DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 412

[CMS–1671–P]

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: Proposed rule.

SUMMARY: This proposed rule would update 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 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. We are also proposing to remove the 25 percent payment penalty for inpatient rehabilitation facility patient assessment instrument (IRF–PAI) late transmissions, remove the voluntary swallowing status item (Item 27) from the IRF–PAI, revise 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,'' solicit comments regarding the criteria used to classify facilities for payment under the IRF PPS, provide for automatic annual updates to presumptive methodology diagnosis code lists, use 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 revise and update quality measures and reporting requirements under the IRF quality reporting program (QRP).

DATES: To be assured consideration, comments must be received at one of the addresses provided below, not later than 5 p.m. on June 26, 2017.

ADDRESSES: In commenting, please refer to file code CMS–1671–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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

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

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1671–P, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1671–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. By hand or courier. Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786 7195 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Gwendolyn Johnson, (410) 786–6954, for general information.

Catie Kraemer, (410) 786–0179, for information about the wage index.

Christine Grose, (410) 786–1362, for information about the quality reporting program.

Kadie Derby, (410) 786–0468, or Susanne Seagrave, (410) 786–0044, for information about the payment policies and payment rates.

SUPPLEMENTARY INFORMATION: The IRF PPS Addenda along with other supporting documents and tables referenced in this proposed rule are available through the Internet on the CMS Web site at *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/*.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period as soon as possible after they have been received at *http://www.regulations.gov*. Follow the search instructions on that Web site to view public comments.

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

Executive Summary

A. Purpose

This proposed rule would update 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 Social Security Act (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 proposed rule would also remove the 25 percent payment penalty for IRF–PAI late transmissions, remove the voluntary swallowing status item (Item 27) from the IRF–PAI, revise the ICD–10–CM diagnosis codes that are used to determine presumptive compliance under the 60 percent rule, provide for automatic annual updates to the presumptive methodology diagnosis

code lists, solicit comments regarding the criteria used to classify facilities for payment under the IRF PPS, 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 the quality measures and reporting requirements under the IRF QRP.

B. Summary of Major Provisions

In this proposed rule, we use the methods described in the FY 2017 IRF PPS final rule (81 FR 52056) to propose updates to 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 proposing to revise and update 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 proposed rule is an estimated $80 million in increased payments from the Federal government to IRFs during FY 2018.
	Costs
New quality reporting program requirements.	The total costs in FY 2018 for IRFs as a result of the new quality reporting requirements are estimated to be $3.4 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

The Affordable Care Act Patient Protection and Affordable Care Act (Pub. L. 111–148, enacted on March 23, 2010)

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 & 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
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 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 ''The Affordable Care Act''), amended section 1886(j)(3)(C) of the Act and added section 1886(j)(3)(D) of the Act. Section 1886(j)(3)(C) of the Act requires the Secretary to estimate a 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 Affordable Care Act, the adjusted FY 2010 rate was only to be applied to discharges occurring on or after April 1, 2010. Based on the self-implementing legislative changes to section 1886(j)(3) of the Act, we adjusted the FY 2010 federal prospective payment rates as required, and applied these rates to IRF discharges occurring on or after April 1, 2010, and on or before September 30, 2010. Thus, the final FY 2010 IRF 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 Affordable Care Act Affecting the IRF PPS in FY 2012 and Beyond

The Affordable Care Act included several provisions that affect the IRF PPS in FYs 2012 and beyond. In addition to what was previously discussed, section 3401(d) of the Affordable Care Act also added section 1886(j)(3)(C)(ii)(I) (providing for a ''productivity adjustment'' for fiscal year 2012 and each subsequent fiscal year). The productivity adjustment for FY 2018 is discussed in section V.B. of this proposed rule. Section 3401(d) of the Affordable Care Act 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 proposed rule. Section 1886(j)(3)(C)(ii)(II) of the Act notes that the application of these adjustments to the market basket update may result in an update that is less than 0.0 for a fiscal year and in payment rates for a fiscal year being less than such payment rates for the preceding fiscal year.

Section 3004(b) of the Affordable Care Act also addressed the IRF PPS. 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 FFS Part A patient is discharged, the IRF submits a Medicare claim as a Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191, enacted on August 21, 1996) (HIPAA) compliant electronic claim or, if the Administrative Simplification Compliance Act of 2002 (Pub. L. 107–105, enacted on December 27, 2002) (ASCA) permits, a paper claim (a UB–04 or a CMS–1450 as appropriate) using the five-character CMG number and sends it to the appropriate Medicare Administrative Contractor (MAC). In addition, once a 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 & 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/acceleratinghieprinciples_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 this rule, we propose to update the IRF prospective payment rates for FY 2018, remove the 25 percent penalty for IRF–PAI late transmissions, remove the voluntary swallowing status item (Item 27) from the IRF–PAI, revise the lists of ICD–10–CM diagnosis codes that are used to determine presumptive compliance under the 60 percent rule, provide for automatic annual updates to presumptive methodology diagnosis code lists, solicit comments regarding the criteria used to classify facilities for payment under the IRF PPS, 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 quality measures and reporting requirements under the IRF QRP.

The proposed updates to the IRF prospective payment rates for FY 2018 are 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 this proposed rule.
- Describe the continued use of FY 2014 facility-level adjustment factors as discussed in section IV. of this proposed rule.
- Update the FY 2018 IRF PPS payment rates by the proposed market basket increase factor, as required by sections 1886(j)(3)(C)(iii) of the Act, as described in section V. of this proposed rule.
- 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 this proposed rule.
- Describe the calculation of the IRF standard payment conversion factor for FY 2018, as discussed in section V. of this proposed rule.
- Update the outlier threshold amount for FY 2018, as discussed in section VI. of this proposed rule.
- Update the cost-to-charge ratio (CCR) ceiling and urban/rural average CCRs for FY 2018, as discussed in section VI. of this proposed rule.
- Describe the proposed removal of the 25 percent payment penalty for IRF–PAI late transmissions in section VII. of this proposed rule.
- Describe proposed revisions to the IRF–PAI to remove the voluntary swallowing status item in section VIII. of this proposed rule.
- Describe proposed refinements to the presumptive compliance methodology ICD–10–CM diagnosis codes in section IX. of this proposed rule.
- Solicit comments regarding the criteria used to classify facilities for payment under the IRF PPS in section IX. of this proposed rule.
- Describe proposed automatic annual updates to the presumptive methodology diagnosis code lists in section X. of this proposed rule.
- 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 in section XI. of this proposed rule.

- Describe proposed revisions and updates to quality measures and reporting requirements under the QRP for IRFs in accordance with sections 1886(j)(7) and 1899B of the Act, as discussed in section XII. of this proposed rule.

III. Proposed 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 this proposed rule, we propose 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 propose 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. Currently, only a small portion of the FY 2016 IRF cost report data are available for analysis, but the majority of the FY 2016 IRF claims data are available for analysis.

In this rule, we propose 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 propose 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 proposed changes to the CMG relative weights (as discussed in this proposed rule).

Step 3. Divide the amount calculated in step 1 by the amount calculated in step 2 to determine the budget neutrality factor (0.9974) that would maintain the same total estimated aggregate payments in FY 2018 with and without the proposed changes to the CMG relative weights.

Step 4. Apply the budget neutrality factor (0.9974) to the FY 2017 IRF PPS standard payment amount after the application of the budget-neutral wage adjustment factor.

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

In Table 1, ''Proposed Relative Weights and Average Length of Stay Values for Case-Mix Groups,'' we present the proposed 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—PROPOSED 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	0.8483	0.7280	0.6724	0.6423	9	9	9	8
0102	Stroke, M>44.45 and M<51.05 and C>18.5	1.0670	0.9157	0.8458	0.8079	11	12	10	10
0103	Stroke, M>44.45 and M<51.05 and C<18.5	1.2069	1.0357	0.9567	0.9138	13	13	12	11
0104	Stroke, M>38.85 and M<44.45	1.2945	1.1109	1.0261	0.9802	13	13	12	12
0105	Stroke, M>34.25 and M<38.85	1.5055	1.2920	1.1934	1.1399	14	14	14	13
0106	Stroke, M>30.05 and M<34.25	1.6678	1.4313	1.3220	1.2628	16	16	15	15
0107	Stroke, M>26.15 and M<30.05	1.8621	1.5980	1.4760	1.4099	17	17	16	16
0108	Stroke, M<26.15 and A>84.5	2.3684	2.0324	1.8773	1.7932	21	23	21	20
0109	Stroke, M>22.35 and M<26.15 and A<84.5	2.1330	1.8304	1.6907	1.6150	19	19	19	19
0110	Stroke, M<22.35 and A<84.5	2.7845	2.3896	2.2072	2.1083	27	26	23	24
0201	Traumatic brain injury, M>53.35 and C>23.5	0.8414	0.6780	0.6173	0.5671	9	9	8	7
0202	Traumatic brain injury, M>44.25 and M<53.35 and C>23.5.	1.0873	0.8762	0.7977	0.7329	11	11	10	9
0203	Traumatic brain injury, M>44.25 and C<23.5	1.2583	1.0140	0.9231	0.8481	12	12	11	11
0204	Traumatic brain injury, M>40.65 and M<44.25	1.3877	1.1182	1.0180	0.9353	11	12	12	12
0205	Traumatic brain injury, M>28.75 and M<40.65	1.6314	1.3146	1.1968	1.0996	15	15	14	13
0206	Traumatic brain injury, M>22.05 and M<28.75	1.9703	1.5877	1.4454	1.3280	18	18	16	15
0207	Traumatic brain injury, M<22.05	2.5103	2.0229	1.8416	1.6920	28	23	19	18
0301	Non-traumatic brain injury, M>41.05	1.1649	0.9439	0.8581	0.8107	10	11	10	10

TABLE 1—PROPOSED 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
0302	Non-traumatic brain injury, M>35.05 and M<41.05.	1.4142	1.1460	1.0418	0.9842	13	13	12	12
0303	Non-traumatic brain injury, M>26.15 and M<35.05.	1.6626	1.3472	1.2248	1.1571	15	15	13	13
0304	Non-traumatic brain injury, M<26.15	2.1547	1.7459	1.5872	1.4995	21	19	17	16
0401	Traumatic spinal cord injury, M>48.45	0.8971	0.8369	0.7456	0.6728	11	11	10	9
0402	Traumatic spinal cord injury, M>30.35 and M<48.45.	1.3102	1.2223	1.0888	0.9825	13	14	13	12
0403	Traumatic spinal cord injury, M>16.05 and M<30.35.	2.1239	1.9813	1.7650	1.5927	22	22	20	18
0404	Traumatic spinal cord injury, M<16.05 and A>63.5.	3.7200	3.4704	3.0915	2.7897	42	36	31	33
0405	Traumatic spinal cord injury, M<16.05 and A<63.5.	3.4257	3.1958	2.8469	2.5690	33	35	31	27
0501	Non-traumatic spinal cord injury, M>51.35	0.9396	0.7059	0.6687	0.6136	9	9	9	7
0502	Non-traumatic spinal cord injury, M>40.15 and M<51.35.	1.2215	0.9178	0.8693	0.7978	12	11	10	10
0503	Non-traumatic spinal cord injury, M>31.25 and M<40.15.	1.5300	1.1496	1.0889	0.9992	16	13	12	12
0504	Non-traumatic spinal cord injury, M>29.25 and M<31.25.	1.7373	1.3053	1.2364	1.1346	17	15	14	13
0505	Non-traumatic spinal cord injury, M>23.75 and M<29.25.	1.9970	1.5004	1.4212	1.3042	18	17	16	15
0506	Non-traumatic spinal cord injury, M<23.75	2.7578	2.0721	1.9627	1.8011	26	23	21	20
0601	Neurological, M>47.75	1.0678	0.8160	0.7570	0.6888	10	9	9	8
0602	Neurological, M>37.35 and M<47.75	1.3930	1.0646	0.9876	0.8986	12	12	11	11
0603	Neurological, M>25.85 and M<37.35	1.7085	1.3056	1.2112	1.1021	14	14	13	13
0604	Neurological, M<25.85	2.2217	1.6978	1.5750	1.4331	19	18	16	16
0701	Fracture of lower extremity, M>42.15	1.0395	0.8307	0.7888	0.7185	12	11	10	9
0702	Fracture of lower extremity, M>34.15 and M<42.15.	1.3168	1.0523	0.9993	0.9102	12	12	11	11
0703	Fracture of lower extremity, M>28.15 and M<34.15.	1.5920	1.2722	1.2082	1.1004	15	14	14	13
0704	Fracture of lower extremity, M<28.15	2.0178	1.6125	1.5313	1.3947	18	18	17	16
0801	Replacement of lower extremity joint, M>49.55	0.8775	0.6453	0.6128	0.5656	8	8	7	7
0802	Replacement of lower extremity joint, M>37.05 and M<49.55.	1.1266	0.8285	0.7868	0.7262	11	10	9	9
0803	Replacement of lower extremity joint, M>28.65 and M<37.05 and A>83.5.	1.4578	1.0721	1.0181	0.9396	13	13	12	11
0804	Replacement of lower extremity joint, M>28.65 and M<37.05 and A<83.5.	1.3414	0.9865	0.9368	0.8646	12	11	11	10
0805	Replacement of lower extremity joint, M>22.05 and M<28.65.	1.5913	1.1703	1.1114	1.0257	14	13	12	12
0806	Replacement of lower extremity joint, M<22.05	1.9238	1.4148	1.3436	1.2400	16	16	14	14
0901	Other orthopedic, M>44.75	1.0100	0.8084	0.7245	0.6736	10	10	9	8
0902	Other orthopedic, M>34.35 and M<44.75	1.3277	1.0627	0.9524	0.8856	12	12	11	10
0903	Other orthopedic, M>24.15 and M<34.35	1.6291	1.3040	1.1686	1.0866	15	14	13	13
0904	Other orthopedic, M<24.15	2.0410	1.6337	1.4641	1.3613	18	18	16	15
1001	Amputation, lower extremity, M>47.65	1.0450	0.9001	0.7939	0.7247	10	11	10	9
1002	Amputation, lower extremity, M>36.25 and M<47.65.	1.3755	1.1847	1.0450	0.9538	13	13	12	11
1003	Amputation, lower extremity, M<36.25	2.0095	1.7308	1.5266	1.3935	18	18	17	16
1101	Amputation, non-lower extremity, M>36.35	1.3101	1.1733	1.0154	0.8784	12	15	12	10
1102	Amputation, non-lower extremity, M<36.35	1.8980	1.6999	1.4711	1.2727	16	23	15	14
1201	Osteoarthritis, M>37.65	1.2205	0.9178	0.8571	0.7889	9	11	10	10
1202	Osteoarthritis, M>30.75 and M<37.65	1.5786	1.1871	1.1086	1.0203	11	13	13	12
1203	Osteoarthritis, M<30.75	1.9315	1.4525	1.3564	1.2485	12	15	15	14
1301	Rheumatoid, other arthritis, M>36.35	1.2280	0.9277	0.8333	0.7974	10	10	10	9
1302	Rheumatoid, other arthritis, M>26.15 and M<36.35.	1.6884	1.2755	1.1457	1.0964	16	14	12	12
1303	Rheumatoid, other arthritis, M<26.15	2.1985	1.6609	1.4919	1.4276	18	18	16	16
1401	Cardiac, M>48.85	0.9282	0.7469	0.6826	0.6196	10	8	8	8
1402	Cardiac, M>38.55 and M<48.85	1.2233	0.9844	0.8997	0.8165	12	11	10	10
1403	Cardiac, M>31.15 and M<38.55	1.4648	1.1787	1.0773	0.9777	13	13	12	11
1404	Cardiac, M<31.15	1.8551	1.4927	1.3643	1.2382	17	16	14	14
1501	Pulmonary, M>49.25	1.0146	0.8485	0.7738	0.7413	10	9	9	8
1502	Pulmonary, M>39.05 and M<49.25	1.3154	1.1001	1.0032	0.9612	11	12	11	10
1503	Pulmonary, M>29.15 and M<39.05	1.5983	1.3367	1.2190	1.1679	14	14	12	12
1504	Pulmonary, M<29.15	1.9815	1.6572	1.5112	1.4478	20	16	15	14
1601	Pain syndrome, M>37.15	1.1541	0.9076	0.8273	0.7600	10	11	10	9
1602	Pain syndrome, M>26.75 and M<37.15	1.5368	1.2085	1.1016	1.0120	12	14	13	12
1603	Pain syndrome, M<26.75	1.9181	1.5084	1.3749	1.2631	14	16	15	14
1701	Major multiple trauma without brain or spinal cord injury, M>39.25.	1.1984	0.9331	0.8430	0.7737	10	11	10	9
1702	Major multiple trauma without brain or spinal cord injury, M>31.05 and M<39.25.	1.5242	1.1867	1.0722	0.9840	14	14	12	12
1703	Major multiple trauma without brain or spinal cord injury, M>25.55 and M<31.05.	1.8018	1.4029	1.2675	1.1633	17	15	14	14

TABLE 1—PROPOSED 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
1704	Major multiple trauma without brain or spinal cord injury, M<25.55.	2.2806	1.7756	1.6043	1.4724	21	19	17	17
1801	Major multiple trauma with brain or spinal cord injury, M>40.85.	1.3059	1.0064	0.8850	0.8157	13	11	10	10
1802	Major multiple trauma with brain or spinal cord injury, M>23.05 and M<40.85.	1.8718	1.4425	1.2685	1.1692	17	16	14	14
1803	Major multiple trauma with brain or spinal cord injury, M<23.05.	2.9245	2.2538	1.9819	1.8267	32	26	21	20
1901	Guillian Barre, M>35.95	1.2961	1.0778	0.9935	0.9522	13	12	12	11
1902	Guillian Barre, M>18.05 and M<35.95	2.2324	1.8563	1.7112	1.6400	23	20	21	18
1903	Guillian Barre, M<18.05	3.6781	3.0585	2.8194	2.7020	39	32	28	30
2001	Miscellaneous, M>49.15	0.9421	0.7634	0.6971	0.6329	9	9	8	8
2002	Miscellaneous, M>38.75 and M<49.15	1.2399	1.0047	0.9174	0.8330	11	11	10	10
2003	Miscellaneous, M>27.85 and M<38.75	1.5409	1.2486	1.1401	1.0351	14	14	12	12
2004	Miscellaneous, M<27.85	1.9681	1.5948	1.4562	1.3222	18	17	15	15
2101	Burns, M>0	1.8414	1.8221	1.3846	1.2977	29	17	14	14
5001	Short-stay cases, length of stay is 3 days or fewer.	.....	.....	.....	0.1567	.....	.....	.....	2
5101	Expired, orthopedic, length of stay is 13 days or fewer.	.....	.....	.....	0.6583	.....	.....	.....	7
5102	Expired, orthopedic, length of stay is 14 days or more.	.....	.....	.....	1.6390	.....	.....	.....	18
5103	Expired, not orthopedic, length of stay is 15 days or fewer.	.....	.....	.....	0.8111	.....	.....	.....	8
5104	Expired, not orthopedic, length of stay is 16 days or more.	.....	.....	.....	2.0333	.....	.....	.....	21

Generally, updates to the CMG relative weights result in some increases and some decreases to the CMG relative weight values. Table 2 shows how we estimate that the application of the proposed revisions for FY 2018 would affect particular CMG relative weight values, which would affect the overall distribution of payments within CMGs and tiers. Note that, because we propose to implement the CMG relative weight revisions in a budget-neutral manner (as previously described), total estimated aggregate payments to IRFs for FY 2018 would not be affected as a result of the proposed CMG relative weight revisions. However, the proposed revisions would affect the distribution of payments within CMGs and tiers.

TABLE 2—DISTRIBUTIONAL EFFECTS OF THE PROPOSED 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%	1,720	0.4
Changed by less than 5%	394,048	99.3
Decreased by between 5% and 15%	850	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 proposed revisions for FY 2018. The largest estimated increase in the proposed CMG relative weight values that affects the largest number of IRF discharges would be a 4.1 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, 1,322 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 2,395 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 invite public comment on our proposed updates to the CMG relative weights and average length of stay values for FY 2018.

IV. 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.

V. Proposed 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, as described in this section. 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 proposed IRF prospective payment rates for FY 2018 in this proposed 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. Proposed FY 2018 Market Basket Update and Productivity Adjustment

As noted above, 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 proposed IRF prospective payment rates for FY 2018 in this proposed rule. For comparison purposes, we are providing an 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 Insight Inc.'s first quarter 2017 forecast of the market basket update and MFP adjustment with historical data through the fourth quarter 2016. IHS Global Insight Inc. 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 proposed FY 2018 payment increase factor would be 1.55 percent (based on IHS Global Insight, Inc.'s first quarter 2017 forecast with historical data through the fourth quarter of 2016), reflecting a FY 2018 estimated market basket update of 2.7 percent as required by section 1886(j)(3)(C) of the Act, with an estimated productivity adjustment of 0.4 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) 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 invite public comment on this proposal.

C. Proposed 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 propose to include in the labor-related share for FY 2018 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 the IHS Global Insight, Inc. first quarter 2017 forecast for the 2012-based IRF market basket,

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 propose that the portion of Capital-Related Costs that is influenced by the local labor market is estimated to be 46 percent. Incorporating the estimate of the FY 2018 relative importance of Capital-Related costs from the 2012-based IRF market basket based on IHS Global Insight's (IGI) first quarter 2017 forecast, which is 8.3 percent, we take 46 percent of 8.3 percent to determine the labor-related share of Capital for FY 2018. We propose to 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 proposed labor-related share for FY 2018 of 70.7 percent. We also propose that if more recent data are subsequently available, we would use such data to determine the FY 2018 IRF labor-related share in the final rule.

We invite public comment on this proposal.

TABLE 3—IRF LABOR-RELATED SHARE

	FY 2018 Proposed labor-related share [1]	FY 2017 Final labor related share [2]
Wages and Salaries	47.7	47.7
Employee Benefits	11.3	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 Insight, Inc. 1st quarter 2017 forecast.
[2] **Federal Register** (81 FR 52073).

D. Proposed 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 propose 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 propose 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 propose 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 invite public comment on this proposal.

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 are proposing 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 invite public comments on this proposal.

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 are proposing 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 lose the 14.9 percent rural adjustment in FY 2018, this provider will experience an increase of 13 percent in their proposed 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 are not proposing 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 are not proposing 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 proposed 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 proposed 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 V.C of this proposed rule. We then multiply the labor-related portion by the applicable IRF wage index from the tables in the addendum to this proposed 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 propose 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 propose to use the listed steps to ensure that the FY 2018 IRF standard payment conversion factor reflects the proposed 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 proposed FY 2018 standard payment

conversion factor and the proposed 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 proposed FY 2018 budget-neutral wage adjustment factor of 1.0007.

Step 4. Apply the proposed 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 proposed FY 2018 standard payment conversion factor.

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

We invite public comment on the proposed IRF wage adjustment for FY 2018.

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

To calculate the proposed standard payment conversion factor for FY 2018, as illustrated in Table 4, we begin by applying the proposed 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 proposed 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 proposed standard payment amount of $15,876. We next apply the proposed budget neutrality factor for the revised CMG relative weights of 0.9974, which results in the proposed standard payment conversion factor of $15,835 for FY 2018.

TABLE 4—CALCULATIONS TO DETERMINE THE PROPOSED 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	× 0.9974
Proposed FY 2018 Standard Payment Conversion Factor	= $15,835

We invite public comment on the proposed FY 2018 standard payment conversion factor.

After the application of the proposed CMG relative weights described in section III of this proposed rule to the proposed FY 2018 standard payment conversion factor ($15,835), the resulting unadjusted IRF prospective payment rates for FY 2018 are shown in Table 5.

TABLE 5—PROPOSED FY 2018 PAYMENT RATES

CMG	Payment rate tier 1	Payment rate tier 2	Payment rate tier 3	Payment rate no comorbidity
0101	$ 13,432.83	$ 11,527.88	$ 10,647.45	$ 10,170.82
0102	16,895.95	14,500.11	13,393.24	12,793.10
0103	19,111.26	16,400.31	15,149.34	14,470.02
0104	20,498.41	17,591.10	16,248.29	15,521.47
0105	23,839.59	20,458.82	18,897.49	18,050.32
0106	26,409.61	22,664.64	20,933.87	19,996.44
0107	29,486.35	25,304.33	23,372.46	22,325.77
0108	37,503.61	32,183.05	29,727.05	28,395.32
0109	33,776.06	28,984.38	26,772.23	25,573.53
0110	44,092.56	37,839.32	34,951.01	33,384.93
0201	13,323.57	10,736.13	9,774.95	8,980.03
0202	17,217.40	13,874.63	12,631.58	11,605.47
0203	19,925.18	16,056.69	14,617.29	13,429.66
0204	21,974.23	17,706.70	16,120.03	14,810.48
0205	25,833.22	20,816.69	18,951.33	17,412.17
0206	31,199.70	25,141.23	22,887.91	21,028.88
0207	39,750.60	32,032.62	29,161.74	26,792.82
0301	18,446.19	14,946.66	13,588.01	12,837.43
0302	22,393.86	18,146.91	16,496.90	15,584.81
0303	26,327.27	21,332.91	19,394.71	18,322.68
0304	34,119.67	27,646.33	25,133.31	23,744.58
0401	14,205.58	13,252.31	11,806.58	10,653.79
0402	20,747.02	19,355.12	17,241.15	15,557.89
0403	33,631.96	31,373.89	27,948.78	25,220.40
0404	58,906.20	54,953.78	48,953.90	44,174.90
0405	54,245.96	50,605.49	45,080.66	40,680.12
0501	14,878.57	11,177.93	10,588.86	9,716.36
0502	19,342.45	14,533.36	13,765.37	12,633.16
0503	24,227.55	18,203.92	17,242.73	15,822.33
0504	27,510.15	20,669.43	19,578.39	17,966.39
0505	31,622.50	23,758.83	22,504.70	20,652.01
0506	43,669.76	32,811.70	31,079.35	28,520.42
0601	16,908.61	12,921.36	11,987.10	10,907.15

TABLE 5—PROPOSED FY 2018 PAYMENT RATES—Continued

CMG	Payment rate tier 1	Payment rate tier 2	Payment rate tier 3	Payment rate no comorbidity
0602	22,058.16	16,857.94	15,638.65	14,229.33
0603	27,054.10	20,674.18	19,179.35	17,451.75
0604	35,180.62	26,884.66	24,940.13	22,693.14
0701	16,460.48	13,154.13	12,490.65	11,377.45
0702	20,851.53	16,663.17	15,823.92	14,413.02
0703	25,209.32	20,145.29	19,131.85	17,424.83
0704	31,951.86	25,533.94	24,248.14	22,085.07
0801	13,895.21	10,218.33	9,703.69	8,956.28
0802	17,839.71	13,119.30	12,458.98	11,499.38
0803	23,084.26	16,976.70	16,121.61	14,878.57
0804	21,241.07	15,621.23	14,834.23	13,690.94
0805	25,198.24	18,531.70	17,599.02	16,241.96
0806	30,463.37	22,403.36	21,275.91	19,635.40
0901	15,993.35	12,801.01	11,472.46	10,666.46
0902	21,024.13	16,827.85	15,081.25	14,023.48
0903	25,796.80	20,648.84	18,504.78	17,206.31
0904	32,319.24	25,869.64	23,184.02	21,556.19
1001	16,547.58	14,253.08	12,571.41	11,475.62
1002	21,781.04	18,759.72	16,547.58	15,103.42
1003	31,820.43	27,407.22	24,173.71	22,066.07
1101	20,745.43	18,579.21	16,078.86	13,909.46
1102	30,054.83	26,917.92	23,294.87	20,153.20
1201	19,326.62	14,533.36	13,572.18	12,492.23
1202	24,997.13	18,797.73	17,554.68	16,156.45
1203	30,585.30	23,000.34	21,478.59	19,770.00
1301	19,445.38	14,690.13	13,195.31	12,626.83
1302	26,735.81	20,197.54	18,142.16	17,361.49
1303	34,813.25	26,300.35	23,624.24	22,606.05
1401	14,698.05	11,827.16	10,808.97	9,811.37
1402	19,370.96	15,587.97	14,246.75	12,929.28
1403	23,195.11	18,664.71	17,059.05	15,481.88
1404	29,375.51	23,636.90	21,603.69	19,606.90
1501	16,066.19	13,436.00	12,253.12	11,738.49
1502	20,829.36	17,420.08	15,885.67	15,220.60
1503	25,309.08	21,166.64	19,302.87	18,493.70
1504	31,377.05	26,241.76	23,929.85	22,925.91
1601	18,275.17	14,371.85	13,100.30	12,034.60
1602	24,335.23	19,136.60	17,443.84	16,025.02
1603	30,373.11	23,885.51	21,771.54	20,001.19
1701	18,976.66	14,775.64	13,348.91	12,251.54
1702	24,135.71	18,791.39	16,978.29	15,581.64
1703	28,531.50	22,214.92	20,070.86	18,420.86
1704	36,113.30	28,116.63	25,404.09	23,315.45
1801	20,678.93	15,936.34	14,013.98	12,916.61
1802	29,639.95	22,841.99	20,086.70	18,514.28
1803	46,309.46	35,688.92	31,383.39	28,925.79
1901	20,523.74	17,066.96	15,732.07	15,078.09
1902	35,350.05	29,394.51	27,096.85	25,969.40
1903	58,242.71	48,431.35	44,645.20	42,786.17
2001	14,918.15	12,088.44	11,038.58	10,021.97
2002	19,633.82	15,909.42	14,527.03	13,190.56
2003	24,400.15	19,771.58	18,053.48	16,390.81
2004	31,164.86	25,253.66	23,058.93	20,937.04
2101	29,158.57	28,852.95	21,925.14	20,549.08
5001	.....	.....	.....	2,481.34
5101	.....	.....	.....	10,424.18
5102	.....	.....	.....	25,953.57
5103	.....	.....	.....	12,843.77
5104	.....	.....	.....	32,197.31

F. Example of the Methodology for Adjusting the Proposed Prospective Payment Rates

Table 6 illustrates the methodology for adjusting the proposed federal prospective payments (as described in sections V.A. through V.F. of this proposed rule). The following examples are based on two hypothetical Medicare beneficiaries, both classified into CMG 0110 (without comorbidities). The proposed 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 V.C. of this proposed rule by the proposed unadjusted prospective payment rate. To determine the non-labor portion of the proposed prospective payment rate, we subtract the labor portion of the proposed federal payment from the proposed unadjusted prospective payment.

To compute the proposed wage-adjusted prospective payment, we multiply the labor portion of the proposed federal payment by the appropriate proposed 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/InpatientRehabFacPPS/Data-Files.html*. The resulting figure is the wage-adjusted labor amount. Next, we compute the proposed wage-adjusted federal payment by adding the wage-adjusted labor amount to the non-labor portion.

Adjusting the proposed 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)
1. Unadjusted Payment	$33,384.93	$33,384.93
2. Labor Share	× 0.707	× 0.707
3. Labor Portion of Payment	= $23,603.15	= $23,603.15
4. CBSA-Based Wage Index (shown in the Addendum, Tables A and B)	× 0.8167	× 0.8859
5. Wage-Adjusted Amount	= $19,276.69	= $20,910.03
6. Non-Labor Amount	+ $9,781.78	+ $9,781.78
7. Wage-Adjusted Payment	= $29,058.47	= $30,691.81
8. Rural Adjustment	× 1.149	× 1.000
9. Wage- and Rural-Adjusted Payment	= $33,388.19	= $30,691.81
10. LIP Adjustment	× 1.0156	× 1.0454
11. Wage-, Rural- and LIP-Adjusted Payment	= $33,909.04	= $32,085.22
12. Wage- and Rural-Adjusted Payment	$33,388.19	$30,691.81
13. Teaching Status Adjustment	× 0	× 0.0784
14. Teaching Status Adjustment Amount	= $0.00	= $2,406.24
15. Wage-, Rural-, and LIP-Adjusted Payment	+ $33,909.04	+ $32,085.22
16. Total Adjusted Payment	= $33,909.04	= $34,491.46

Thus, the proposed adjusted payment for Facility A would be $33,909.04, and the proposed adjusted payment for Facility B would be $34,491.46.

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

A. Proposed 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 propose 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 propose 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.

Although our analysis shows that we achieved our goal to have estimated outlier payments equal 3.0 percent of total IRF payments for FY 2017, 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 proposed rule, we are proposing to increase 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 propose to update the outlier threshold amount from $7,984 for FY 2017 to $8,656 for FY 2018 to account for the increases in IRF PPS payments and estimated costs, to maintain estimated outlier payments at approximately 3 percent of total estimated aggregate IRF payments for FY 2018.

We invite public comment 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.

B. Proposed 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 propose to apply a ceiling to IRFs' CCRs. Using the methodology described in that final rule, we propose 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 propose 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 propose 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 proposed 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.

In accordance with past practice, we propose to set the national CCR ceiling at 3 standard deviations above the mean CCR. Using this method, the proposed national CCR ceiling would be 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.

The proposed national average rural and urban CCRs and the proposed national CCR ceiling in this section will be updated in the final rule if more recent data becomes available to use in these analyses.

We invite public comment on the proposed update to the IRF CCR ceiling and the urban/rural averages for FY 2018.

VII. Proposed 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 are not

proposing 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 this 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 inflect 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.

We are not proposing any changes to the timely filing requirements at § 412.614(c). However, we are proposing 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. These changes would become 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).
- Reserve § 412.614(d)(1)(ii).
- Revise § 412.614(e) Exemption to the consequences for transmitting the IRF–PAI data late. We invite public comment on our proposal to remove and revise the regulations pertaining to the 25 percent payment penalty for late transmission of the IRF–PAI.

VIII. Proposed Revision to the IRF–PAI To Remove the Voluntary Item 27 (Swallowing Status)

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 as we believed that the information should be well documented in the patient's medical record at the IRF. 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.

In the FY 2016 IRF PPS final rule (80 FR 47113 through 47117), we revised the IRF–PAI to include new items that assess functional status and the risk factor items. Section K-Swallowing/Nutritional Status, was added to the IRF–PAI as a risk adjustor for the functional outcome measures. We believe that continuing to collect data for voluntary item 27: Swallowing status, on the IRF–PAI would be duplicative since the new quality item captures very similar data. Furthermore, to the extent that such information would be relevant to the provision of patient care, this information should be captured in either the transfer documentation from the referring physician, or the patient's initial assessment documentation. At this time, we no longer believe that voluntary item 27 is necessary, and in the interest of reducing burden on providers, we are proposing to remove this item from the IRF–PAI for all IRF discharges beginning on or after October 1, 2017.

We invite public comment on our proposal to remove the swallowing status item from the IRF–PAI.

IX. Proposed 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 Inpatient Prospective Payment System (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 intension 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 delete 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. Proposed 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 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 is being 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 are proposing to revise the codes on the list. The complete revised lists are posted on the IRF PPS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Downloads/ICD-10-CM-DataFiles.zip.* The proposed revisions discussed below are 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. Proposed 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 this 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 this analysis, we propose 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 propose to retain exclusion of ''IGC Brain Dysfunction—0002.22 Traumatic, Closed Injury we have retained S06.9X9A—Unspecified intracranial injury with loss of consciousness of unspecified duration, initial encounter,'' 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 this 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 are proposing 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 are proposing to remove the diagnosis code exclusions for a fracture of ''*unspecified* part of neck of femur.'' However, we are proposing to retain the diagnosis code exclusions with the code label, ''fracture of unspecified part of neck of femur of *unspecified femur*.'' That is, we believe that documentation should support which femur (left/right or bilateral) is injured.

We invite public comment on our proposed revisions involving TBI and hip fracture codes.

F. Proposed 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 propose 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 propose 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 invite public comment on our proposed revisions to the presumptive methodology list for major multiple trauma.

G. Proposed Removal 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 this 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. Now, in light of our findings and consistent with our rationale for removing codes in the FY 2014 IRF PPS final rule (78 FR 47860, 47884 through 47885), we propose to remove certain unspecified diagnosis codes that, on review, we believe are inappropriate to include in the Presumptive Compliance list. These codes are listed on the CMS IRF PPS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Downloads/ICD-10-CM-DataFiles.zip.*

If finalized, we believe that ICD–10–CM codes that provide more specific information to describe medical disease, condition, or injury would remain available on the presumptive compliance list that facilities could use to code cases that should be included in their facility's presumptive compliance percentage compliance count. For example, we propose to remove the diagnosis code T22.559S—Corrosion of first degree of unspecified shoulder, sequela. However, we propose that T22.551S—Corrosion of the first degree of right shoulder, sequela and T22.552S—Corrosion of first degree of left shoulder, sequela remain on the Presumptive List. We believe documentation of anatomic location of injury should be readily available in the medical record and that this information should be used to appropriately code claims in the facility's presumptive methodology percentage using the IRF–PAI.

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. However, in analyzing the ICD–10–CM diagnosis codes for this proposed rule and consistent with our FY 2014 IRF PPS final rule rationale for removing ICD–9–CM arthritis diagnosis codes from the ICD–9–CM Codes That Meet Presumptive Compliance Criteria list, we propose to remove 15 ICD–10–CM diagnosis codes related to ''rheumatoid polyneuropathy with rheumatoid arthritis.''

We welcome 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.

H. Proposed Removal 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 some 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).

Therefore, to avoid the improper inclusion of cases that do not meet the requirements in the 60 percent rule under § 412.29(b) in IRFs' presumptive compliance, we are proposing to remove G72.89—Other Specified Myopathies from the presumptive compliance list. If finalized, IRFs would not be able to use this code to meet the 60 percent rule requirements using the presumptive compliance methodology, but patients with other specified myopathies that can be verified through a review of the patient's medical record would continue to count toward an IRF's compliance percentage using the medical review method.

We welcome public comment on our proposal to remove ICD–10–CM code G72.89—Other specified myopathies from the presumptive compliance list.

Again, the proposed revised ICD–10–CM Presumptive List and the proposed revised IGCs That Meet Presumptive Compliance Criteria list 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.*

I. Solicitation 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 inpatient prospective payment system (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, 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 have 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 International (RTI)) 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, we are specifically soliciting public comments from stakeholders on the 60 percent rule, including but not limited to, the list of conditions in § 412.29(b)(2).

X. Proposed 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 this proposed rule, we propose 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 sub-regulatory 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 this proposed rule, we are proposing 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 propose 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 proposed subregulatory process would be 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 propose to publish the updated lists of codes on the IRF PPS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Criteria.html* 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 are proposing in this 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 are proposing 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 are proposing 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 proposed presumptive compliance lists are available for download from the IRF PPS Web site *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 proposed 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/Downloads/ICD-10-CM-DataFiles.zip.* These lists reflect the proposed substantive revisions outlined in this proposed 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 the FY 2018 IRF PPS final rule will constitute the baseline for any future updates to the presumptive methodology lists.

We invite public comment on the proposed subregulatory process for certain updates to the presumptive methodology ICD–10–CM code lists.

XI. Proposed 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 this proposed rule, we propose 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 invite public comment on the proposed plan to calculate BMI greater than 50 for cases of lower extremity single joint replacement.

XII. Proposed Revisions and Updates to the IRF Quality Reporting Program (QRP)

A. Background and Statutory Authority

Section 3004(b) of the Affordable Care Act 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).

Please note that term ''FY [year] IRF QRP'' refers 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 their respective quality reporting program (which, for IRFs, is found at section 1886(m)(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. All of the data that must be reported in accordance with section 1899B(a)(1)(A) must be standardized and interoperable so as 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

[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.*

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, it means 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 an Application of Percent of Residents Experiencing One or More Falls With Major Injury (Long Stay) (NQF #0674), which is 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.''

1. Accounting for Social Risk Factors in the IRF QRP

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' value-based purchasing and quality reporting 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 final rule, the NQF has undertaken 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. Measures from the IRF QRP are being addressed in this trial. This trial entails temporarily allowing inclusion of social risk factors in the risk-adjustment approach for these measures. At the conclusion of the trial, 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, we are also seeking 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 are seeking 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 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 also welcome 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.

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

1. Proposed Definition of Standardized Patient Assessment Data

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. 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

[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.

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 rule, we are proposing to 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 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 are proposing 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 and to inform payment models that take into account patient characteristics rather than setting, as described in the IMPACT Act.

We are inviting public comment on this proposed definition.

2. General Considerations Used for the Selection of Proposed 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 Proposal To Apply 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 propose to apply this policy to the standardized patient assessment data that we adopt for the IRF QRP.

We are inviting public comment on our proposal.

E. Policy for Adopting Changes to IRF QRP Measures and Proposal To Apply That Policy to Standardized Patient Assessment Data

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. Substantive changes will be proposed and finalized through rulemaking. For further information on what constitutes a substantive versus a non-substantive change and the subregulatory process for non-substantive changes, please refer to the CY 2013 OPPS/ASC final rule (77 FR 68500). We propose to apply this policy to the standardized patient assessment data that we adopt for the IRF QRP.

We are inviting public comment on our proposal.

F. Quality Measures Currently Adopted for the IRF QRP

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

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).

TABLE 7—QUALITY MEASURES CURRENTLY ADOPTED FOR THE IRF QRP—Continued

Short name	Measure name and data source
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 Proposed Beginning With the FY 2020 IRF QRP

Beginning with the FY 2020 IRF QRP, in addition to the quality measures we are retaining under our policy described in section XII.F. of this proposed rule, we are proposing to 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 to replace it with a modified version of the measure entitled Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury. We are also proposing 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. Proposal To Replace 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 this proposed rule, we are proposing 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 are proposing 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. 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

[6] Casey, G. (2013). ''Pressure ulcers reflect quality of nursing care.'' Nurs N Z 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.*

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. 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.[15]

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 proposed 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 November 15, 2013, which had recommended that we update the specifications for the pressure ulcer measure to include unstageable pressure ulcers in the numerator.[16] [17] 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, due to non-removable dressing/device, and DTIs in the proposed quality measure. Other commenters did not support the inclusion of DTIs in the proposed 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

[15] 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.

[16] 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.*

[17] 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.*

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 are proposing 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 would 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 is described in section XII.K of this proposed 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 were used in 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 proposed 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, *Proposed Specifications for IRF QRP Quality Measures and Standardized 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 are proposing that IRFs would begin reporting the proposed pressure ulcer measure Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, which will replace the current pressure ulcer measure, with data collection beginning October 1, 2018.

We are inviting 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.

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

We are proposing to remove the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from IRFs (NQF #2502) from the 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. 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.

We are proposing to remove the All-Cause Readmission measure beginning with the FY 2019 IRF QRP. We are proposing 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 XII.N of this proposed rule for more information regarding our proposal to publicly report 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 are inviting 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.

I. IRF QRP Quality Measures Under Consideration for Future Years

We are inviting 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.

In this proposed rule, we are soliciting 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 are inviting public comment on the possible inclusion of such a measure in future years of the IRF QRP.

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 are inviting 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.

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 are engaging 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.

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

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

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

1. Proposed 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 above, we are proposing that the current pressure ulcer measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), 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 are proposing 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.[18] [19] [20] [21] [22] [23] Pressure related wounds are considered healthcare acquired conditions.

As we note above, 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.[24] 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 not available), ranged from 0.91 to 0.99 for these data elements. These kappa scores indicate ''almost perfect'' agreement using the Landis and Koch standard for strength of agreement.[25]

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/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We are inviting public comment on this proposal.

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

We describe below in this section 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. The BIMS, Hearing, and Vision data elements would be assessed at admission only due to the relatively stable nature of the types of cognitive function, hearing impairment, and vision impairment, making it unlikely that these assessments would change between the start and end of the IRF stay. Assessment of the BIMS, Hearing, and Vision data elements at discharge would introduce additional burden without improving the quality or usefulness of the data, and is unnecessary. 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 described below in this section, 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 note that the patient and resident 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 Post-Acute Care Payment Reform Demonstration. 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 note that there is no additional data collection burden for standardized data already collected and submitted on the quality measures.

a. Proposed Standardized Patient Assessment Data by Category

(1) Functional Status Data

We are proposing 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

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

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

[20] 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.

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

[22] 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.

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

[24] 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.*

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

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.'' [26] 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'' [27] 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.'' [28] 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 are inviting public comment on this proposal.

(2) Cognitive Function and Mental Status Data

Cognitive function and mental status in PAC patient and resident populations can be affected by a number of underlying conditions, including dementia, stroke, traumatic brain injury, side effects of medication, metabolic and/or endocrine imbalances, delirium, and depression.[29] The assessment of cognitive function and mental status by PAC providers is important because of the high percentage of patients and residents with these conditions,[30] and the opportunity for improving the quality of care. Symptoms of dementia may improve with pharmacotherapy, occupational therapy, or physical activity,[31] [32] [33] and promising treatments for severe traumatic brain injury are currently being tested.[34] For older patients and residents diagnosed with depression, treatment options to reduce symptoms and improve quality of life include antidepressant medication and psychotherapy,[35] [36] [37] [38] and targeted services, such as therapeutic recreation, exercise, and restorative nursing, to increase opportunities for psychosocial interaction.[39]

Accurate assessment of cognitive function and mental status of patients and residents in PAC would be expected to have a positive impact on the National Quality Strategy's domains of patient and family engagement, patient safety, care coordination, clinical process/effectiveness, and efficient use of healthcare resources. For example, standardized assessment of cognitive function and mental status of patients and residents in PAC will support establishing a baseline for identifying changes in cognitive function and mental status (for example, delirium), anticipating the patient or resident's ability to understand and participate in treatments during a PAC stay, ensuring patient and resident safety (for example, risk of falls), and identifying appropriate support needs at the time of discharge or transfer. Standardized assessment data elements will enable or support clinical decision-making and early clinical intervention; person-centered, high quality care through: Facilitating better care continuity and coordination; better data exchange and interoperability between settings; and longitudinal outcome analysis. Hence, reliable data elements assessing cognitive impairment and mental status are needed in order to initiate a management program that can optimize a patient or resident's prognosis and reduce the possibility of adverse events.

(i) Brief Interview for Mental Status (BIMS)

We are proposing that the data elements that comprise the Brief Interview for Mental Status meet the definition of standardized patient assessment data for cognitive function and mental status under section 1899B(b)(1)(B)(ii) of the Act. The proposed data elements consist of seven BIMS questions that result in a cognitive function score. For more information on the BIMS, we refer readers to the document titled, *Proposed Specifications for IRF QRP Quality Measures and Standardized Data Elements,* available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.*

The BIMS is a performance-based cognitive assessment that assesses repetition, recall with and without prompting, and temporal orientation. It was developed to be a brief screener to assess cognition, with a focus on learning and memory. Dementia and cognitive impairment are associated with long-term functional dependence and, consequently, poor quality of life and increased health care costs and mortality.[40] This makes assessment of mental status and early detection of cognitive decline or impairment critical in the PAC setting. The burden of cognitive impairment in PAC is high. The intensity of routine nursing care is higher for patients and residents with cognitive impairment than those without, and dementia is a significant variable in predicting readmission after discharge to the community from PAC

[26] 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).

[27] Ibid.

[28] Ibid.

[29] National Institute on Aging. (2014). Assessing Cognitive Impairment in Older Patients. A Quick Guide for Primary Care Physicians. Retrieved from *https://www.nia.nih.gov/alzheimers/publication/assessing-cognitive-impairment-older-patients.*

[30] Gage B., Morley M., Smith L., et al. (2012). Post-Acute Care Payment Reform Demonstration (Final report, Volume 4 of 4). Research Triangle Park, NC: RTI International.

[31] Casey D.A., Antimisiaris D., O'Brien J. (2010). Drugs for Alzheimer's Disease: Are They Effective? *Pharmacology & Therapeutics,* 35, 208–11.

[32] Graff M.J., Vernooij-Dassen M.J., Thijssen M., Dekker J., Hoefnagels W.H., Rikkert M.G.O. (2006). Community Based Occupational Therapy for Patients with Dementia and their Care Givers: Randomised Controlled Trial. BMJ, 333(7580): 1196.

[33] Bherer L., Erickson K.I., Liu-Ambrose T. (2013). A Review of the Effects of Physical Activity and Exercise on Cognitive and Brain Functions in Older Adults. Journal of Aging Research, 657508.

[34] Giacino J.T., Whyte J., Bagiella E., et al. (2012). Placebo-controlled trial of amantadine for severe traumatic brain injury. New England Journal of Medicine, 366(9), 819–826.

[35] Alexopoulos G.S., Katz I.R., Reynolds C.F. 3rd, Carpenter D., Docherty J.P., Ross R.W. (2001). Pharmacotherapy of depression in older patients: a summary of the expert consensus guidelines. *Journal of Psychiatric Practice,* 7(6), 361–376.

[36] Arean P.A., Cook B.L. (2002). Psychotherapy and combined psychotherapy/pharmacotherapy for late life depression. *Biological Psychiatry,* 52(3), 293–303.

[37] Hollon S.D., Jarrett R.B., Nierenberg A.A., Thase M.E., Trivedi M., Rush A.J. (2005). Psychotherapy and medication in the treatment of adult and geriatric depression: which monotherapy or combined treatment? *Journal of Clinical Psychiatry,* 66(4), 455–468.

[38] Wagenaar D, Colenda CC, Kreft M, Sawade J, Gardiner J, Poverejan E. (2003). Treating depression in nursing homes: practice guidelines in the real world. *J Am Osteopath Assoc.* 103(10), 465–469.

[39] Crespy SD, Van Haitsma K, Kleban M, Hann CJ. Reducing Depressive Symptoms in Nursing Home Residents: Evaluation of the Pennsylvania Depression Collaborative Quality Improvement Program. J Healthc Qual. 2016. Vol. 38, No. 6, pp. e76–e88.

[40] Agüero-Torres, H., Fratiglioni, L., Guo, Z., Viitanen, M., von Strauss, E., & Winblad, B. (1998). ''Dementia is the major cause of functional dependence in the elderly: 3-year follow-up data from a population-based study.'' Am J of Public Health 88(10): 1452–1456.

providers.[41] The BIMS data elements are currently in use in two of the PAC assessments: The MDS 3.0 in SNFs and the IRF–PAI in IRFs. The BIMS was tested in the PAC PRD where it was found to have substantial to almost perfect agreement for inter-rater reliability (kappa range of 0.71 to 0.91) when tested in all four PAC settings.[42] Clinical and subject matter expert advisors working with our data element contractor agreed that the BIMS is a feasible data element for use by PAC providers. Additionally, discussions during a TEP convened on April 6 and 7, 2016, demonstrated support for the BIMS. The Development and Maintenance of Post-Acute Care Cross-Setting Standardized Patient Assessment Data Technical Expert Panel 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.*

To solicit additional feedback on the BIMS, we requested public comment from August 12 to September 12, 2016. Many commenters expressed support for use of the BIMS, noting that it is reliable, feasible to use across settings, and will provide useful information about patients and residents. These comments noted that the data collected through the BIMS will provide a clearer picture of patient or resident complexity, help with the care planning process, and be useful during care transitions and when coordinating across providers. A full report of the comments 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.*

Therefore, we are proposing to adopt the BIMS for use in the IRF QRP. As noted above in this section, the BIMS is already included on the IRF–PAI. For purposes of reporting for the FY 2020 IRF QRP, IRFs would be required to report these data on admission for all Medicare Part A and MA patients discharged between October 1, 2018 and December 31, 2018. 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. The BIMS data element would be assessed at admission only due to the relatively stable nature of the types of cognitive function assessed by the BIMS, making it unlikely that a patient's score on this assessment would change between the start and end of the PAC stay. Assessment at discharge would introduce additional burden without improving the quality or usefulness of the data, and we believe that it is unnecessary.

We are inviting public comment on these proposals.

(ii) Confusion Assessment Method (CAM)

We are proposing that the data elements that comprise the Confusion Assessment Method (CAM) meet the definition of standardized patient assessment data for cognitive function and mental status under section 1899B(b)(1)(B)(ii) of the Act. The CAM is a six-question instrument that screens for overall cognitive impairment, as well as distinguishes delirium or reversible confusion from other types of cognitive impairment. For more information on the CAM, we refer readers to the document titled, *Proposed Specifications for IRF QRP Quality Measures and Standardized Data Elements,* available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.*

The CAM was developed to identify the signs and symptoms of delirium. It results in a score that suggests whether the patient or resident should be assigned a diagnosis of delirium. Because patients and residents with multiple comorbidities receive services from PAC providers, it is important to assess delirium, which is associated with a high mortality rate and prolonged duration of stay in hospitalized older adults.[43] Assessing these signs and symptoms of delirium is clinically relevant for care planning by PAC providers.

The CAM is currently in use in two of the PAC assessments: The MDS 3.0 in SNFs and the LCDS in LTCHs. The CAM was tested in the PAC PRD where it was found to have substantial agreement for inter-rater reliability for the ''Inattention and Disorganized Thinking'' questions (kappa range of 0.70 to 0.73); and moderate agreement for the ''Altered Level of Consciousness'' question (kappa of 0.58).[44]

Clinical and subject matter expert advisors working with our data element contractor agreed that the CAM is feasible for use by PAC providers, that it assesses key aspects of cognition, and that this information about patient or resident cognition would be clinically useful both within and across PAC provider types. The CAM was also supported by a TEP that discussed and rated candidate data elements during a meeting on April 6 and 7, 2016. The Development and Maintenance of Post-Acute Care Cross-Setting Standardized Patient Assessment Data Technical Expert Panel 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.* We requested public comment on the CAM from August 12 to September 12, 2016. Many commenters expressed support for use of the CAM, noting that it would provide important information for care planning and care coordination, and therefore, contribute to quality improvement. The commenters noted it is particularly helpful in distinguishing delirium and reversible confusion from other types of cognitive impairment. A full report of the comments 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.*

Therefore, we are proposing to add the CAM data elements to the IRF–PAI, and that IRFs would be required to report these data for the FY 2020 IRF QRP on admission and discharge for all Medicare Part A and MA patients discharged between October 1, 2018 and December 31, 2018. 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.

We are inviting public comment on these proposals.

(iii) Behavioral Signs and Symptoms

We are proposing that the Behavioral Signs and Symptoms data elements meet the definition of standardized patient assessment data for cognitive

[41] RTI International. Proposed Measure Specifications for Measures Proposed in the FY 2017 LTCH QRP Proposed Rule. Research Triangle Park, NC. 2016.

[42] Gage B., Morley M., Smith L., et al. (2012). *Post-Acute Care Payment Reform Demonstration* (Final report, Volume 2 of 4). Research Triangle Park, NC: RTI International.

[43] Fick, D. M., Steis, M. R., Waller, J. L., & Inouye, S. K. (2013). ''Delirium superimposed on dementia is associated with prolonged length of stay and poor outcomes in hospitalized older adults.'' J of Hospital Med 8(9): 500–505.

[44] Gage B., Morley M., Smith L., et al. (2012). Post-Acute Care Payment Reform Demonstration (Final report, Volume 2 of 4). Research Triangle Park, NC: RTI International.

function and mental status under section 1899B(b)(1)(B)(ii) of the Act. The proposed data elements consist of three Behavioral Signs and Symptoms questions and result in three scores that categorize respondents as having or not having certain types of behavioral signs and symptoms. For more information on the Behavioral Signs and Symptoms data elements, we refer readers to the document titled, *Proposed Specifications for IRF QRP Quality Measures and Standardized Data Elements,* available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.*

The questions included in the Behavioral Signs and Symptoms group assess whether the patient or resident has exhibited any behavioral symptoms that may indicate cognitive impairment or other mental health issues during the assessment period, including physical, verbal, and other disruptive or dangerous behavioral symptoms, but excluding patient wandering. Such behavioral disturbances can indicate unrecognized needs and care preferences and are associated most commonly with dementia and other cognitive impairment, and less commonly with adverse drug events, mood disorders, and other conditions. Assessing behavioral disturbances can lead to early intervention, patient- and resident-centered care planning, clinical decision support, and improved staff and patient or resident safety through early detection. Assessment and documentation of these disturbances can help inform care planning and patient transitions and provide important information about resource use.

Data elements that capture behavioral symptoms are currently included in two of the PAC assessments: The MDS 3.0 in SNFs and the OASIS–C2 in HHAs. In the MDS, each question includes four response options ranging from ''behavior not exhibited'' (0) to behavior ''occurred daily'' (3). The OASIS–C2 includes some similar data elements which record the frequency of disruptive behaviors on a 6-point scale ranging from ''never'' (0) to ''at least daily'' (5). Data elements that mirror those used in the MDS and serve the same assessment purpose were tested in post-acute providers in the PAC PRD and found to be clinically relevant, meaningful for care planning, and feasible for use in each of the four PAC settings.[45]

The proposed data elements were supported by comments from the Standardized Patient Assessment Data TEP held by our data element contractor. The TEP identified patient and resident behaviors as an important consideration for resource intensity and care planning, and affirmed the importance of the standardized assessment of patient behaviors through data elements such as those in use in the MDS. The Development and Maintenance of Post-Acute Care Cross-Setting Standardized Patient Assessment Data Technical Expert Panel 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.*

Because the PAC PRD version of the Behavioral Signs and Symptoms data elements were previously tested across PAC providers, we solicited additional feedback on this version of the data elements by including these data elements in a call for public comment that was open from August 12 to September 12, 2016. Consistent with the TEP discussion on the importance of patient and resident behaviors, many commenters expressed support for use of the Behavioral Signs and Symptoms data elements, noting that they would provide useful information about patient and resident behavior at both admission and discharge and contribute to care planning related to what treatment is appropriate for the patient or resident and what resources are needed. Public comment also supported the use of highly similar MDS version of the data element in order to provide continuity with existing assessment processes in SNFs. A full report of the comments 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.*

Therefore, we are proposing the MDS version of the Behavioral Signs and Symptoms data elements because they focus more closely on behavioral symptoms than the OASIS data elements, and include more detailed response categories than those used in the PAC PRD version, capturing more information about the frequency of behaviors. We are proposing to add the Behavioral Signs and Symptoms data elements to the IRF–PAI, and that IRFs would be required to report these data for the FY 2020 IRF QRP on admission and discharge for all Medicare Part A and MA patients discharged between October 1, 2018 and December 31, 2018. 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.

We are inviting public comment on these proposals.

(iv) Patient Health Questionnaire-2 (PHQ–2)

We are proposing that the PHQ–2 data elements meet the definition of standardized patient assessment data for cognitive function and mental status under section 1899B(b)(1)(B)(ii) of the Act. The proposed data elements consist of the PHQ–2 two-item questionnaire that assesses the cardinal criteria for depression: Depressed mood and anhedonia (inability to feel pleasure). For more information on the PHQ–2, we refer readers to the document titled, *Proposed Specifications for IRF QRP Quality Measures and Standardized Data Elements,* available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.*

Depression is a common mental health condition often missed and under-recognized. Assessments of depression help PAC providers better understand the needs of their patients and residents by: Prompting further evaluation (that is, to establish a diagnosis of depression); elucidating the patient's or resident's ability to participate in therapies for conditions other than depression during their stay; and identifying appropriate ongoing treatment and support needs at the time of discharge. A PHQ–2 score beyond a predetermined threshold signals the need for additional clinical assessment in order to determine a depression diagnosis.

The proposed data elements that comprise the PHQ–2 are currently used in the OASIS–C2 for HHAs and the MDS 3.0 for SNFs (as part of the PHQ–9). The PHQ–2 data elements were tested in the PAC PRD, where they were found to have almost perfect agreement for inter-rater reliability (kappa range of

[45] Gage B., Morley M., Smith L., et al. (2012). Post-Acute Care Payment Reform Demonstration (Final report, Volume 2 of 4). Research Triangle Park, NC: RTI International.

0.84 to 0.91) when tested by all four PAC providers.[46]

Clinical and subject matter expert advisors working with our data element contractor agreed that the PHQ–2 is feasible for use in PAC, that it assesses key aspects of mental status, and that this information about patient or resident mood would be clinically useful both within and across PAC provider types. We note that both the PHQ–9 and the PHQ–2 were supported by TEP members who discussed and rated candidate data elements during a meeting on April 6 and 7, 2016. They particularly noted that the brevity of the PHQ–2 made it feasible with low burden for both assessors and PAC patients or residents. The Development and Maintenance of Post-Acute Care Cross-Setting Standardized Patient Assessment Data Technical Expert Panel 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.*

To solicit additional feedback on the PHQ–2, we requested public comment from August 12 to September 12, 2016. Many commenters provided feedback on using the PHQ–2 for the assessment of mood. Overall, commenters believed that collecting these data elements across PAC provider types was appropriate, given the role that depression plays in well-being. Several commenters expressed support for an approach that would use PHQ–2 as a gateway to the longer PHQ–9 and would maintain the reduced burden on most patients and residents, as well as test administrators, which is a benefit of the PHQ–2, while ensuring that the PHQ–9, which exhibits higher specificity,[47] would be administered for patients and residents who showed signs and symptoms of depression on the PHQ–2. Specific comments are described in a full report 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.*

Therefore, we are proposing to add the PHQ–2 data elements to the IRF–PAI, and that IRFs would be required to report these data for the FY 2020 IRF QRP on admission and discharge for all Medicare Part A and MA patients discharged between October 1, 2018 and December 31, 2018. 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.

We are inviting public comment on these proposals.

(3) Special Services, Treatments, and Interventions Data

Special services, treatments, and interventions performed in PAC can have a major effect on an individual's health status, self-image, and quality of life. The assessment of these special services, treatments, and interventions in PAC is important to ensure the continuing appropriateness of care for the patients and residents receiving them, and to support care transitions from one PAC provider to another, an acute care hospital, or discharge. Accurate assessment of special services, treatments, and interventions of patients and residents served by PAC providers are expected to have a positive impact on the National Quality Strategy's domains of patient and family engagement, patient safety, care coordination, clinical process/effectiveness, and efficient use of healthcare resources.

For example, standardized assessment of special services, treatments, and interventions used in PAC can promote patient and resident safety through appropriate care planning (for example, mitigating risks such as infection or pulmonary embolism associated with central intravenous access), and identifying life-sustaining treatments that must be continued, such as mechanical ventilation, dialysis, suctioning, and chemotherapy, at the time of discharge or transfer. Standardized assessment of these data elements will enable or support: Clinical decision-making and early clinical intervention; person-centered, high quality care through, for example, facilitating better care continuity and coordination; better data exchange and interoperability between settings; and longitudinal outcome analysis. Hence, reliable data elements assessing special services, treatments, and interventions are needed to initiate a management program that can optimize a patient or resident's prognosis and reduce the possibility of adverse events.

We are proposing 15 special services, treatments, and interventions as presented below in this section grouped by cancer treatments, respiratory treatments, other treatments, and nutritional approaches. A TEP convened by our data element contractor provided input on the 15 data elements for Special Services, Treatments, and Interventions. This TEP, held on January 5 and 6, 2017, opined that these data elements are appropriate for standardization because they would provide useful clinical information to inform care planning and care coordination. The TEP affirmed that assessment of these services and interventions is standard clinical practice, and that the collection of these data by means of a list and checkbox format would conform to common workflow for PAC providers. A full report of the TEP discussion 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.*

(i) Cancer Treatment: Chemotherapy (IV, Oral, Other)

We are proposing that the Chemotherapy (IV, Oral, Other) data elements meet the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data elements consist of the principal Chemotherapy data element and three sub-elements: IV Chemotherapy, Oral Chemotherapy, and Other. For more information on the Chemotherapy data element, we refer readers to the document titled, *Proposed Specifications for IRF QRP Quality Measures and Standardized Data Elements,* available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.*

Chemotherapy is a type of cancer treatment that uses drugs to destroy cancer cells. It is sometimes used when a patient has a malignancy (cancer), which is a serious, often life-threatening or life-limiting condition. Both intravenous (IV) and oral chemotherapy have serious side effects, including nausea/vomiting, extreme fatigue, risk of infection due to a suppressed immune system, anemia, and an increased risk of bleeding due to low platelet counts. Oral chemotherapy can be as potent as chemotherapy given by IV, but can be significantly more

[46] Gage B., Smith L., Ross J. et al. (2012). The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set (Final Report on Reliability Testing, Volume 2 of 3). Research Triangle Park, NC: RTI International.

[47] Arroll B, Goodyear-Smith F, Crengle S, Gunn J, Kerse N, Fishman T, et al. Validation of PHQ–2 and PHQ–9 to screen for major depression in the primary care population. *Annals of family medicine.* 2010;8(4):348–53. doi: 10.1370/afm.1139 pmid:20644190; PubMed Central PMCID: PMC2906530.

convenient and less resource-intensive to administer. Because of the toxicity of these agents, special care must be exercised in handling and transporting chemotherapy drugs. IV chemotherapy may be given by peripheral IV, but is more commonly given via an indwelling central line, which raises the risk of bloodstream infections. Given the significant burden of malignancy, the resource intensity of administering chemotherapy, and the side effects and potential complications of these highly-toxic medications, assessing the receipt of chemotherapy is important in the PAC setting for care planning and determining resource use.

The need for chemotherapy predicts resource intensity, both because of the complexity of administering these potent, toxic drug combinations under specific protocols, and because of what the need for chemotherapy signals about the patient's underlying medical condition. Furthermore, the resource intensity of IV chemotherapy is higher than for oral chemotherapy, as the protocols for administration and the care of the central line (if present) require significant resources.

The Chemotherapy (IV, Oral, Other) data elements consist of a principal data element and three sub-elements: IV chemotherapy, which is generally resource-intensive; oral chemotherapy, which is less invasive and generally less intensive with regard to administration protocols; and a third category provided to enable the capture of other less common chemotherapeutic approaches. This third category is potentially associated with higher risks and is more resource intensive due to delivery by other routes (for example, intraventricular or intrathecal).

The principal Chemotherapy data element is currently in use in the MDS 3.0. One proposed sub-element, IV Chemotherapy, was tested in the PAC PRD and found feasible for use in each of the four PAC settings. We solicited public comment on IV Chemotherapy from August 12 to September 12, 2016. Several commenters provided support for the data element and suggested it be included as standardized patient assessment data. Commenters stated that assessing the use of chemotherapy services is relevant to share across the care continuum to facilitate care coordination and care transitions and noted the validity of the data element. Commenters also noted the importance of capturing all types of chemotherapy, regardless of route, and stated that collecting data only on patients and residents who received chemotherapy by IV would limit the usefulness of this standardized data element. A full report of the comments 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.*

As a result of the comments and input received from clinical and subject matter experts, we are proposing a principal Chemotherapy data element with three sub-elements, including Oral and Other for standardization. Our data element contractor then presented the proposed data elements to the Standardized Patient Assessment Data TEP on January 5 and 6, 2017, who supported these data elements for standardization. A full report of the TEP discussion 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.*

Therefore, we are proposing that the Chemotherapy (IV, Oral, Other) data elements with a principal data element and three sub-elements meet the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing to add the Chemotherapy (IV, Oral, Other) data elements to the IRF–PAI, and that IRFs would be required to report these data for the FY 2020 IRF QRP on admission and discharge for all Medicare Part A and MA patients discharged between October 1, 2018 and December 31, 2018. 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.

We are inviting public comment on these proposals.

(ii) Cancer Treatment: Radiation

We are proposing that the Radiation data element meets the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data element consists of the single Radiation data element. For more information on the Radiation data element, we refer readers to the document titled, *Proposed Specifications for IRF QRP Quality Measures and Standardized Data Elements,* available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.*

Radiation is a type of cancer treatment that uses high-energy radioactivity to stop cancer by damaging cancer cell DNA, but it can also damage normal cells. Radiation is an important therapy for particular types of cancer, and the resource utilization is high, with frequent radiation sessions required, often daily for a period of several weeks. Assessing whether a patient or resident is receiving radiation therapy is important to determine resource utilization because PAC patients and residents will need to be transported to and from radiation treatments, and monitored and treated for side effects after receiving this intervention. Therefore, assessing the receipt of radiation therapy, which would compete with other care processes given the time burden, would be important for care planning and care coordination by PAC providers.

The Radiation data element is currently in use in the MDS 3.0. This data element was not tested in the PAC PRD. However, public comment and other expert input on the Radiation data element supported its importance and clinical usefulness for patients in PAC settings, due to the side effects and consequences of radiation treatment on patients that need to be considered in care planning and care transitions. To solicit additional feedback on the Radiation data element we are proposing, we requested public comment from August 12 to September 12, 2016. Several commenters provided support for the data element, noting the relevance of this data element to facilitating care coordination and supporting care transitions, the feasibility of the item, and the potential for it to improve quality. A full report of the comments 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.*

The proposed data element was presented to and supported by the TEP held by our data element contractor on January 5 and 6, 2017, which opined that Radiation was important corollary information about cancer treatment to collect alongside Chemotherapy (IV, Oral, Other), and that, because capturing this information is a customary part of clinical practice, the proposed data element would be feasible, reliable, and easily incorporated into existing workflow.

Therefore, we are proposing that the Radiation data element meets the definition of standardized patient assessment data for special services,

treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing to add the Radiation data element to the IRF–PAI, and that IRFs would be required to report these data for the FY 2020 IRF QRP on admission and discharge for all Medicare Part A and MA patients discharged between October 1, 2018 and December 31, 2018. 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.

We are inviting public comment on these proposals.

(iii) Respiratory Treatment: Oxygen Therapy (Continuous, Intermittent)

We are proposing that the Oxygen Therapy (Continuous, Intermittent) data elements meet the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data elements consist of the principal Oxygen data element and two sub-elements, ''Continuous'' (whether the oxygen was delivered continuously, typically defined as ≧14 hours per day), or ''Intermittent.'' For more information on the Oxygen Therapy (Continuous, Intermittent) data elements, we refer readers to the document titled, *Proposed Specifications for IRF QRP Quality Measures and Standardized Data Elements,* available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.*

Oxygen therapy provides a patient or resident with extra oxygen when medical conditions such as chronic obstructive pulmonary disease, pneumonia, or severe asthma prevent the patient or resident from getting enough oxygen from breathing. Oxygen administration is a resource-intensive intervention, as it requires specialized equipment such as a source of oxygen, delivery systems (for example, oxygen concentrator, liquid oxygen containers, and high-pressure systems), the patient interface (for example, nasal cannula or mask), and other accessories (for example, regulators, filters, tubing). These data elements capture patient or resident use of two types of oxygen therapy (continuous and intermittent) which are reflective of intensity of care needs, including the level of monitoring and bedside care required. Assessing the receipt of this service is important for care planning and resource use for PAC providers.

The proposed data elements were developed based on similar data elements that assess oxygen therapy, currently in use in the MDS 3.0 (''Oxygen Therapy'') and OASIS–C2 (''Oxygen (intermittent or continuous)''), and a data element tested in the PAC PRD that focused on intensive oxygen therapy (''High O2 Concentration Delivery System with FiO2 > 40%'').

As a result of input from expert advisors, we solicited public comment on the single data element, Oxygen (inclusive of intermittent and continuous oxygen use), from August 12 to September 12, 2016. Several commenters supported the importance of the Oxygen data element, noting feasibility of this item in PAC, and the relevance of it to facilitating care coordination and supporting care transitions, but suggesting that the extent of oxygen use be documented. A full report of the comments 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.*

As a result of public comment and input from expert advisors about the importance and clinical usefulness of documenting the extent of oxygen use, we expanded the single data element to include two sub-elements, intermittent and continuous.

Therefore, we are proposing that the Oxygen Therapy (Continuous, Intermittent) data elements with a principal data element and two sub-elements meet the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing to add the Oxygen Therapy (Continuous, Intermittent) data elements to the IRF–PAI, and that IRFs would be required to report these data for the FY 2020 IRF QRP on admission and discharge for all Medicare Part A and MA patients discharged between October 1, 2018 and December 31, 2018. 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.

We are inviting public comment on these proposals.

(iv) Respiratory Treatment: Suctioning (Scheduled, as Needed)

We are proposing that the Suctioning (Scheduled, As needed) data elements meet the definition of standardized patient assessment data element for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data elements consist of the principal Suctioning data element, and two sub-elements, ''Scheduled'' and ''As needed.'' These sub-elements capture two types of suctioning. ''Scheduled'' indicates suctioning based on a specific frequency, such as every hour; ''As needed'' means suctioning only when indicated. For more information on the Suctioning (Scheduled, As needed) data elements, we refer readers to the document titled, *Proposed Specifications for IRF QRP Quality Measures and Standardized Data Elements,* available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.*

Suctioning is a process used to clear secretions from the airway when a person cannot clear those secretions on his or her own. It is done by aspirating secretions through a catheter connected to a suction source. Types of suctioning include oropharyngeal and nasopharyngeal suctioning, nasotracheal suctioning, and suctioning through an artificial airway such as a tracheostomy tube. Oropharyngeal and nasopharyngeal suctioning are a key part of many patients' care plans, both to prevent the accumulation of secretions than can lead to aspiration pneumonias (a common condition in patients with inadequate gag reflexes), and to relieve obstructions from mucus plugging during an acute or chronic respiratory infection, which often lead to desaturations and increased respiratory effort. Suctioning can be done on a scheduled basis if the patient is judged to clinically benefit from regular interventions; or can be done as needed, such as when secretions become so prominent that gurgling or choking is noted, or a sudden desaturation occurs from a mucus plug. As suctioning is generally performed by a care provider rather than independently, this intervention can be quite resource-intensive if it occurs every hour, for example, rather than once a shift. It also signifies an underlying medical condition that prevents the patient from clearing his/her secretions effectively (such as after a stroke, or during an acute respiratory infection). Generally, suctioning is necessary to ensure that the airway is clear of secretions which can inhibit successful oxygenation of the individual. The intent of suctioning is to maintain a patent airway, the loss of which can lead to death, or complications associated with hypoxia.

The proposed data elements are based on an item currently in use in the MDS 3.0 (''Suctioning'' without the two sub-elements), and data elements tested in the PAC PRD that focused on the frequency of suctioning required for patients with tracheostomies (''Trach Tube with Suctioning: Specify most intensive frequency of suctioning during stay [Every __hours]'').

Clinical and subject matter expert advisors working with our data element contractor agreed that the proposed Suctioning (Scheduled, As needed) data elements are feasible for use in PAC, and that they indicate important treatment that would be clinically useful to capture both within and across PAC providers. We solicited public comment on the suctioning data element currently included in the MDS 3.0 between August 12 and September 12, 2016. Several commenters wrote in support of this data element, noting feasibility of this item in PAC, and the relevance of this data element to facilitating care coordination and supporting care transitions. We also received comments suggesting that we examine the frequency of suctioning in order to better understand the use of staff time, the impact on a patient or resident's capacity to speak and swallow, and intensity of care required. Based on these comments, we decided to add two sub-elements (scheduled and as needed) to the suctioning element. The proposed data elements, Suctioning (Scheduled, As needed) includes both the principal suctioning data element that is included on the MDS 3.0 and two sub-elements, ''scheduled'' and ''as needed.'' A full report of the comments 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.*

A TEP convened by the data element contractor provided input on the proposed data elements. This TEP, held on January 5 and 6, 2017, opined that these data elements are appropriate for standardization because they would provide useful clinical information to inform care planning and care coordination. The TEP affirmed that assessment of these services and interventions is standard clinical practice. A full report of the TEP discussion 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.*

Therefore, we are proposing that the Suctioning (Scheduled, As needed) data elements with a principal data element and two sub-elements meet the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing to add the Suctioning (Scheduled, As needed) data elements to the IRF–PAI, and that IRFs would be required to report these data for the FY 2020 IRF QRP on admission and discharge for all Medicare Part A and MA patients discharged between October 1, 2018 and December 31, 2018. 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.

We are inviting public comment on these proposals.

(v) Respiratory Treatment: Tracheostomy Care

We are proposing that the Tracheostomy Care data element meets the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data element consists of the single Tracheostomy Care data element. For more information on the Tracheostomy Care data element, we refer readers to the document titled, *Proposed Specifications for IRF QRP Quality Measures and Standardized Data Elements,* available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.*

A tracheostomy provides an air passage to help a patient or resident breathe when the usual route for breathing is obstructed or impaired. Generally, in all of these cases, suctioning is necessary to ensure that the tracheostomy is clear of secretions which can inhibit successful oxygenation of the individual. Often, individuals with tracheostomies are also receiving supplemental oxygenation. The presence of a tracheostomy, albeit permanent or temporary, warrants careful monitoring and immediate intervention if the tracheostomy becomes occluded or in the case of a temporary tracheostomy, the device used becomes dislodged. While in rare cases the presence of a tracheostomy is not associated with increased care demands (and in some of those instances, the care of the ostomy is performed by the patient) in general the presence of such as device is associated with increased patient risk, and clinical care services will necessarily include close monitoring to ensure that no life-threatening events occur as a result of the tracheostomy, often considered part of the patient's life line. In addition, tracheostomy care, which primarily consists of cleansing, dressing changes, and replacement of the tracheostomy cannula (tube), is also a critical part of the care plan. Regular cleansing is important to prevent infection such as pneumonia and to prevent any occlusions with which there are risks for inadequate oxygenation.

The proposed data element is currently in use in the MDS 3.0 (''Tracheostomy care''). Data elements (''Trach Tube with Suctioning'') that were tested in the PAC PRD included an equivalent principal data element on the presence of a tracheostomy. This data element was found feasible for use in each of the four PAC settings as the data collection aligned with usual work flow.

Clinical and subject matter expert advisors working with our data element contractor agreed that the Tracheostomy Care data element is feasible for use in PAC and that it assesses an important treatment that would be clinically useful both within and across PAC provider types.

We solicited public comment on this data element from August 12 to September 12, 2016. Several commenters wrote in support of this data element, noting the feasibility of this item in PAC, and the relevance of this data element to facilitating care coordination and supporting care transitions. A full report of the comments 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.*

A TEP convened by the data element contractor provided input on the proposed data elements. This TEP, held on January 5 and 6, 2017, opined that these data elements are appropriate for standardization because they would provide useful clinical information to inform care planning and care coordination. The TEP affirmed that assessment of these services and interventions is standard clinical practice. A full report of the TEP discussion 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.*

Therefore, we are proposing that the Tracheostomy Care data element meets

the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing to add the Tracheostomy Care data element to the IRF–PAI, and that IRFs would be required to report these data for the FY 2020 IRF QRP on admission and discharge for all Medicare Part A and MA patients discharged between October 1, 2018 and December 31, 2018. 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.

We are inviting public comment on these proposals.

(vi) Respiratory Treatment: Non-Invasive Mechanical Ventilator (BiPAP, CPAP)

We are proposing that the Non-invasive Mechanical Ventilator (Bilevel Positive Airway Pressure [BiPAP], Continuous Positive Airway Pressure [CPAP]) data elements meet the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data elements consist of the principal Non-invasive Mechanical Ventilator data element and two sub-elements, BiPAP and CPAP. For more information on the Non-invasive Mechanical Ventilator (BiPAP, CPAP) data element, we refer readers to the document titled, *Proposed Specifications for IRF QRP Quality Measures and Standardized Data Elements,* available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.*

BiPAP and CPAP are respiratory support devices that prevent the airways from closing by delivering slightly pressurized air via electronic cycling throughout the breathing cycle (Bilevel PAP, referred to as BiPAP) or through a mask continuously (Continuous PAP, referred to as CPAP). Assessment of non-invasive mechanical ventilation is important in care planning, as both CPAP and BiPAP are resource-intensive (although less so than invasive mechanical ventilation) and signify underlying medical conditions about the patient or resident who requires the use of this intervention. Particularly when used in settings of acute illness or progressive respiratory decline, additional staff (for example, respiratory therapists) are required to monitor and adjust the CPAP and BiPAP settings and the patient or resident may require more nursing resources.

Data elements that assess BiPAP and CPAP are currently included on the OASIS–C2 for HHAs (''Continuous/Bi-level positive airway pressure''), LCDS for the LTCH setting (''Non-invasive Ventilator (BIPAP, CPAP)''), and the MDS 3.0 for the SNF setting (''BiPAP/CPAP''). A data element that focused on CPAP was tested across the four PAC providers in the PAC–PRD study and found to be feasible for standardization. All of these data elements assess BiPAP or CPAP with a single check box, not separately.

Clinical and subject matter expert advisors working with our data element contractor agreed that the standardized assessment of Non-invasive Mechanical Ventilator (BiPAP, CPAP) data elements would be feasible for use in PAC, and assess an important treatment that would be clinically useful both within and across PAC provider types.

To solicit additional feedback on the form of the Non-invasive Mechanical Ventilator (BiPAP, CPAP) data elements best suited for standardization, we requested public comment on a single data element, BiPAP/CPAP, equivalent (but for labeling) to what is currently in use on the MDS, OASIS, and LCDS, from August 12 to September 12, 2016. Several commenters wrote in support of this data element, noting the feasibility of these items in PAC, and the relevance of these data elements for facilitating care coordination and supporting care transitions. In addition, there was support in the public comment responses for separating out BiPAP and CPAP as distinct sub-elements, as they are therapies used for different types of patients and residents. A full report of the comments 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.*

A TEP convened by the data element contractor provided input on the proposed data elements. This TEP, held on January 5 and 6, 2017, opined that these data elements are appropriate for standardization because they would provide useful clinical information to inform care planning and care coordination. The TEP affirmed that assessment of these services and interventions is standard clinical practice. A full report of the TEP discussion 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.*

Therefore, we are proposing that the Non-invasive Mechanical Ventilator (BiPAP, CPAP) data elements with a principal data element and two sub-elements meet the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing that the Non-invasive Mechanical Ventilator (BiPAP, CPAP) data elements would be added to the IRF–PAI, and that IRFs would be required to report these data for the FY 2020 IRF QRP on admission and discharge for all Medicare Part A and MA patients discharged between October 1, 2018 and December 31, 2018. 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.

We are inviting public comment on these proposals.

(vii) Respiratory Treatment: Invasive Mechanical Ventilator

We are proposing that the Invasive Mechanical Ventilator data element meets the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data element consists of a single Invasive Mechanical Ventilator data element. For more information on the Invasive Mechanical Ventilator data element, we refer readers to the document titled, *Proposed Specifications for IRF QRP Quality Measures and Standardized Data Elements,* available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.*

Invasive mechanical ventilation includes ventilators and respirators that ventilate the patient through a tube that extends via the oral airway into the pulmonary region or through a surgical opening directly into the trachea. Thus, assessment of invasive mechanical ventilation is important in care planning and risk mitigation. Ventilation in this manner is a resource-intensive therapy associated with life-threatening conditions without which the patient or resident would not survive. However, ventilator use has inherent risks requiring close monitoring. Failure to adequately care for the patient or resident who is ventilator dependent can lead to iatrogenic events such as death, pneumonia and sepsis. Mechanical ventilation further signifies

the complexity of the patient's underlying medical and or surgical condition. Of note, invasive mechanical ventilation is associated with high daily and aggregate costs.[48]

Data elements that capture invasive mechanical ventilation, but vary in their level of specificity, are currently in use in the MDS 3.0 (''Ventilator or respirator'') and LCDS (''Invasive Mechanical Ventilator: Weaning'' and ''Invasive Mechanical Ventilator: Non-weaning''), and related data elements that assess invasive ventilator use and weaning status were tested in the PAC PRD (''Ventilator—Weaning'' and ''Ventilator—Non-Weaning'') and found feasible for use in each of the four PAC settings.

Clinical and subject matter expert advisors working with our data element contractor agreed that assessing Invasive Mechanical Ventilator use is feasible in PAC, and would be clinically useful both within and across PAC providers.

To solicit additional feedback on the form of a data element on this topic that would be appropriate for standardization, data element that assess invasive ventilator use and weaning status that were tested in the PAC PRD (''Ventilator—Weaning'' and ''Ventilator—Non-Weaning'') were included in a call for public comment that was open from August 12 to September 12, 2016 because they were being considered for standardization. Several commenters wrote in support of these data elements, highlighting the importance of this information in supporting care coordination and care transitions. Some commenters expressed concern about the appropriateness for standardization, given the prevalence of ventilator weaning across PAC providers; the timing of administration; how weaning is defined; and how weaning status in particular relates to quality of care. These comments guided the decision to propose a single data element focused on current use of invasive mechanical ventilation only, and does not attempt to capture weaning status. A full report of the comments 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.*

A TEP convened by the data element contractor provided input on the proposed data elements. This TEP, held on January 5 and 6, 2017, opined that these data elements are appropriate for standardization because they would provide useful clinical information to inform care planning and care coordination. The TEP affirmed that assessment of these services and interventions is standard clinical practice. A full report of the TEP discussion 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.*

Therefore, we are proposing that the Invasive Mechanical Ventilator data element that assesses the use of an invasive mechanical ventilator, but does not assess weaning status, meets the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing to add the Invasive Mechanical Ventilator data element to the IRF–PAI, and that IRFs would be required to report these data for the FY 2020 IRF QRP on admission and discharge for all Medicare Part A and MA patients discharged between October 1, 2018 and December 31, 2018. 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.

We are inviting public comment on these proposals.

(viii) Other Treatment: Intravenous (IV) Medications (Antibiotics, Anticoagulation, Other)

We are proposing that the IV Medications (Antibiotics, Anticoagulation, Other) data elements meet the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data elements consist of the principal IV Medications data element and three sub-elements, Antibiotics, Anticoagulation, and Other. For more information on the IV Medications (Antibiotics, Anticoagulation, Other) data element, we refer readers to the document titled, *Proposed Specifications for IRF QRP Quality Measures and Standardized Data Elements,* available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.*

IV medications are solutions of a specific medication (for example, antibiotics, anticoagulants) administered directly into the venous circulation via a syringe or intravenous catheter (tube). IV medications are administered via intravenous push (bolus), single, intermittent, or continuous infusion through a tube placed into the vein (for example, commonly referred to as central, midline, or peripheral ports). Further, IV medications are more resource intensive to administer than oral medications, and signify a higher patient complexity (and often higher severity of illness).

The clinical indications for each of the sub-elements of the IV Medication data element (Antibiotics, Anticoagulants, and Other) are very different. IV antibiotics are used for severe infections when: (1) The bioavailability of the oral form of the medication would be inadequate to kill the pathogen; (2) an oral form of the medication does not exist; or (3) the patient is unable to take the medication by mouth. IV anticoagulants refer to anti-clotting medications (that is, ''blood thinners''), often used for the prevention and treatment of deep vein thrombosis and other thromboembolic complications. IV anticoagulants are commonly used in patients with limited mobility (either chronically or acutely, in the post-operative setting), who are at risk of deep vein thrombosis, or patients with certain cardiac arrhythmias such as atrial fibrillation. The indications, risks, and benefits of each of these classes of IV medications are distinct, making it important to assess each separately in PAC. Knowing whether or not patients are receiving IV medication and the type of medication provided by each PAC provider will improve quality of care.

The principal IV Medication data element is currently in use on the MDS 3.0 and there is a related data element in OASIS–C2 that collects information on Intravenous and Infusion Therapies. One sub-element of the proposed data elements, IV Anti-coagulants, and two other data elements related to IV therapy (IV Vasoactive Medications and IV Chemotherapy), were tested in the PAC PRD and found feasible for use in that the data collection aligned with usual work flow in each of the four PAC settings, demonstrating the feasibility of collecting IV medication information, including type of IV medication, through similar data elements in these settings.

Clinical and subject matter expert advisors working with our data element contractor agreed that standardized collection of information on medications, including IV medications, would be feasible in PAC, and assess an important treatment that would be

[48] Wunsch, H., Linde-Zwirble, W. T., Angus, D. C., Hartman, M. E., Milbrandt, E. B., & Kahn, J. M. (2010). ''The epidemiology of mechanical ventilation use in the United States.'' Critical Care Med 38(10): 1947–1953.

clinically useful both within and across PAC provider types.

We solicited public comment on a related data element, Vasoactive Medications, from August 12 to September 12, 2016. While commenters supported this data element with one noting the importance of this data element in supporting care transitions, others criticized the need for collecting specifically on Vasoactive Medications, giving feedback that the data element was too narrowly focused. Additionally, comment received indicated that the clinical significance of vasoactive medications administration alone was not high enough in PAC to merit mandated assessment, noting that related and more useful information could be captured in an item that assessed all IV medication use.

Overall, public comment indicated the importance of including the additional check box data elements to distinguish particular classes of medications. A full report of the comments 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.*

A TEP convened by the data element contractor provided input on the proposed data elements. This TEP, held on January 5 and 6, 2017, opined that these data elements are appropriate for standardization because they would provide useful clinical information to inform care planning and care coordination. The TEP affirmed that assessment of these services and interventions is standard clinical practice. A full report of the TEP discussion 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.*

Therefore, we are proposing that the IV Medications (Antibiotics, Anticoagulation, Other) data elements with a principal data element and three sub-elements meet the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing to add the IV Medications (Antibiotics, Anticoagulation, Other) data elements to the IRF–PAI, and that IRFs would be required to report these data for the FY 2020 IRF QRP on admission and discharge for all Medicare Part A and MA patients discharged between October 1, 2018 and December 31, 2018. 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.

We are inviting public comment on these proposals.

(ix) Other Treatment: Transfusions

We are proposing that the Transfusions data element meets the definition of standardized patient assessment data element for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data element consists of the single Transfusions data element. For more information on the Transfusions data element, we refer readers to the document titled, *Proposed Specifications for IRF QRP Quality Measures and Standardized Data Elements,* available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.*

Transfusion refers to introducing blood, blood products, or other fluid into the circulatory system of a person. Blood transfusions are based on specific protocols, with multiple safety checks and monitoring required during and after the infusion in case of adverse events. Coordination with the provider's blood bank is necessary, as well as documentation by clinical staff to ensure compliance with regulatory requirements. In addition, the need for transfusions signifies underlying patient complexity that is likely to require care coordination and patient monitoring, and impacts planning for transitions of care, as transfusions are not performed by all PAC providers.

The proposed data element was selected from three existing assessment items on transfusions and related services, currently in use in the MDS 3.0 (''Transfusions'') and OASIS–C2 (''Intravenous or Infusion Therapy''), and a data element tested in the PAC PRD (''Blood Transfusions''), that was found feasible for use in each of the four PAC settings. We chose to propose the MDS version because of its greater level of specificity over the OASIS–C2 data element. This selection was informed by expert advisors and reviewed and supported in the proposed form by the Standardized Patient Assessment Data TEP held by our data element contractor on January 5 and 6, 2017. A full report of the TEP discussion 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.*

Therefore, we are proposing that the Transfusions data element that is currently in use in the MDS meets the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing to add the Transfusions data element to the IRF–PAI, and that IRFs would be required to report these data for the FY 2020 IRF QRP on admission and discharge for all Medicare Part A and MA patients discharged between October 1, 2018 and December 31, 2018. 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.

We are inviting public comment on these proposals.

(x) Other Treatment: Dialysis (Hemodialysis, Peritoneal Dialysis)

We are proposing that the Dialysis (Hemodialysis, Peritoneal dialysis) data elements meet the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data elements consist of the principal Dialysis data element and two sub-elements, Hemodialysis and Peritoneal dialysis. For more information on the Dialysis (Hemodialysis, Peritoneal dialysis) data elements, we refer readers to the document titled, *Proposed Specifications for IRF QRP Quality Measures and Standardized Data Elements,* available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.*

Dialysis is a treatment primarily used to provide replacement for lost kidney function. Both forms of dialysis (hemodialysis and peritoneal dialysis) are resource intensive, not only during the actual dialysis process but before, during and following. Patients and residents who need and undergo dialysis procedures are at high risk for physiologic and hemodynamic instability from fluid shifts and electrolyte disturbances as well as infections that can lead to sepsis. Further, patients or residents receiving hemodialysis are often transported to a different facility, or at a minimum, to a different location in the same facility. Close monitoring for fluid shifts, blood pressure abnormalities, and other adverse effects is required prior to,

during and following each dialysis session. Nursing staff typically perform peritoneal dialysis at the bedside, and as with hemodialysis, close monitoring is required.

The principal Dialysis data element is currently included on the MDS 3.0 and the LCDS v3.0 and assesses the overall use of dialysis. The sub-elements for Hemodialysis and Peritoneal dialysis were tested across the four PAC providers in the PAC PRD study, and found to be feasible for standardization. Clinical and subject matter expert advisors working with our data element contractor opined that the standardized assessment of dialysis is feasible in PAC, and that it assesses an important treatment that would be clinically useful both within and across PAC providers. As the results of expert and public feedback, described below, we decided to propose a data element that includes both the principal Dialysis data element and the two sub-elements (hemodialysis and peritoneal dialysis).

The Hemodialysis data element, which was tested in the PAC PRD, was included in a call for public comment that was open from August 12 to September 12, 2016. Commenters supported the assessment of hemodialysis and recommended that the data element be expanded to include peritoneal dialysis. Several commenters supported the Hemodialysis data element, noting the relevance of this information for sharing across the care continuum to facilitate care coordination and care transitions, the potential for this data element to be used to improve quality, and the feasibility for use in PAC. In addition, we received comment that the item would be useful in improving patient and resident transitions of care. Several commenters also stated that peritoneal dialysis should be included in a standardized data element on dialysis and recommended collecting information on peritoneal dialysis in addition to hemodialysis. The rationale for including peritoneal dialysis from commenters included the fact that patients and residents receiving peritoneal dialysis will have different needs at post-acute discharge compared to those receiving hemodialysis or not having any dialysis. Based on these comments, the Hemodialysis data element was expanded to include a principal Dialysis data element and two sub-elements, hemodialysis and peritoneal dialysis; these are the same two data elements that were tested in the PAC PRD. This expanded version, Dialysis (Hemodialysis, Peritoneal dialysis), are the data elements being proposed. A full report of the comments 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 note that the Dialysis (Hemodialysis, Peritoneal dialysis) data elements were also supported by the TEP that discussed candidate data elements for Special Services, Treatments, and Interventions during a meeting on January 5 and 6, 2017. A full report of the TEP discussion 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.*

Therefore, we are proposing that the Dialysis (Hemodialysis, Peritoneal dialysis) data elements with a principal data element and two sub-elements meet the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing that the Dialysis (Hemodialysis, Peritoneal dialysis) data elements would be added to the IRF–PAI, and that IRFs would be required to report these data for the FY 2020 IRF QRP on admission and discharge for all Medicare Part A and MA patients discharged between October 1, 2018 and December 31, 2018. 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.

We are inviting public comment on these proposals.

(xi) Other Treatment: Intravenous (IV) Access (Peripheral IV, Midline, Central Line, Other)

We are proposing that the IV Access (Peripheral IV, Midline, Central line, Other) data elements meet the definition of standardized patient assessment data element for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data elements consist of the principal IV Access data element and four sub-elements, Peripheral IV, Midline, Central line, and Other. For more information on the IV Access data element, we refer readers to the document titled, *Proposed Specifications for IRF QRP Quality Measures and Standardized Data Elements,* available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.*

Patients or residents with central lines, including those peripherally inserted or who have subcutaneous central line ''port'' access, always require vigilant nursing care to keep patency of the lines and ensure that such invasive lines remain free from any potentially life-threatening events such as infection, air embolism, or bleeding from an open lumen. Clinically complex patients and residents are likely to be receiving medications or nutrition intravenously. The sub-elements included in the IV Access data elements distinguish between peripheral access and different types of central access. The rationale for distinguishing between a peripheral IV and central IV access is that central lines confer higher risks associated with life-threatening events such as pulmonary embolism, infection, and bleeding.

The proposed IV Access (Peripheral IV, Midline, Central line, Other) data elements are not currently included on any of the mandated PAC assessment instruments. However, related data elements (for example, IV Medication in MDS 3.0 for SNF, Intravenous or infusion therapy in OASIS–C2 for HHAs) currently assess types of IV access. Several related data elements that describe types of IV access (for example, Central Line Management, IV Vasoactive Medications) were tested across the four PAC providers in the PAC PRD study, and found to be feasible for standardization.

Clinical and subject matter expert advisors working with our data element contractor agreed that assessing type of IV access would be feasible for use in PAC and that it assesses an important treatment that would be clinically useful both within and across PAC provider types. We requested public comment on one of the PAC PRD data elements, Central Line Management, from August 12 to September 12, 2016. A central line is one type of IV access. Commenters supported the assessment of central line management and recommended that the data element be broadened to also include other types of IV access. Several commenters supported the data element, noting feasibility and importance for facilitating care coordination and care transitions. However, a few commenters recommended that the definition of this data element be broadened to include peripherally inserted central catheters (''PICC lines'') and midline IVs. Based on public comment feedback and in consultation with clinical and subject matters experts, we expanded the Central Line Management data element to include more types of IV access (Peripheral IV, Midline, Central line,

Other). This expanded version, IV Access (Peripheral IV, Midline, Central line, Other), are the data elements being proposed. A full report of the comments 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 note that the IV Access (Peripheral IV, Midline, Central line, Other) data elements were supported by the TEP that discussed candidate data elements for Special Services, Treatments, and Interventions during a meeting on January 5 and 6, 2017. A full report of the TEP discussion 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.*

Therefore, we are proposing that the IV access (Peripheral IV, Midline, Central line, Other) data elements with a principal data element and four sub-elements meet the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing to add the IV Access (Peripheral IV, Midline, Central line, Other) data elements to the IRF–PAI and that IRFs would be required to report these data for the FY 2020 IRF QRP on admission and discharge for all Medicare Part A and MA patients discharged between October 1, 2018 and December 31, 2018. 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.

We are inviting public comment on these proposals.

(xii) Nutritional Approach: Parenteral/IV Feeding

We are proposing that the Parenteral/IV Feeding data element meets the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data element consists of the single Parenteral/IV Feeding data element. For more information on the Parenteral/IV Feeding data element, we refer readers to the document titled, *Proposed Specifications for IRF QRP Quality Measures and Standardized Data Elements,* available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.*

Parenteral/IV Feeding refers to a patient or resident being fed intravenously using an infusion pump, bypassing the usual process of eating and digestion. The need for IV/parenteral feeding indicates a clinical complexity that prevents the patient or resident from meeting his/her nutritional needs enterally, and is more resource intensive than other forms of nutrition, as it often requires monitoring of blood chemistries, and maintenance of a central line. Therefore, assessing a patient or resident's need for parenteral feeding is important for care planning and resource use. In addition to the risks associated with central and peripheral intravenous access, total parenteral nutrition is associated with significant risks such as embolism and sepsis.

The Parenteral/IV Feeding data element is currently in use in the MDS 3.0, and equivalent or related data elements are in use in the LCDS, IRF–PAI, and the OASIS–C2. An equivalent data element was tested in the PAC PRD (''Total Parenteral Nutrition'') and found feasible for use in each of the four PAC settings, demonstrating the feasibility of collecting information about this nutritional service in these settings.

Total Parenteral Nutrition (an item with the same meaning as the proposed data element, but with the label used in the PAC PRD) was included in a call for public comment that was open from August 12 to September 12, 2016. Several commenters supported this data element, noting its relevance to facilitating care coordination and supporting care transitions. After the public comment period, the Total Parenteral Nutrition data element was re-named Parenteral/IV Feeding, to be consistent with how this data element is referred to in the MDS. A full report of the comments 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.*

A TEP convened by the data element contractor provided input on the proposed data elements. This TEP, held on January 5 and 6, 2017, opined that these data elements are appropriate for standardization because they would provide useful clinical information to inform care planning and care coordination. The TEP affirmed that assessment of these services and interventions is standard clinical practice. A full report of the TEP discussion 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.*

Therefore, we are proposing that the Parenteral/IV Feeding data element meets the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing to modify the existing Tube/Parenteral feeding item in the IRF–PAI to the Parenteral/IV Feeding data element, and that IRFs would be required to report these data for the FY 2020 IRF QRP on admission and discharge for all Medicare Part A and MA patients discharged between October 1, 2018 and December 31, 2018. 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.

We are inviting public comment on these proposals.

(xiii) Nutritional Approach: Feeding Tube

We are proposing that the Feeding Tube data element meets the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data element consists of the single Feeding Tube data element. For more information on the Feeding Tube data element, we refer readers to the document titled, *Proposed Specifications for IRF QRP Quality Measures and Standardized Data Elements,* available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.*

The majority of patients admitted to acute care hospitals experience deterioration of their nutritional status during their hospital stay, making assessment of nutritional status and method of feeding if unable to eat orally very important in PAC. A feeding tube can be inserted through the nose or the skin on the abdomen to deliver liquid nutrition into the stomach or small intestine. Feeding tubes are resource intensive and are therefore important to assess for care planning and resource use. Patients with severe malnutrition are at higher risk for a variety of complications.[49] In PAC settings, there

[49] Dempsey, D.T., Mullen, J.L., & Buzby, G.P. (1988). ''The link between nutritional status and clinical outcome: can nutritional intervention

are a variety of reasons that patients and residents may not be able to eat orally (including clinical or cognitive status).

The Feeding Tube data element is currently included in the MDS 3.0 for SNFs, and in the OASIS–C2 for HHAs, where it is labeled Enteral Nutrition. A related data element is collected in the IRF–PAI for IRFs (Tube/Parenteral Feeding). The testing of similar nutrition-focused data elements in the PAC PRD, and the current assessment of feeding tubes and related nutritional services and devices, demonstrates the feasibility of collecting information about this nutritional service in these settings.

Clinical and subject matter expert advisors working with our data element contractor opined that the Feeding Tube data element is feasible for use in PAC, and supported its importance and clinical usefulness for patients in PAC settings, due to the increased level of nursing care and patient monitoring required for patients who received enteral nutrition with this device.

We solicited additional feedback on an Enteral Nutrition data element (an item with the same meaning as the proposed data element, but with the label used in the OASIS) in a call for public comment that was open from August 12 to September 12, 2016. Several commenters supported the data element, noting the importance of assessing enteral nutrition status for facilitating care coordination and care transitions. After the public comment period, the Enteral Nutrition data element used in public comment was renamed Feeding Tube, indicating the presence of an assistive device. A full report of the comments 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 note that the Feeding Tube data element was also supported by the TEP that discussed candidate data elements for Special Services, Treatments, and Interventions during a meeting on January 5 and 6, 2017. A full report of the TEP discussion 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.*

Therefore, we are proposing that the Feeding Tube data element meets the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing to modify the existing Tube/Parenteral feeding item in the IRF–PAI to the Feeding Tube data element and that IRFs would be required to report these data for the FY 2020 IRF QRP on admission and discharge for all Medicare Part A and MA patients discharged between October 1, 2018 and December 31, 2018. 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.

We are inviting public comment on these proposals.

(xiv) Nutritional Approach: Mechanically Altered Diet

We are proposing that the Mechanically Altered Diet data element meets the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data element consists of the single Mechanically Altered Diet data element. For more information on the Mechanically Altered Diet data element, we refer readers to the document titled, *Proposed Specifications for IRF QRP Quality Measures and Standardized Data Elements,* available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.*

The Mechanically Altered Diet data element refers to food that has been altered to make it easier for the patient or resident to chew and swallow, and this type of diet is used for patients and residents who have difficulty performing these functions. Patients with severe malnutrition are at higher risk for a variety of complications.[50] In PAC settings, there are a variety of reasons that patients and residents may have impairments related to oral feedings, including clinical or cognitive status. The provision of a mechanically altered diet may be resource intensive, and can signal difficulties associated with swallowing/eating safety, including dysphagia. In other cases, it signifies the type of altered food source, such as ground or puree that will enable the safe and thorough ingestion of nutritional substances and ensure safe and adequate delivery of nourishment to the patient. Often, patients on mechanically altered diets also require additional nursing supports such as individual feeding, or direct observation, to ensure the safe consumption of the food product. Assessing whether a patient or resident requires a mechanically altered diet is therefore important for care planning and resource identification.

The proposed data element for a mechanically altered diet is currently included on the MDS 3.0 for SNFs. A related data element for modified food consistency/supervision is currently included on the IRF–PAI for IRFs. A related data element is included in the OASIS–C2 for HHAs that collects information about independent eating that requires ''a liquid, pureed or ground meat diet.'' The testing of similar nutrition-focused data elements in the PAC PRD, and the current assessment of various nutritional services across the four PAC settings, demonstrates the feasibility of collecting information about this nutritional service in these settings.

Clinical and subject matter expert advisors working with our data element contractor agreed that the proposed Mechanically Altered Diet data element is feasible for use in PAC, and it assesses an important treatment that would be clinically useful both within and across PAC settings. Expert input on the Mechanically Altered Diet data element highlighted its importance and clinical usefulness for patients in PAC settings, due to the increased monitoring and resource use required for patients on special diets. We note that the Mechanically Altered Diet data element was also supported by the TEP that discussed candidate data elements for Special Services, Treatments, and Interventions during a meeting on January 5 and 6, 2017. A full report of the TEP discussion 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.*

Therefore, we are proposing that the Mechanically Altered Diet data element meets the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing to modify the existing Modified food consistency/supervision data element in the IRF–PAI to the Mechanically Altered Diet data element and that IRFs would be required to report these data for the FY 2020 IRF QRP on admission and discharge for all Medicare Part A and

modify it?'' Am J of Clinical Nutrition 47(2): 352–356.

[50] Dempsey, D.T., Mullen, J.L., & Buzby, G.P. (1988). ''The link between nutritional status and clinical outcome: can nutritional intervention modify it?'' Am J of Clinical Nutrition 47(2): 352–356.

MA patients discharged between October 1, 2018 and December 31, 2018. 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.

We are inviting public comment on these proposals.

(xv) Nutritional Approach: Therapeutic Diet

We are proposing that the Therapeutic Diet data element meets the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data element consists of the single Therapeutic Diet data element. For more information on the Therapeutic Diet data element, we refer readers to the document titled, *Proposed Specifications for IRF QRP Quality Measures and Standardized Data Elements,* available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.*

Therapeutic Diet refers to meals planned to increase, decrease, or eliminate specific foods or nutrients in a patient or resident's diet, such as a low-salt diet, for the purpose of treating a medical condition. The use of therapeutic diets among patients in PAC provides insight on the clinical complexity of these patients and their multiple comorbidities. Therapeutic diets are less resource intensive from the bedside nursing perspective, but do signify one or more underlying clinical conditions that preclude the patient from eating a regular diet. The communication among PAC providers about whether a patient is receiving a particular therapeutic diet is critical to ensure safe transitions of care.

The Therapeutic Diet data element is currently in use in the MDS 3.0. The testing of similar nutrition-focused data elements in the PAC PRD, and the current assessment of various nutritional services across the four PAC settings, demonstrates the feasibility of collecting information about this nutritional service in these settings.

Clinical and subject matter expert advisors working with our data element contractor supported the importance and clinical usefulness of the proposed Therapeutic Diet data element for patients in PAC settings, due to the increased monitoring and resource use required for patients on special diets, and agreed that it is feasible for use in PAC and that it assesses an important treatment that would be clinically useful both within and across PAC settings. We note that the Therapeutic Diet data element was also supported by the TEP that discussed candidate data elements for Special Services, Treatments, and Interventions during a meeting on January 5 and 6, 2017.

Therefore, we are proposing that the Therapeutic Diet data element meets the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing to add the Therapeutic Diet data element to the IRF–PAI, and that IRFs would be required to report these data for the FY 2020 IRF QRP on admission and discharge for all Medicare Part A and MA patients discharged between October 1, 2018 and December 31, 2018. 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.

We are inviting public comment on these proposals.

(4) Medical Condition and Comorbidity Data

We are proposing 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 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 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 proposed 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 proposed rule.

We are inviting public comment on this proposal.

(5) Impairment Data

Hearing and vision impairments are conditions that, if unaddressed, affect activities of daily living, communication, physical functioning, rehabilitation outcomes, and overall quality of life. Sensory limitations can lead to confusion in new settings, increase isolation, contribute to mood disorders, and impede accurate assessment of other medical conditions. Failure to appropriately assess, accommodate, and treat these conditions increases the likelihood that patients will require more intensive and prolonged treatment. Onset of these

conditions can be gradual, so individualized assessment with accurate screening tools and follow-up evaluations are essential to determining which patients need hearing- or vision-specific medical attention or assistive devices, and accommodations, including auxiliary aids and/or services, and to ensure that person-directed care plans are developed to accommodate a patient's needs. Accurate diagnosis and management of hearing or vision impairment would likely improve rehabilitation outcomes and care transitions, including transition from institutional-based care to the community. Accurate assessment of hearing and vision impairment would be expected to lead to appropriate treatment, accommodations, including the provision of auxiliary aids and services during the stay, and ensure that patients continue to have their vision and hearing needs met when they leave the facility.

Accurate individualized assessment, treatment, and accommodation of hearing and vision impairments of patients and residents in PAC would be expected to have a positive impact on the National Quality Strategy's domains of patient and family engagement, patient safety, care coordination, clinical process/effectiveness, and efficient use of healthcare resources. For example, standardized assessment of hearing and vision impairments used in PAC will support ensuring patient safety (for example, risk of falls) identifying accommodations needed during the stay, and appropriate support needs at the time of discharge or transfer. Standardized assessment of these data elements will enable or support clinical decision-making and early clinical intervention; person-centered, high quality care (for example, facilitating better care continuity and coordination); better data exchange and interoperability between settings; and longitudinal outcome analysis. Hence, reliable data elements assessing hearing and vision impairments are needed to initiate a management program that can optimize a patient or resident's prognosis and reduce the possibility of adverse events.

(i) Hearing

We are proposing that the Hearing data element meets the definition of standardized patient assessment data for impairments under section 1899B(b)(1)(B)(v) of the Act. The proposed data element consists of the single Hearing data element. This data element assesses level of hearing impairment, and consists of one question. For more information on the Hearing data element, we refer readers to the document titled, *Proposed Specifications for IRF QRP Quality Measures and Standardized Data Elements,* available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.*

Accurate assessment of hearing impairment is important in the PAC setting for care planning and resource use. Hearing impairment has been associated with lower quality of life, including poorer physical, mental, and social functioning, and emotional health.[51] [52] Treatment and accommodation of hearing impairment led to improved health outcomes, including but not limited to quality of life.[53] For example, hearing loss in elderly individuals has been associated with depression and cognitive impairment,[54] [55] [56] higher rates of incident cognitive impairment and cognitive decline,[57] and less time in occupational therapy.[58] Accurate assessment of hearing impairment is important in the PAC setting for care planning and defining resource use.

The proposed data element was selected from two forms of the Hearing data element based on expert and stakeholder feedback. We considered the two forms of the Hearing data element, one of which is currently in use in the MDS 3.0 (Hearing) and another data element with different wording and fewer response option categories that is currently in use in the OASIS–C2 (Ability to Hear). Ability to Hear was also tested in the PAC PRD and found to have substantial agreement for inter-rater reliability across PAC settings (kappa of 0.78).[59]

Several data elements that assess hearing impairment were presented to the Standardized Patient Assessment Data TEP held by our data element contractor. The TEP did not reach consensus on the ideal number of response categories or phrasing of response options, which are the primary differences between the current MDS (Hearing) and OASIS (Ability to Hear) items. The Development and Maintenance of Post-Acute Care Cross-Setting Standardized Patient Assessment Data Technical Expert Panel 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.*

The PAC PRD form of the data element (Ability to Hear) was included in a call for public comment that was open from August 12 to September 12, 2016. This data element includes three response choices, in contrast to the Hearing data element (in use in the MDS 3.0 and being proposed for standardization), which includes four response choices. Several commenters supported the use of the Ability to Hear data element, although some commenters raised concerns that the three-level response choice was not compatible with the current, four-level response used in the MDS, and favored the use of the MDS version of the Hearing data element. In addition, we received comments stating that standardized assessment related to hearing impairment has the ability to improve quality of care if information on hearing is included in medical records of patients and residents, which would improve care coordination and facilitate the development of patient- and resident-centered treatment plans. Based on comments that the three-level response choice (Ability to Hear) was not congruent with the current, four-level response used in the MDS (Hearing), and support for the use of the MDS version of the Hearing data element received in the public comment, we are proposing the Hearing data element. A full report of the

[51] Dalton DS, Cruickshanks KJ, Klein BE, Klein R, Wiley TL, Nondahl DM. The impact of hearing loss on quality of life in older adults. *Gerontologist.* 2003;43(5):661–668.

[52] Hawkins K, Bottone FG, Jr., Ozminkowski RJ, et al. The prevalence of hearing impairment and its burden on the quality of life among adults with Medicare Supplement Insurance. *Qual Life Res.* 2012;21(7):1135–1147.

[53] Horn KL, McMahon NB, McMahon DC, Lewis JS, Barker M, Gherini S. Functional use of the Nucleus 22-channel cochlear implant in the elderly. *The Laryngoscope.* 1991;101(3):284–288.

[54] Sprinzl GM, Riechelmann H. Current trends in treating hearing loss in elderly people: A review of the technology and treatment options—a mini-review. *Gerontology.* 2010;56(3):351–358.

[55] Lin FR, Thorpe R, Gordon-Salant S, Ferrucci L. Hearing Loss Prevalence and Risk Factors Among Older Adults in the United States. *The Journals of Gerontology Series A: Biological Sciences and Medical Sciences.* 2011;66A(5):582–590.

[56] Hawkins K, Bottone FG, Jr., Ozminkowski RJ, et al. The prevalence of hearing impairment and its burden on the quality of life among adults with Medicare Supplement Insurance. *Qual Life Res.* 2012;21(7):1135–1147.

[57] Lin FR, Metter EJ, O'Brien RJ, Resnick SM, Zonderman AB, Ferrucci L. Hearing Loss and Incident Dementia. *Arch Neurol.* 2011;68(2):214–220.

[58] Cimarolli VR, Jung S. Intensity of Occupational Therapy Utilization in Nursing Home Residents: The Role of Sensory Impairments. *J Am Med Dir Assoc.* 2016;17(10):939–942.

[59] Gage B., Smith L., Ross J. et al. (2012). The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set (Final Report on Reliability Testing, Volume 2 of 3). Research Triangle Park, NC: RTI International.

comments 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.*

Therefore, we are proposing the Hearing data element currently in use in the MDS. We are proposing to add the Hearing data element to the IRF–PAI, and that IRFs would be required to report these data for the FY 2020 IRF QRP on admission for all Medicare Part A and MA patients discharged between October 1, 2018 and December 31, 2018. 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. The Hearing data element would be assessed at admission only due to the relatively stable nature of hearing impairment, making it unlikely that this assessment would change between the start and end of the PAC stay. Assessment at discharge would introduce additional burden without improving the quality or usefulness of the data, and we believe it is unnecessary.

We are inviting public comment on these proposals.

(ii) Vision

We are proposing that the Vision data element meets the definition of standardized patient assessment data element for impairments under section 1899B(b)(1)(B)(v) of the Act. The proposed data element consists of the single Vision (Ability To See in Adequate Light) data element that consists of one question with five response categories. For more information on the Vision data element, we refer readers to the document titled, *Proposed Specifications for IRF QRP Quality Measures and Standardized Data Elements,* available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.*

Evaluation of an individual's ability to see is important for assessing for risks such as falls and provides opportunities for improvement through treatment and the provision of accommodations, including auxiliary aids and services, which can safeguard patients and improve their overall quality of life. Further, vision impairment is often a treatable risk factor associated with adverse events and poor quality of life. For example, individuals with visual impairment are more likely to experience falls and hip fracture, have less mobility, and report depressive symptoms.[60] [61] [62] [63] [64] [65] [66]

Individualized initial screening can lead to life-improving interventions such as accommodations, including the provision of auxiliary aids and services, during the stay and/or treatments that can improve vision and prevent or slow further vision loss. For patients with some types of visual impairment, use of glasses and contact lenses can be effective in restoring vision.[67] Other conditions, including glaucoma [68] and age-related macular degeneration,[69] [70] have responded well to treatment. In addition, vision impairment is often a treatable risk factor associated with adverse events which can be prevented and accommodated during the stay. Accurate assessment of vision impairment is important in the PAC setting for care planning and defining resource use.

The Vision data element that we are proposing for standardization was tested as part of the development of the MDS 3.0 and is currently in use in that assessment. Similar data elements, but with different wording and fewer response option categories, are in use in the OASIS–C2 and were tested in post-acute providers in the PAC PRD and found to be clinically relevant, meaningful for care planning, reliable (kappa of 0.74),[71] and feasible for use in each of the four PAC settings.

Several data elements that assess vision were presented to the TEP held by our data element contractor. The TEP did not reach consensus on the ideal number of response categories or phrasing of response options, which are the primary differences between the current MDS and OASIS items; some members preferring more granular response options (for example, mild impairment and moderate impairment) while others were comfortable with collapsed response options (that is, mild/moderate impairment). The Development and Maintenance of Post-Acute Care Cross-Setting Standardized Patient Assessment Data Technical Expert Panel 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.* We solicited public comment from August 12 to September 12, 2016, on the Ability to See in Adequate Light data element (version tested in the PAC PRD with three response categories). The data element in public comment differed from the proposed data element, but the comments supported the assessment of vision in PAC settings and the useful information a vision data element would provide. The commenters stated that the Ability to See item would provide important information that would facilitate care coordination and care planning, and consequently improve the quality of care. Other commenters suggested it would be helpful as an indicator of resource use and noted that the item would provide useful information about the abilities of patients and residents to care for themselves. Additional commenters noted that the item could feasibly be implemented across PAC providers and that its kappa scores from the PAC PRD support its validity. Some commenters noted a preference for MDS version of the Vision data element over the form put forward in public comment, citing the widespread use of this data element.

[60] Colon-Emeric CS, Biggs DP, Schenck AP, Lyles KW. Risk factors for hip fracture in skilled nursing facilities: Who should be evaluated? *Osteoporos Int.* 2003;14(6):484–489.

[61] Freeman EE, Munoz B, Rubin G, West SK. Visual field loss increases the risk of falls in older adults: The Salisbury eye evaluation. *Invest Ophthalmol Vis Sci.* 2007;48(10):4445–4450.

[62] Keepnews D, Capitman JA, Rosati RJ. Measuring patient-level clinical outcomes of home health care. *J Nurs Scholarsh.* 2004;36(1):79–85.

[63] Nguyen HT, Black SA, Ray LA, Espino DV, Markides KS. Predictors of decline in MMSE scores among older Mexican Americans. *J Gerontol A Biol Sci Med Sci.* 2002;57(3):M181–185.

[64] Prager AJ, Liebmann JM, Cioffi GA, Blumberg DM. Self-reported Function, Health Resource Use, and Total Health Care Costs Among Medicare Beneficiaries With Glaucoma. *JAMA ophthalmology.* 2016;134(4):357–365.

[65] Rovner BW, Ganguli M. Depression and disability associated with impaired vision: The MoVies Project. *J Am Geriatr Soc.* 1998;46(5):617–619.

[66] Tinetti ME, Ginter SF. The nursing home life-space diameter. A measure of extent and frequency of mobility among nursing home residents. *J Am Geriatr Soc.* 1990;38(12):1311–1315.

[67] Rein DB, Wittenborn JS, Zhang X, et al. The Cost-effectiveness of Welcome to Medicare Visual Acuity Screening and a Possible Alternative Welcome to Medicare Eye Evaluation Among Persons Without Diagnosed Diabetes Mellitus. *Archives of ophthalmology.* 2012;130(5):607–614.

[68] Leske M, Heijl A, Hussein M, et al. Factors for glaucoma progression and the effect of treatment: The early manifest glaucoma trial. *Archives of Ophthalmology.* 2003;121(1):48–56.

[69] Age-Related Eye Disease Study Research G. A randomized, placebo-controlled, clinical trial of high-dose supplementation with vitamins c and e, beta carotene, and zinc for age-related macular degeneration and vision loss: AREDS report no. 8. *Archives of Ophthalmology.* 2001;119(10):1417–1436.

[70] Takeda AL, Colquitt J, Clegg AJ, Jones J. Pegaptanib and ranibizumab for neovascular age-related macular degeneration: A systematic review. *The British Journal of Ophthalmology.* 2007;91(9):1177–1182.

[71] Gage B., Smith L., Ross J. et al. (2012). The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set (Final Report on Reliability Testing, Volume 2 of 3). Research Triangle Park, NC: RTI International.

A full report of the comments 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.*

Therefore, we are proposing the Vision data element from the MDS. We are proposing to add the Vision data element to the IRF–PAI and that IRFs would be required to report these data for the FY 2020 IRF QRP on admission for all Medicare Part A and MA patients discharged between October 1, 2018 and December 31, 2018. 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. The Vision data element would be assessed at admission only due to the relatively stable nature of vision impairment, making it unlikely that this assessment would change between the start and end of the PAC stay. Assessment at discharge would introduce additional burden without improving the quality or usefulness of the data, and we believe that it is unnecessary.

We are inviting public comment on these proposals.

K. Proposals Relating to the Form, Manner, and Timing of Data Submission Under the IRF QRP

1. Proposed 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 are proposing in this proposed rule that new IRFs will be required to begin reporting standardized patient assessment data on the same schedule. We are inviting public comment on this proposal.

2. Proposed 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.* The proposed standardized patient assessment data elements 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 are inviting public comments on this proposal.

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

Starting with the FY 2019 IRF QRP, we are proposing 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 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 are inviting public comment on 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. Proposed Schedule for Reporting the Proposed Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury Measure Beginning With the FY 2020 IRF QRP

As discussed in section XII.G. of this proposed rule, we are proposing to adopt the Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury measure beginning with the FY 2020 IRF QRP. We are proposing 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.

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 are seeking 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 are seeking comments on this topic.

L. Proposal To Apply the IRF QRP Submission Requirements and Payment Impact to the Standardized Patient Assessment Data Beginning With the FY 2019 IRF QRP

We are proposing 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 are inviting public comment on this proposal.

M. Proposal To Apply 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 are proposing 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 are inviting public comment on this proposal.

N. Proposal To Apply 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).

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 note 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. We are proposing to extend our current IRF QRP data completion requirements to the reporting of standardized patient assessment data.

We are also proposing 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 invite 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.

O. Proposals and 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).

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) will initially be based on data collected from January 1, 2015, through December 31, 2015 and will be displayed based on four rolling quarters. 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 this FY 2018 IRF PPS proposed rule, pending the availability of data, we are proposing 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 are proposing 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 are proposing 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 are proposing to transition from calendar year to fiscal year to make these measure data publicly available by October 2018. Thus, we are proposing 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 are proposing 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 XII.H. of this proposed rule for additional information regarding the proposed removal of this measure from quality reporting and public display. We also propose 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 XII.G. of this proposed 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 are proposing 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 are proposing 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 are proposing 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 PROPOSED 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 are inviting 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.

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 one 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 are not proposing any changes to this policy.

Q. Proposed 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 propose 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 invite 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.

Table 12 shows the calculation of the proposed 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 PROPOSED 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	× 0.9974
Adjusted FY 2018 Standard Payment Conversion Factor	= $ 15,521

XIII. Request for Information on CMS Flexibilities and Efficiencies

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

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

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

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

XIV. 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 proposed 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 1137 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 1137 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 ($/hr)	Fringe benefit ($/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 proposes to: (1) 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 XII.G.1 of this proposed rule). The measure would 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 also proposing to require IRFs to report certain standardized patient assessment data beginning with the FY 2019 IRF QRP (see section XII.J of this proposed rule). We are proposing to define 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 is 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.

Pursuant to 1899B(m) of the Act, the Paperwork Reduction Act does not apply to the specific changes in the collections of information described in this proposed rule.

These changes to the collections of information arise from Section 2(a) of the IMPACT Act, which added new section 1899B to the Act. That section requires IRFs to report standardized patient assessment data, data on quality measures, and data on resource use and other measures. All of this data must, under section 1899B(a)(1)(B) of the Act, be standardized and interoperable to allow for its exchange among PAC providers and other providers and the use by such providers in order to provide access to longitudinal information to facilitate coordinated care and improved Medicare beneficiary outcomes. Section 1899B(a)(1)(C) of the Act requires us to modify the IRF–PAI to allow for the submission of quality measure data and standardized patient assessment data to enable its comparison across IRFs and other providers.

As noted in section VIII, we are also proposing to remove item 27 (Swallowing Status) from the IRF–PAI, on admission and discharge.

We are also proposing to remove 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 would 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 would 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 36,878.51 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 $2,255.26 per IRF annually, or $2,564,229.74 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 will send the revised information collection request to OMB for review and approval.

In section XII.J. of this proposed rule, we are proposing requirements related to the reporting of standardized patient assessment data beginning with the FY 2019 IRF QRP. Some of these data elements are already included on the IRF–PAI assessment and are already included in current burden estimates. We are proposing, however, to require IRFs to report 24 new standardized patient assessment data elements on IRF admissions and 24 new standardized patient assessment data elements on IRF discharges. We estimate that it will take an IRF's clinical staff 7.2 minutes to report the data elements required on admission and 7.2 minutes to report the data elements required on discharge, for a total of 14.4 additional minutes. This equates to 96,554.64 additional burden hours per year (0.24 hours × 402,311 discharges).

We believe that the additional IRF–PAI items we are proposing would be completed by the following clinicians: RN (approximately 50 percent of the time), LVN (approximately 30 percent of the time), RT (approximately 7 percent of the time), SLP (approximately 6 percent of the time), and other therapists, including OT and psychologist (approximately 7 percent of the time). We estimate 402,311 discharges from 1,137 IRFs annually based on the numbers obtained February 1, 2017. To estimate the mean hourly wage for ''other therapists,'' we averaged the mean hourly wage of OTs and psychologists for a mean hourly rate of $39.51, doubled to $79.02 to account for overhead and fringe benefits. Individual providers determine the staffing resources necessary. Given the

clinician times and wages in Table 13, completing an average of 354 IRF–PAIs per provider per year, the total cost related to the additional standardized patient assessment data elements is estimated at $5,244.73 per IRF annually, or $5,963,253.19 for all IRFs annually. This increase in burden will be accounted for in the information collection under OMB control number (0938–0842). We will send the revised information collection request to OMB for review and approval.

In summary, given the 5.5-minute reduction in burden for items being removed from the IRF–PAI), and the 14.4 additional minutes of burden for the proposed standardized patient assessment data elements, the overall cost associated with proposed changes to the IRF QRP is estimated at an additional $2,989.47 per IRF annually, or $3,399,023.45 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 proposed rule. We are, however, setting out the burden as a courtesy to advise interested parties of the proposed actions' time and costs and for reference refer to section XVI of this proposed rule of 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 have achieved standardization and are no longer exempt from the requirements under section 1899B(m) of the Act.

XV. Response to Public Comments

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

XVI. 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 proposed rule would 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 603 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 proposed rule would 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 proposed 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. Section 2(a) of Executive Order 13771 requires an agency, unless prohibited by law, to identify at least two existing regulations to be repealed when the agency publicly proposes for notice and comment, or otherwise promulgates, a new regulation. In furtherance of this requirement, section 2(c) of Executive Order 13771 requires that the new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations. OMB's implementation guidance, issued on April 5, 2017, explains that ''Federal spending regulatory actions that cause only income transfers between taxpayers and program beneficiaries (*e.g.,* regulations

associated with . . . Medicare spending) are considered 'transfer rules' and are not covered by EO 13771. . . . However . . . such regulatory actions may impose requirements apart from transfers . . . In those cases, the actions would need to be offset to the extent they impose more than *de minimis* costs. Examples of ancillary requirements that may require offsets include new reporting or recordkeeping requirements . . . . ''

Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on last year's proposed rule will be the number of reviewers of this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed last year's 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 past commenters would be a fair estimate of the number of reviewers of this rule. We welcome any comments on the approach in estimating the number of entities which will review this proposed rule.

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

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $90.16 per hour, including overhead and fringe benefits *https://www.bls.gov/oes/2015/may/naics4_621100.htm.* Assuming an average reading speed, we estimate that it would take approximately 2 hours for the staff to review half of this proposed rule. For each IRF that reviews the rule, the estimated cost is $180.32 (2 hours × $90.16). Therefore, we estimate that the total cost of reviewing this regulation is $12,262 ($180.32 × 68 reviewers).

Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/sites/default/files/omb/assets/omb/circulars/a004/a-4.pdf*), in Table 14, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this proposed 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 proposed rule based on the data for 1,137 IRFs in our database. In addition, Table 14 presents the costs associated with the proposed 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	$80 million.
From Whom to Whom?	Federal Government to IRF Medicare Providers.
Category	Costs
FY 2018 Cost to Updating the Quality Reporting Program	
Cost for IRFs to Submit Data for the Quality Reporting Program	$3.4 million.

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 Department of Health and Human Services proposes to amend 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 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 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: April 12, 2017.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Approved: April 17, 2017.

Thomas E. Price,

Secretary, Department of Health and Human Services.

[FR Doc. 2017–08428 Filed 4–27–17; 4:15 pm]

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