rehabilitation physician as part of the overall plan of care for the patient. Recreational therapy may be offered as an additional service above and beyond the core skilled therapy services used to demonstrate the provision of an intensive rehabilitation therapy program, but may not replace one of these therapies.

*Comment:* One commenter expressed concerns that the presumptive methodology specifications might not be appropriately counting patients' comorbidities, as required by section 115 of the Medicare, Medicaid and SCHIP Extension Act of 2007, because the presence of an etiologic diagnosis exclusion on the IRF–PAI will cause the case to fail the presumptive methodology, and the algorithm does not proceed further to examine the comorbidities. This commenter requested that we review and modify the specifications and software, as needed.

*Response:* As we did not propose any changes to the presumptive methodology specifications, this comment is outside the scope of the proposed rule. However, section 115 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 requires comorbidities to be included with respect to an IRF's 60 percent rule compliance percentage, not the presumptive compliance methodology specifically. Even though an individual case may fail to meet the requirements under the presumptive methodology if an excluded etiologic diagnosis is present, this does not mean that the IRF is out of compliance with the 60 percent rule. Rather, the IRF would undergo medical review, which would assess all relevant factors, including comorbidities.

*Comment:* One commenter reiterated a recommendation from MedPAC's March 2016 Report to Congress, Chapter 9 (available at *http://www.medpac.gov/-documents-/reports*) that we should analyze patterns of coding across IRFs and reassess the inter-rater reliability of the IRF–PAI.

*Response:* This comment addresses data monitoring activities that were not discussed in the proposed rule, and are therefore outside the scope of the rule. However, we have shared this recommendation from MedPAC's March 2016 Report to Congress, Chapter 9 with the appropriate components within CMS for their consideration.

## XV. Provisions of the Final Regulations

In this final rule, we are adopting the provisions set forth in the FY 2018 IRF PPS proposed rule (82 FR 20690). Specifically:

- We will update the FY 2018 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.
- As established in the FY 2015 IRF PPS final rule (79 FR 45872 at 45882), the facility-level adjustments will remain frozen 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), as discussed in section V. of this final rule.
- We will update the FY 2018 IRF PPS payment rates by the market basket increase factor, as required by section 1886(j)(3)(C)(iii) of the Act, as described in section VI. of this final rule.
- We will update the FY 2018 IRF PPS payment rates by the FY 2018 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 2018, as discussed in section VI. of this final rule.
- We will update the outlier threshold amount for FY 2018, as discussed in section VII. of this final rule.
- We will update the CCR ceiling and urban/rural average CCRs for FY 2018, as discussed in section VII. of this final rule.
- We will remove the 25 percent payment penalty for IRF–PAI late transmissions, as discussed in section VIII. of this final rule.
- We will adopt revisions to the IRF–PAI to remove the voluntary swallowing status item, as discussed in section IX. of this final rule.
- We will adopt refinements to the presumptive compliance methodology ICD–10–CM diagnosis codes, as discussed in section X. of this final rule.
- We will consider the comments we received in response to our solicitation regarding the criteria used to classify facilities for payment under the IRF PPS, as discussed in section X. of this final rule.
- We will adopt the subregulatory process for certain updates to the presumptive methodology diagnosis code lists, as discussed in section XI. of this final rule.
- We will adopt the use of height/weight items on the IRF–PAI to determine patient BMI greater than 50 for cases of lower extremity single joint replacement under the presumptive methodology, as discussed in section XII. of this final rule.
- We will adopt revisions and updates to measures and reporting requirements under the IRF QRP in accordance with sections 1886(j)(7) and 1899B of the Act, as discussed in section XIII. of this final rule.

## XVI. Collection of Information Requirements

### *A. Statutory Requirement for Solicitation of Comments*

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

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

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

### *B. Collection of Information Requirements for Updates Related to the IRF QRP*

Failure to submit data required under section 1886(j)(7)(C) and (F) of the Act will result in the reduction of the annual update to the standard federal rate for discharges occurring during such fiscal year by 2 percentage points for any IRF that does not comply with the requirements established by the Secretary. At the time that this analysis was prepared, 80, or approximately 7 percent, of the 1,137 active Medicare-certified IRFs did not receive the full annual percentage increase for the FY 2017 annual payment update determination. Information is not available to determine the precise number of IRFs that will not meet the requirements to receive the full annual percentage increase for the FY 2018 payment determination.

We believe that the burden associated with the IRF QRP is the time and effort associated with data collection and reporting. As of February 1, 2017, there

are approximately 1,137 IRFs currently reporting quality data to CMS. For the purposes of calculating the costs associated with the collection of information requirements, we obtained mean hourly wages for these staff from the U.S. Bureau of Labor Statistics' May 2016 National Occupational Employment and Wage Estimates (*http://www.bls.gov/oes/current/oes_nat.htm*). To account for overhead and fringe benefits, we have doubled the hourly wage. These amounts are detailed in Table 13.

TABLE 13—U.S. BUREAU OF LABOR STATISTICS' MAY 2016 NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

| Occupation title | Occupation code | Mean hourly wage ($/hr) | Overhead and fringe benefit ($/hr) | Adjusted hourly wage ($/hr) |
|---|---|---|---|---|
| Registered Nurse (RN) | 29–1141 | $34.70 | $34.70 | $69.40 |
| Licensed Practical and Licensed Vocational Nurses (LVN) | 29–2061 | 21.56 | 21.56 | 43.12 |
| Respiratory Therapists (RT) | 29–1126 | 29.15 | 29.15 | 58.30 |
| Speech-Language Pathologists (SLP) | 29–1127 | 37.60 | 37.60 | 75.20 |
| Occupational Therapists (OT) | 29–1122 | 40.25 | 40.25 | 80.50 |
| Psychologist | 19–3030 | 38.77 | 38.77 | 77.54 |

As discussed elsewhere, this rule finalizes the proposal to adopt one new pressure ulcer measure that has been specified under section 1899B(c)(1)(C) of the Act, beginning with the FY 2020 IRF QRP (see section XIII.G.1 of this final rule). The measure will be calculated using data elements that are currently included in the IRF–PAI. The data elements are discrete questions and response codes that collect information on an IRF patient's health status, preferences, goals, and general administrative information.

We are requiring that IRFs report certain standardized patient assessment data beginning with the FY 2019 IRF QRP (see section XIII.J of this final rule). We defined the term ''standardized patient assessment data'' as patient assessment questions and response options that are identical in all four PAC assessment instruments, and to which identical standards and definitions apply. The standardized patient assessment data are intended to be shared electronically among PAC providers and will otherwise enable the data to be comparable for various purposes, including the development of cross-setting quality measures and to inform payment models that take into account patient characteristics rather than setting.

Under 1899B(m) of the Act, the Paperwork Reduction Act does not apply to the specific changes in the collection of information described in this final rule. The requirement and burden will be submitted to OMB for review and approval when the modifications to the IRF–PAI are not used to achieve standardization and are not exempt from the requirements under section 1899B(m) of the Act.

These changes to the collections of information arise from section 2(a) of the IMPACT Act, which added new section 1899B of the Act. That section requires IRFs to report standardized patient assessment data, data on quality measures, and data on resource use and other measures.

As noted in section VIII of this final rule, we are removing item 27 (Swallowing Status) from the IRF–PAI on admission and discharge, which will result in a 0.5 minute reduction in clinical staff time to report data.

We are also removing the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from IRFs (NQF #2502). This is a claims-based measure, and IRFs will still be required to submit the claims on which this measure is calculated. Therefore, we believe the IRF QRP burden estimate is unaffected by the proposed removal of this measure.

Adoption of the Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury measure will result in the removal of some data items related to pressure ulcer assessment that we believe are duplicative or no longer necessary. As a result, the estimated burden and cost for IRFs to report the updated version of the measure will be reduced from the burden and cost to report the current version of the measure. Specifically, we believe that there will be a 5-minute reduction in clinical staff time to report data, and we believe the items being removed would be completed by RNs. In addition, the removal of item 27 (Swallowing Status) on both admission and discharge will result in a 0.5 minute reduction in clinical staff time to report data. We believe that these swallowing items would be completed by RNs (approximately 75 percent of the time) and SLPs (approximately 25 percent of the time). We estimate 402,311 discharges from 1,137 IRFs annually. This equates to 36,879 hours (0.0917 hours × 402,311 discharges) decrease in burden for all IRFs. Given 5.4 minutes of RN time and 0.1 minutes of SLP time, completing an average of 354 IRF–PAIs per provider per year, and the wages listed in Table 13, we estimated the total cost would be reduced by $2,255 per IRF annually, or $2,564,2230 for all IRFs annually. This decrease in burden will be accounted for in the information collection under OMB control number (0938–0842) which expires July 31, 2017. We have sent the revised information collection request to OMB for review and approval.

In section XIII.J. of this final rule, we are finalizing requirements related to the reporting of standardized patient assessment data beginning with the FY 2019 IRF QRP. The data elements being finalized for the FY 2019 IRF QRP with respect to the Functional Status and Medical Condition and Comorbidity categories are already included on the current IRF–PAI assessment. Therefore, there is no new burden associated with the standardized patient assessment data being finalized for the IRF QRP in this final rule.

However, as noted in section XIII.J of this final rule, we are not finalizing our proposal to require IRFs to submit data on 24 new standardized patient assessment data elements on IRF admissions and 24 new standardized patient assessment data elements on IRF discharges. This results in a reduction to the burden estimate that appeared in the proposed rule. We refer readers to the FY 2018 IRF PPS proposed rule (82 FR 20743 through 20745) for a discussion of our burden estimates for these proposals.

In summary, no new burden related to standardized patient assessment data is being added to the IRF–PAI, which is a reduction from the burden estimate in the proposed rule. Given the 5.5-minute

reduction in burden for items being removed from the IRF PAI, the overall cost associated with changes to the IRF QRP is a reduction of 36,879 hours in burden for all IRFs. This equates to a reduction of $2,255.26 per IRF annually, or $2,564,229.74 for all IRFs annually. Under section 1899B(m) of the Act, the Paperwork Reduction Act does not apply to the specific changes to the collections of information described in this final rule. We are, however, setting out the burden as a courtesy to advise interested parties of the proposed actions' time and costs and refer readers to section XV of this final rule for the regulatory impact analysis (RIA). The requirement and burden will be submitted to OMB for review and approval when the modifications to the IRF–PAI are not used to achieve standardization and are not exempt from the requirements under section 1899B(m) of the Act.

We received several comments about the collection of information requirements associated with the IRF QRP.

*Comment:* Several commenters supported the removal of item 27 (swallowing status) from the IRF–PAI, stating that they appreciate the decrease in administrative burden.

*Response:* We appreciate the commenters' support for the removal of item 27 (swallowing status) from the IRF–PAI.

*Comment:* We received a number of comments related to training, data specifications, and support that CMS has provided related to the implementation of the quality measures and standardized patient assessment data elements. Commenters stated that the guidance has been inconsistent and that CMS has not provided the necessary responses to questions from IRFs, and that due to inconsistencies, the commenters are concerned about the accuracy and reliability of the data.

One commenter was concerned that the reliability of data was threatened by the data elements changing frequently, by different data elements being used for quality and payment, citing an example of functional status data elements, and by confusion over entering dashes for voluntary items. Several commenters requested that CMS provide training materials and data specifications in advance of implementation.

*Response:* With regard to training and provider support, we acknowledge the importance of thorough and comprehensive training. We intend to provide both in-person and webinar-based training in advance of the IRF–PAI Version 2.0 release on October 1, 2018. When new quality measure data elements are implemented, we examine early data that is submitted in order to look for possible issues, such as unexpected patterns and inconsistent data for 2 or more items. If we identify any issues, we address them in updated training materials. For example, we examined the first three months of functional status data, and we identified areas of coding that could be clarified and scheduled a supplemental training via webinar. Information about and materials from each IRF QRP training are posted on the IRF–QRP Training Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/Training.html.*

We disagree with the commenters' suggestion that guidance has been inconsistent and that data collected has been unreliable. We maintain an IRF QRP help desk that responds to providers' data element coding questions, and keep a repository of past questions and responses in order to address questions in a consistent manner. Between June 1, 2016 and June 1, 2017, we responded to more than 1,000 inquiries. The questions submitted by IRFs have provided us with various ''real life'' scenarios and these questions have helped us to create new examples for training, new coding tips that reinforce key training issues and we have updated definitions on the IRF–PAI to ensure the guidance is shared with all IRFs. For example, we received several inquiries regarding non-verbal communication, and based on that input, we modified the IRF–PAI definition in the IRF–PAI Training Manual to clarify that both verbal and non-verbal communication are considered in coding the item.

With regard to the comments about different functional items being used for payment than those used in the IRF QRP, we refer the reader to the discussion in the FY 2016 IRF PPS final rule (80 FR 47086 through 47120) about the differences between the CARE function items and the FIM® items.

With regard to the comments related to the data specifications and the use of dashes, we post data specifications and errata on the CMS Web site so that vendors and providers are able to review and understand the valid data codes for all items and the associated requirements: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Software.html.* We wish to note that upon internal review, we believe that the data specifications have been misinterpreted by some IRFs based on questions that have been submitted to the IRF QRP Help Desk, and we would like to make clear that the information and Section 9 (Required/Voluntary IRF–PAI Items) of the IRF–PAI Training Manual is correct.

*Comment:* We received several comments related to the burden associated with the IRF–PAI. Although we did not solicit feedback on the burden associated with the measures finalized in the FY 2016 IRF PPS final rule (80 FR 47100 through 47120), including functional status measures, or the FY 2017 IRF PPS final rule (81 FR 52080 through 52135), we received several comments about the increase in the length of the IRF–PAI over the last several releases, particularly since the IMPACT Act of 2014. Commenters noted that additions and changes to the IRF–PAI require extensive staff training time and operational procedures that impose a significant burden on providers. Some commenters were concerned that additional IRF–PAI requirements would take away from patient care time, especially in facilities with multiple admissions and discharges per day.

One commenter appreciated the advanced release of the proposed item sets and specification documents for review, while another stated that these documents were difficult to locate on the Web site.

*Response:* We recognize the commenter's concerns pertaining to burden being added to the IRF QRP in fulfillment of the requirements of the IMPACT Act. At every step of the process of standardizing the IRF–PAI with other PAC assessment instruments in order to meet the requirements of the IMPACT Act, CMS has been keenly aware of the need to minimize additional burden on providers. We make efforts to offset or decrease burden, as evidenced by the 5 minute reduction of items related to pressure ulcer assessment that we believe are duplicative or no longer necessary.

We are sensitive to the issue of burden associated with data collection and acknowledge the commenters' concerns about taking away from patient care time. In ongoing item development work to identify and test standardized patient assessment data elements, we are seeking data elements that will capture the unique environment of the IRF PAC setting. This includes data elements that can help establish the required amount of provider time at the bedside, and intensive nature of patient care provided in IRFs, and help IRFs make care decisions that are uniquely tailored to each patient. Ideal data elements would leverage information that is already collected or documented

in IRFs as part of standard clinical practice, while providing valuable information to inform care planning, clinical decision-making, care transitions and resource utilization.

With regard to the burden added to IRF–PAI versions finalized in previous rules, we refer the reader to our discussion of burden due to data set revisions, data collection, or training of staff due to the revisions to the IRF–PAI in the FY 2016 IRF PPS final rule (80 FR 47129 through 47131), and in the FY 2017 IRF PPS final rule (81 FR 52133 through 52135).

Though we recognize that new IRF–PAI items will require additional activities and efforts by providers, we would like to clarify that burden estimates are intended to reflect only the time needed to complete IRF–PAI items, independent of clinical time spent assessing the patient. Similarly, burden estimates are not intended to reflect costs of training and operational processes; these are considered part of the operating costs for an IRF. It should be noted that with each assessment release, we provide free software to our providers that allows for the completion and submission of any required assessment data. Free downloads of the Inpatient Rehabilitation Validation and Entry (IRVEN) software product are available on the CMS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Software.html.*

With regard to the posting of the proposed item set and specifications, we strive to be transparent and consistent in posting item set information to the IRF–PAI and IRF QRP Manual Page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-PAI-and-IRF-QRP-Manual.html,* and posting specifications to the IRF QRP Measures Information Page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.* We encourage the reader to check the IRF QRP Spotlight and Announcement page for updates at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/Spotlights-Announcements.html.*

*Comment:* One commenter commended CMS for ensuring robust and accurate quality reporting, but had concerns that many IRF providers do not have effective EHRs and that the proposed revisions to the IRF–PAI would require extra staff to collect, process, and transmit the necessary data. The commenter suggested that CMS did not provide an easy mechanism to collect, process and transmit the necessary data.

*Response:* While we support the use of EHRs, we do not require that providers use EHRs to populate assessment data. We disagree with the commenter's suggestion that CMS does not provide a mechanism for collecting, processing and transmitting data, and we note that with each assessment release, we provide free software to providers that allows for the completion and submission of any required assessment data. Free downloads of the Inpatient Rehabilitation Validation and Entry (IRVEN) software product are available on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Feefor-Service-Payment/InpatientRehabFacPPS/Software.html.*

*Comment:* One commenter had concerns about smaller units in rural areas, suggesting that they would be unable to increase staff to accommodate for increased data collection.

*Response:* We appreciate the concern about the increase in staff to accommodate for increased data collection in rural areas, and are sensitive to the challenges that small and rural facilities face. Taking into consideration the increase in burden that additional data collection may place on all facilities, we have decided to delay the adoption of the standardized patient assessment data elements to fulfill the requirements of the IMPACT Act in the categories of cognitive function and mental status, special services, treatments, and interventions, and impairments. However, we note that high quality care should be provided wherever patient services are administered.

As noted in section XIII.J in this final rule, after consideration of public comments, we will not be finalizing the proposals that would add standardized patient assessment data elements related to the categories of cognitive function; special services, treatments and interventions; and impairments to the IRF–PAI effective October 1, 2018. The data elements that satisfy the categories of functional status and medical conditions and comorbidities are already being collected on the IRF–PAI and do not add burden.

Therefore, given the 5.5-minute reduction in burden for items being removed from the IRF–PAI, the burden related to the IRF QRP is reduced by $2,255.26 per IRF annually, or $2,564,229.74 for all IRFs annually.

## XVII. Regulatory Impact Statement

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This rule does not reach the economic threshold and thus is not considered a major rule.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $7.5 million to $38.5 million 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 (65 FR 69432) at *http://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf,* effective March 26, 2012 and updated on February 26, 2016.) 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 HHS generally uses a revenue impact of 3 to 5 percent as a significance threshold under the RFA. We estimate that the net revenue impact of this final rule on all IRFs is to increase estimated payments

by approximately 1.0 percent. The rates and policies set forth in this final rule will not have a significant impact (not greater than 3 percent) 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. We are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that this rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a RIA 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 for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2017, that threshold is approximately $148 million. This final rule will impose no mandates on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this regulation does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017. This final rule is considered an EO 13771 deregulatory action. Details on the $2.6 million estimated net cost savings of this rule can be found in the preceding and subsequent analyses.

Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this final rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on the published proposed rule will be the number of reviewers of this final rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this final rule. It is possible that not all commenters reviewed the proposed rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we thought that the number of comments received on the proposed rule would be a fair estimate of the number of reviewers of this final rule.

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

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $105.16 per hour, including overhead and fringe benefits *https://www.bls.gov/oes/current/oes_nat.htm.* Assuming an average reading speed, we estimate that it would take approximately 3 hours for the staff to review half of this final rule. For each IRF that reviews the rule, the estimated cost is approximately $315 (3 hours × $105.16). Therefore, we estimate that the total cost of reviewing this regulation is $23,940 ($315 × 76 reviewers).

Accounting Statement

As required by OMB Circular A–4 (available at *https://www.whitehouse.gov/omb/circulars_a004_a-4*), 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 1,137 IRFs in our database. In addition, Table 14 presents the costs associated with the new IRF QRP requirements for FY 2018.

TABLE 14—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES

| Category | Transfers |
|---|---|
| **Change in Estimated Transfers from FY 2017 IRF PPS to FY 2018 IRF PPS** | |
| Annualized Monetized Transfers. | $75 million. |
| From Whom to Whom? | Federal Government to IRF Medicare Providers. |
| **FY 2018 Cost to Updating the Quality Reporting Program** | |
| Cost for IRFs to Submit Data for the Quality Reporting Program. * | Reduction of $2.6 million. |

* Costs associated with the submission of data for the quality reporting program will occur in 2018 and likely continue in the future years.

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

**List of Subjects in 42 CFR Part 412**

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

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

## PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

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

**Authority:** Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), sec. 124 of Pub. L. 106–113 (113 Stat. 1501A–332), sec. 1206 of Pub. L. 113–67, sec.112 of Pub. L. 113–93, and sec. 231 of Pub. L. 114–113.

■ 2. Section 412.614 is amended by revising paragraphs (d) heading, (d)(1), and (e) to read as follows:

**§ 412.614 Transmission of patient assessment data.**

* * * * *

(d) *Failure to submit complete and timely IRF–PAI data, as required under paragraph (c) of this section*—(1) *Medicare Part-A fee-for-service.* (i) A given Medicare Part-A fee-for-service IRF claim will not be accepted and processed for payment until a corresponding IRF–PAI has been received and accepted by CMS.

(ii) [Reserved]

* * * * *

(e) *Exemption to the consequences for transmitting the IRF–PAI data late for Medicare Part C (Medicare Advantage) patients.* CMS may waive the consequences of failure to submit complete and timely IRF–PAI data specified in paragraph (d) of this section when, due to an extraordinary situation that is beyond the control of an inpatient rehabilitation facility, the inpatient rehabilitation facility is unable to transmit the patient assessment data in accordance with paragraph (c) of this section. Only CMS can determine if a situation encountered by an inpatient rehabilitation facility is extraordinary and qualifies as a situation for waiver of the forfeiture specified in paragraph (d)(2) of this section. An extraordinary situation may be due to, but is not limited to, fires, floods, earthquakes, or similar unusual events that inflect extensive damage to an inpatient facility. An extraordinary situation may be one that produces a data transmission problem that is beyond the control of the inpatient rehabilitation facility, as well as other situations determined by CMS to be beyond the control of the inpatient rehabilitation facility. An extraordinary situation must be fully documented by the inpatient rehabilitation facility.

**§ 412.624 [Amended]**

■ 3. In § 412.624—

■ a. Amend paragraph (d)(4) by removing the reference ''paragraph (e)(2), (e)(3), (e)(4) and (e)(7), of this section,'' and adding in its place the reference ''paragraph (e)(2), (3), (4) and (6) of this section,'';

■ b. Remove paragraph (e)(6);

■ c. Redesignate paragraph (e)(7) as paragraph (e)(6);

■ d. Amend newly redesignated paragraph (e)(6)(ii) by removing the reference ''paragraph (e)(7)(i)(A) and (e)(7)(i)(B) of this section'' and adding in its place the reference ''paragraph (e)(6)(i)(A) and (B) of this section''; and

■ e. Amend paragraph (f)(2)(v) by removing the reference ''paragraphs (e)(1), (e)(2), (e)(3), (e)(4), and (e)(7) of this section'' and adding in its place the reference ''paragraphs (e)(1), (2), (3), (4), and (6) of this section''.

■ 4. Section 412.634 is amended by revising paragraphs (b)(1), (c)(1), (f)(1) and (2) to read as follows:

**§ 412.634 Requirements under the Inpatient Rehabilitation Facility (IRF) Quality Reporting Program (QRP).**

* * * * *

(b) * * *

(1) IRFs must submit to CMS data on measures specified under section 1886(j)(7)(D), 1899B(c)(1), and 1899B(d)(1) of the Act, as applicable. Such data must be submitted in the form and manner, and at a time, specified by CMS.

* * * * *

(c) * * *

(1) An IRF may request and CMS may grant exceptions or extensions to the measures data or standardized patient assessment data reporting requirements, for one or more quarters, when there are certain extraordinary circumstances beyond the control of the IRF.

* * * * *

(f) * * *

(1) IRFs must meet or exceed two separate data completeness thresholds: One threshold set at 95 percent for completion of required quality measures data and standardized patient assessment data collected using the IRF–PAI submitted through the QIES, and a second threshold set at 100 percent for measures data collected and submitted using the CDC NHSN.

(2) These thresholds (95 percent for completion of required quality measures data and standardized patient assessment data on the IRF–PAI; 100 percent for CDC NHSN data) will apply to all measures and standardized patient assessment data requirements adopted into the IRF QRP.

* * * * *

Dated: July 26, 2017.

**Seema Verma,**

*Administrator, Centers for Medicare & Medicaid Services.*

Dated: July 27, 2017.

**Thomas E. Price,**

*Secretary, Department of Health and Human Services.*

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