



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 412

[CMS-1647-F]

RIN 0938-AS78

Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2017

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

ACTION: Final rule.

SUMMARY: This final rule will update the prospective payment rates for inpatient rehabilitation facilities (IRFs) for federal fiscal year (FY) 2017 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's) case-mix groups and a description of the methodologies and data used in computing the prospective payment rates for FY 2017. This final rule also revises and updates quality measures and reporting requirements under the IRF quality reporting program (QRP).

DATES: Effective Dates: These regulations are effective on October 1, 2016.

Applicability Dates: The updated IRF prospective payment rates are applicable for IRF discharges occurring on or after October 1, 2016, and on or before September 30, 2017 (FY 2017). The updated quality measures and reporting requirements under the IRF QRP are effective for IRF discharges occurring on or after October 1, 2016.

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SUPPLEMENTARY INFORMATION:

The IRF PPS Addenda along with other supporting documents and tables referenced in this final rule are available through the Internet on the CMS Web site at

<http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/>.

Executive Summary

A. Purpose

This final rule updates the prospective payment rates for IRFs for FY 2017 (that is, for discharges occurring on or after October 1, 2016, and on or before September 30, 2017) 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 2017. This final rule also finalizes revisions and updates to the quality measures and reporting requirements under the IRF QRP.

B. Summary of Major Provisions

In this final rule, we use the methods described in the FY 2016 IRF PPS final rule (80 FR 47036) to update the federal prospective payment rates for FY 2017 using updated FY 2015 IRF claims and the most recent available IRF cost report data, which is FY 2014 IRF cost report data. We are also finalizing revisions and updates to the quality measures and reporting requirements under the IRF QRP.

C. Summary of Impacts

Provision Description	Transfers
FY 2017 IRF PPS payment rate update	The overall economic impact of this final rule is an estimated \$145 million in increased payments from the Federal government to IRFs during FY 2017.
Provision Description	Costs
New quality reporting program requirements	The total costs in FY 2017 for IRFs as a result of the new quality reporting requirements are estimated to be \$5,231,398.17.

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
ADC	Average Daily Census
ADE	Adverse Drug Events
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
APU	Annual Payment Update
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
BLS	U.S. Bureau of Labor Statistics
BMI	Body Mass Index
CAH	Critical Access Hospitals
CASPER	Certification and Survey Provider Enhanced Reports
CAUTI	Catheter-Associated Urinary Tract Infection

CBSA	Core-Based Statistical Area
CCR	Cost-to-Charge Ratio
CDC	The Centers for Disease Control and Prevention
CDI	<u>Clostridium difficile</u> Infection
CFR	Code of Federal Regulations
CMG	Case-Mix Group
CMS	Centers for Medicare & Medicaid Services
COA	Care for Older Adults
CY	Calendar year
DSH	Disproportionate Share Hospital
DSH PP	Disproportionate Share Patient Percentage
DRG	Diagnosis-Related Group
eCQMs	Electronically Specified Clinical Quality Measures
ESRD	End-Stage Renal Disease
FFS	Fee-for-Service
FR	Federal Register
FY	Federal Fiscal Year
GEMS	General Equivalence Mapping
GPCI	Geographic Practice Cost Index
HAI	Healthcare Associated Infection
HCC	Hierarchical Condition Category
HHA	Home Health Agencies
HCP	Home Care Personnel

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)
Hospital VBP	Hospital Value-Based Purchasing Program (also HVBP)
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)
IME	Indirect Medical Education
IPF	Inpatient Psychiatric Facility
IPPS	Inpatient prospective payment system
IQR	Inpatient Quality Reporting Program
IRF	Inpatient Rehabilitation Facility
IRF-PAI	Inpatient Rehabilitation Facility-Patient Assessment Instrument
IRF PPS	Inpatient Rehabilitation Facility Prospective Payment System
IRF QRP	Inpatient Rehabilitation Facility Quality Reporting Program
IRVEN	Inpatient Rehabilitation Validation and Entry
LIP	Low-Income Percentage
IVS	Influenza Vaccination Season

LTCH	Long-Term Care Hospital
MA (Medicare Part C)	Medicare Advantage
MAC	Medicare Administrative Contractor
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 <u>Staphylococcus aureus</u>
MSPB	Medicare Spending Per Beneficiary
MUC	Measures under Consideration
NHSN	National Healthcare Safety Network
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
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
QM	Quality Measure
QRP	Quality Reporting Program
RIA	Regulatory Impact Analysis
RIC	Rehabilitation Impairment Category
RFA	Regulatory Flexibility Act (Pub. L. 96-354, enacted on September 19, 1980)
RN	Registered Nurse
RPL	Rehabilitation, Psychiatric, and Long-Term Care market basket
RSRR	Risk-standardized readmission rate
SIR	Standardized Infection Ratio
SNF	Skilled Nursing Facilities
SRR	Standardized Risk Ratio
SSI	Supplemental Security Income
TEP	Technical Expert Panel

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 below a general description of the IRF PPS for FYs 2002 through 2016.

Under the IRF PPS from FY 2002 through FY 2005 the federal 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 federal prospective payment rates under the IRF PPS from FYs 2002

through 2005. Within the structure of the payment system, we then made adjustments to account for interrupted stays, transfers, short stays, and deaths. Finally, we applied the applicable adjustments to account for geographic variations in wages (wage index), the percentage of low-income patients, location in a rural area (if applicable), and outlier payments (if applicable) to the IRFs' unadjusted federal prospective payment rates.

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

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

Section 1886(j) of the Act confers broad statutory authority upon the Secretary to propose refinements to the IRF PPS. In the FY 2006 IRF PPS final rule (70 FR 47880) and in correcting amendments to the FY 2006 IRF PPS final rule (70 FR 57166) that we published on September 30, 2005, we finalized a number of refinements to the IRF PPS case-mix

classification system (the CMGs and the corresponding relative weights) and the case-level and facility-level adjustments. These refinements included the adoption of the Office of Management and Budget's (OMB) Core-Based Statistical Area (CBSA) market definitions, modifications to the CMGs, tier comorbidities, and CMG relative weights, implementation of a new teaching status adjustment for IRFs, revision and rebasing of the market basket index used to update IRF payments, and updates to the rural, low-income percentage (LIP), and high-cost outlier adjustments. Beginning with the FY 2006 IRF PPS final rule (70 FR 47908 through 47917), the market basket index used to update IRF payments was a market basket reflecting the operating and capital cost structures for freestanding IRFs, freestanding inpatient psychiatric facilities (IPFs), 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 federal prospective payment rates and the outlier threshold, revised the IRF wage index policy, and clarified how we determine high-cost outlier payments for transfer cases. For more information on the policy changes implemented for FY 2008, please refer to the FY 2008 IRF PPS final rule

(72 FR 44284), in which we published the final FY 2008 IRF federal prospective payment rates.

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

In the FY 2009 IRF PPS final rule (73 FR 46370), we updated the CMG relative weights, the average length of stay values, and the outlier threshold; clarified IRF wage index policies regarding the treatment of “New England deemed” counties and multi-campus hospitals; and revised the regulation text in response to section 115 of the MMSEA to set the IRF compliance percentage at 60 percent (the “60 percent rule”) and continue the practice of including comorbidities in the calculation of compliance percentages. We also applied a zero percent market basket increase factor for FY 2009 in accordance with section 115 of the MMSEA. For

more information on the policy changes implemented for FY 2009, please refer to the FY 2009 IRF PPS final rule (73 FR 46370), in which we published the final FY 2009 IRF federal prospective payment rates.

In the FY 2010 IRF PPS final rule (74 FR 39762) and in correcting amendments to the FY 2010 IRF PPS final rule (74 FR 50712) that we published on October 1, 2009, we updated the federal prospective payment rates, the CMG relative weights, the average length of stay values, the rural, LIP, teaching status adjustment factors, and the outlier threshold; implemented new IRF coverage requirements for determining whether an IRF claim is reasonable and necessary; and revised the regulation text to require IRFs to submit patient assessments on Medicare Advantage (MA) (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 federal prospective payment rates.

After publication of the FY 2010 IRF PPS final rule (74 FR 39762), section 3401(d) of the Patient Protection and Affordable Care Act (Pub. L. 111-148, enacted on March 23, 2010), as amended by section 10319 of the same Act and by section 1105 of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152, enacted on March 30, 2010) (collectively, 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 adjustment to the market basket increase factor, and to apply other adjustments as defined by the Act. The productivity

adjustment applies to FYs from 2012 forward. The other adjustments apply to FYs 2010 to 2019.

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

In addition, sections 1886(j)(3)(C) and (D) of the Act also affected the FY 2010 IRF outlier threshold amount because they required an adjustment to the FY 2010 RPL market basket increase factor, which changed the standard payment conversion factor for FY 2010. Specifically, the original FY 2010 IRF outlier threshold amount was determined based on the original estimated FY 2010 RPL market basket increase factor of 2.5 percent and the standard

payment conversion factor of \$13,661. However, as adjusted, the IRF prospective payments are based on the adjusted RPL market basket increase factor of 2.25 percent and the revised standard payment conversion factor of \$13,627. To maintain estimated outlier payments for FY 2010 equal to the established standard of 3 percent of total estimated IRF PPS payments for FY 2010, we revised the IRF outlier threshold amount for FY 2010 for discharges occurring on or after April 1, 2010, and on or before September 30, 2010. The revised IRF outlier threshold amount for FY 2010 was \$10,721.

Sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(i) of the Act also required the Secretary to reduce the market basket increase factor in FY 2011 by a 0.25 percentage point adjustment. The FY 2011 IRF PPS notice (75 FR 42836) and the correcting amendments to the FY 2011 IRF PPS notice (75 FR 70013) described the required adjustments to the FY 2011 and FY 2010 IRF PPS federal prospective payment rates and outlier threshold amount for IRF discharges occurring on or after April 1, 2010, and on or before September 30, 2011. It also updated the FY 2011 federal prospective payment rates, the CMG relative weights, and the average length of stay values. Any reference to the FY 2011 IRF PPS notice in this final rule also includes the provisions effective in the correcting amendments. For more information on the FY 2010 and FY 2011 adjustments or the updates for FY 2011, please refer to the FY 2011 IRF PPS notice (75 FR 42836 and 75 FR 70013).

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

PPS final rule (76 FR 47836), in which we published the final FY 2012 IRF federal prospective payment rates.

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

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

In the FY 2015 IRF PPS final rule (79 FR 45872), we updated the federal 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 quality reporting program. 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 federal 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).

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 2017 is discussed in section VI.B. of this final 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 2017 is discussed in section VI.B. of this final rule. Section 1886(j)(3)(C)(ii)(II) of the Act notes that the application of these adjustments to the market basket update may result in an update that is less than 0.0 for a fiscal year and in payment rates for a fiscal year being less than such payment rates for the preceding fiscal year.

Section 3004(b) of the Affordable Care Act also addressed the IRF PPS program. It

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

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

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

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 Medicare Advantage (MA) (formerly called Medicare Part C) 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 Medicare Advantage patient is discharged, in accordance with the Medicare Claims Processing

Manual, chapter 3, section 20.3 (Pub. 100-04), hospitals (including IRFs) must submit an informational-only bill (Type of Bill (TOB) 111), which includes Condition Code 04 to their MAC. This will ensure that the Medicare Advantage days are included in the hospital's Supplemental Security Income (SSI) ratio (used in calculating the IRF low-income percentage adjustment) for fiscal year 2007 and beyond. Claims submitted to Medicare must comply with both ASCA and HIPAA.

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

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

<http://www.cms.gov/ElectronicBillingEDITrans/> and listed in the addenda to the Medicare Intermediary Manual, Part 3, section 3600).

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

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). HHS believes 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 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” (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 in order 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 2016 Interoperability Standards Advisory (available at <https://www.healthit.gov/standards-advisory/2016>), which provides a list of the best available standards and implementation specifications to enable priority health information exchange functions. Providers, payers, and vendors are encouraged to take these “best available

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 (eCQMs), 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.

We received one comment on health information exchange, which is summarized below.

Comment: A commenter stated that the rule focuses only on providers, vendors, and institutions, not individuals and that sharing information requires standardized data exchange. The commenter suggested that CMS add a system-wide measure to assess whether robust data standards, policies, and governance infrastructure exists to support widespread industry and individual participation.

Response: We agree with the commenter that all individuals, families, and healthcare providers should have consistent and timely access to health information, in accordance with applicable law, in a standardized format that can be securely exchanged to support the health and wellness of individuals and shared decision-making. We agree nationwide interoperability across the care continuum will require stakeholders to agree to and follow a common set of standards, services, policies and practices that facilitates the exchange and use of interoperable health information. ONC recently requested comment on system-wide measures of interoperability required under the Medicare Access and CHIP Reauthorization Act of 2015 (81 FR 20651, <https://federalregister.gov/a/2016-08134>).

II. Summary of Provisions of the Proposed Rule

In the FY 2017 IRF PPS proposed rule (81 FR 24178), we proposed to update the IRF federal prospective payment rates for FY 2017 and to revise and update quality measures and reporting requirements under the IRF QRP.

The proposed updates to the IRF federal prospective payment rates for FY 2017 were as follows:

- Update the FY 2017 IRF PPS relative weights and average length of stay values using the most current and complete Medicare claims and cost report data in a budget-neutral manner, as discussed in section III of the FY 2017 IRF PPS proposed rule (81 FR 24178, 24184 through 24187).
- Describe the continued use of FY 2014 facility-level adjustment factors as discussed in section IV of the FY 2017 IRF PPS proposed rule (81 FR 24178 at 24187).
- Update the FY 2017 IRF PPS payment rates by the proposed market basket increase factor, based upon the most current data available, with 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 and a proposed productivity adjustment required by section 1886(j)(3)(C)(ii)(I) of the Act, as described in section V of the FY 2017 IRF PPS proposed rule (81 FR 24178, 24187 through 24189).
- Update the FY 2017 IRF PPS payment rates by the FY 2017 wage index and the labor-related share in a budget-neutral manner, as discussed in section V of the FY 2017 IRF PPS proposed rule (81 FR 24178, 24189 through 24190).
- Describe the calculation of the IRF standard payment conversion factor for FY 2017, as discussed in section V of the FY 2017 IRF PPS proposed rule (81 FR 24178, 24190 through 24192).

- Update the outlier threshold amount for FY 2017, as discussed in section VI of the FY 2017 IRF PPS proposed rule (81 FR 24178, at 24193).
- Update the cost-to-charge ratio (CCR) ceiling and urban/rural average CCRs for FY 2017, as discussed in section VI of the FY 2017 IRF PPS proposed rule (81 FR 24178, 24193 through 24194).
- Describe proposed revisions and updates to quality measures and reporting requirements under the quality reporting program for IRFs in accordance with section 1886(j)(7) of the Act, as discussed in section VII of the FY 2017 IRF PPS proposed rule (81 FR 24194 through 24220).

III. Analysis and Responses to Public Comments

We received 61 timely responses from the public, many of which contained multiple comments on the FY 2017 IRF PPS proposed rule (81 FR 24178). We received comments from various trade associations, inpatient rehabilitation facilities, individual physicians, therapists, clinicians, health care industry organizations, and health care consulting firms. The following sections, arranged by subject area, include a summary of the public comments that we received, and our responses.

IV. Update to the Case-Mix Group (CMG) Relative Weights and Average Length of Stay Values for FY 2017

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

helps to ensure that IRF PPS payments support beneficiary access to care, as well as provider efficiency.

In the FY 2017 IRF PPS proposed rule (81 FR 24178, 24184 through 24187), we proposed to update the CMG relative weights and average length of stay values for FY 2017. 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 2017, we proposed to use the FY 2015 IRF claims and FY 2014 IRF cost report data. These data are the most current and complete data available at this time. We note that, as we typically do, we updated our data between the FY 2017 IRF PPS proposed and final rules to ensure that we use the most recent available data in calculating IRF PPS payments. This updated data reflects a more complete set of claims for FY 2015 and additional cost report data for FY 2014.

In the FY 2017 IRF PPS proposed rule, we proposed to apply these data using the same methodologies that we have used to update the CMG relative weights and average length of stay values each fiscal year since we implemented an update to the methodology to use the more detailed CCR data from the cost reports of IRF subprovider units of primary acute care hospitals, instead of CCR data from the associated primary care hospitals, to calculate IRFs' average costs per case, as discussed in the FY 2009 IRF PPS final rule (73 FR 46372). In calculating the CMG relative weights, we use a hospital-specific relative value method to estimate operating (routine and ancillary services) and capital costs of IRFs. The process used to calculate the CMG relative weights for this final rule is as follows:

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

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

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

Step 4. We normalize the FY 2017 CMG relative weights to the same average CMG relative weight from the CMG relative weights implemented in the FY 2016 IRF PPS final rule (80 FR 47036).

Consistent with the methodology that we have used to update the IRF classification system in each instance in the past, we proposed to update the CMG relative weights for FY 2017 in such a way that total estimated aggregate payments to IRFs for FY 2017 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 2017 CMG relative weights, we use the following steps:

Step 1. Calculate the estimated total amount of IRF PPS payments for FY 2017 (with no changes to the CMG relative weights).

Step 2. Calculate the estimated total amount of IRF PPS payments for FY 2017 by applying the changes to the CMG relative weights (as discussed in this final rule).

Step 3. Divide the amount calculated in step 1 by the amount calculated in step 2 to determine the budget neutrality factor (0.9992) that would maintain the same total estimated aggregate payments in FY 2017 with and without the changes to the CMG relative weights.

Step 4. Apply the budget neutrality factor (0.9992) to the FY 2016 IRF PPS standard payment amount after the application of the budget-neutral wage adjustment factor.

In section VI.E. of this final rule, we discuss the proposed use of the existing methodology to calculate the standard payment conversion factor for FY 2017.

In Table 1, “Relative Weights and Average Length of Stay Values for Case-Mix

Groups,” we present the CMGs, the comorbidity tiers, the corresponding relative weights, and the average length of stay values for each CMG and tier for FY 2017. The average length of stay for each CMG is used to determine when an IRF discharge meets the definition of a short-stay transfer, which results in a per diem case level adjustment.

TABLE 1: Relative Weights and Average Length of Stay Values for Case-Mix Groups

CMG	CMG Description (M=motor, C=cognitive, A=age)	Relative Weight				Average Length of Stay			
		Tier 1	Tier 2	Tier 3	None	Tier 1	Tier 2	Tier 3	None
0101	Stroke M>51.05	0.7992	0.7117	0.6511	0.6215	8	9	9	8
0102	Stroke M>44.45 and M<51.05 and C>18.5	1.0130	0.9020	0.8252	0.7877	11	12	10	10
0103	Stroke M>44.45 and M<51.05 and C<18.5	1.1836	1.0540	0.9642	0.9204	11	13	12	12
0104	Stroke M>38.85 and M<44.45	1.2598	1.1218	1.0263	0.9796	12	12	12	12
0105	Stroke M>34.25 and M<38.85	1.4572	1.2976	1.1871	1.1331	14	15	14	14
0106	Stroke M>30.05 and M<34.25	1.6296	1.4511	1.3275	1.2671	16	16	15	15
0107	Stroke M>26.15 and M<30.05	1.8187	1.6195	1.4815	1.4142	17	19	17	17
0108	Stroke M<26.15 and A>84.5	2.2893	2.0386	1.8649	1.7801	21	22	21	20
0109	Stroke M>22.35 and M<26.15 and A<84.5	2.0584	1.8329	1.6768	1.6005	19	20	18	19
0110	Stroke M<22.35 and A<84.5	2.7320	2.4327	2.2255	2.1243	29	27	24	24
0201	Traumatic brain injury M>53.35 and C>23.5	0.7753	0.6341	0.5715	0.5343	8	8	8	7

CMG	CMG Description (M=motor, C=cognitive, A=age)	Relative Weight				Average Length of Stay			
0202	Traumatic brain injury M>44.25 and M<53.35 and C>23.5	1.0945	0.8951	0.8067	0.7542	12	10	9	10
0203	Traumatic brain injury M>44.25 and C<23.5	1.2173	0.9955	0.8973	0.8388	11	12	11	11
0204	Traumatic brain injury M>40.65 and M<44.25	1.3455	1.1003	0.9918	0.9272	16	13	12	11
0205	Traumatic brain injury M>28.75 and M<40.65	1.6224	1.3269	1.1959	1.1181	14	15	14	13
0206	Traumatic brain injury M>22.05 and M<28.75	1.9239	1.5734	1.4182	1.3258	19	18	16	15
0207	Traumatic brain injury M<22.05	2.5284	2.0678	1.8637	1.7424	31	23	20	19
0301	Non-traumatic brain injury M>41.05	1.1424	0.9432	0.8571	0.8002	10	11	10	10
0302	Non-traumatic brain injury M>35.05 and M<41.05	1.4063	1.1610	1.0551	0.9850	13	13	12	12
0303	Non-traumatic brain injury M>26.15 and M<35.05	1.6490	1.3614	1.2372	1.1550	15	15	14	14
0304	Non-traumatic brain injury M<26.15	2.1336	1.7614	1.6007	1.4944	21	20	17	16
0401	Traumatic spinal cord injury M>48.45	0.9799	0.8616	0.7947	0.7213	11	11	10	9
0402	Traumatic spinal cord injury M>30.35 and M<48.45	1.4052	1.2357	1.1396	1.0344	14	14	14	13
0403	Traumatic spinal cord injury	2.2165	1.9492	1.7976	1.6316	20	21	20	19

CMG	CMG Description (M=motor, C=cognitive, A=age)	Relative Weight				Average Length of Stay			
	M>16.05 and M<30.35								
0404	Traumatic spinal cord injury M<16.05 and A>63.5	3.8702	3.4033	3.1387	2.8489	46	37	34	31
0405	Traumatic spinal cord injury M<16.05 and A<63.5	3.4395	3.0246	2.7894	2.5319	49	33	28	28
0501	Non-traumatic spinal cord injury M>51.35	0.8524	0.6715	0.6395	0.5751	9	8	7	8
0502	Non-traumatic spinal cord injury M>40.15 and M<51.35	1.1600	0.9139	0.8703	0.7827	11	11	10	10
0503	Non-traumatic spinal cord injury M>31.25 and M<40.15	1.4557	1.1469	1.0921	0.9822	14	13	13	12
0504	Non-traumatic spinal cord injury M>29.25 and M<31.25	1.7087	1.3462	1.2819	1.1529	19	16	14	14
0505	Non-traumatic spinal cord injury M>23.75 and M<29.25	1.9607	1.5447	1.4709	1.3229	20	17	17	16
0506	Non-traumatic spinal cord injury M<23.75	2.7151	2.1391	2.0369	1.8320	28	24	22	21
0601	Neurological M>47.75	1.0352	0.8205	0.7577	0.6939	10	9	9	9
0602	Neurological M>37.35 and M<47.75	1.3322	1.0560	0.9751	0.8930	12	12	11	11
0603	Neurological M>25.85 and M<37.35	1.6411	1.3008	1.2012	1.1001	14	14	13	13
0604	Neurological M<25.85	2.1752	1.7241	1.5922	1.4581	20	18	17	16

CMG	CMG Description (M=motor, C=cognitive, A=age)	Relative Weight				Average Length of Stay			
0701	Fracture of lower extremity M>42.15	0.9991	0.8136	0.7767	0.7052	10	9	9	9
0702	Fracture of lower extremity M>34.15 and M<42.15	1.2759	1.0390	0.9919	0.9006	12	12	12	11
0703	Fracture of lower extremity M>28.15 and M<34.15	1.5383	1.2527	1.1958	1.0858	15	14	14	13
0704	Fracture of lower extremity M<28.15	1.9943	1.6240	1.5503	1.4076	18	18	17	16
0801	Replacement of lower extremity joint M>49.55	0.7983	0.6443	0.5958	0.5476	8	8	7	7
0802	Replacement of lower extremity joint M>37.05 and M<49.55	1.0333	0.8340	0.7713	0.7089	11	10	9	9
0803	Replacement of lower extremity joint M>28.65 and M<37.05 and A>83.5	1.3823	1.1156	1.0317	0.9482	13	13	12	12
0804	Replacement of lower extremity joint M>28.65 and M<37.05 and A<83.5	1.2445	1.0044	0.9289	0.8537	12	12	11	10
0805	Replacement of lower extremity joint M>22.05 and M<28.65	1.4806	1.1949	1.1051	1.0157	15	13	12	12
0806	Replacement of lower extremity joint M<22.05	1.7987	1.4517	1.3425	1.2339	16	16	15	14
0901	Other orthopedic	0.9839	0.7940	0.7356	0.6693	11	10	9	8

CMG	CMG Description (M=motor, C=cognitive, A=age)	Relative Weight				Average Length of Stay			
	M>44.75								
0902	Other orthopedic M>34.35 and M<44.75	1.2583	1.0155	0.9408	0.8560	12	12	11	10
0903	Other orthopedic M>24.15 and M<34.35	1.5810	1.2760	1.1821	1.0755	15	15	13	13
0904	Other orthopedic M<24.15	2.0014	1.6153	1.4965	1.3615	18	18	16	16
1001	Amputation, lower extremity M>47.65	1.0715	0.9448	0.8199	0.7400	11	11	10	9
1002	Amputation, lower extremity M>36.25 and M<47.65	1.3906	1.2261	1.0641	0.9604	14	15	12	12
1003	Amputation, lower extremity M<36.25	1.9639	1.7317	1.5029	1.3564	18	19	17	16
1101	Amputation, non-lower extremity M>36.35	1.3222	1.1985	0.9739	0.8842	12	12	10	11
1102	Amputation, non-lower extremity M<36.35	1.8953	1.7181	1.3961	1.2676	17	16	16	14
1201	Osteoarthritis M>37.65	1.0379	1.0241	0.9306	0.8231	10	11	11	10
1202	Osteoarthritis M>30.75 and M<37.65	1.2061	1.1900	1.0813	0.9564	12	13	12	11
1203	Osteoarthritis M<30.75	1.5370	1.5165	1.3780	1.2188	14	17	15	14
1301	Rheumatoid, other arthritis M>36.35	1.1939	0.9393	0.8690	0.8007	13	10	10	10
1302	Rheumatoid, other arthritis M>26.15 and M<36.35	1.6397	1.2900	1.1935	1.0997	14	15	13	13
1303	Rheumatoid, other arthritis	2.0215	1.5904	1.4715	1.3558	16	20	15	15

CMG	CMG Description (M=motor, C=cognitive, A=age)	Relative Weight				Average Length of Stay			
	M<26.15								
1401	Cardiac M>48.85	0.8666	0.7324	0.6639	0.6025	9	7	8	8
1402	Cardiac M>38.55 and M<48.85	1.1810	0.9981	0.9047	0.8211	11	11	11	10
1403	Cardiac M>31.15 and M<38.55	1.4079	1.1899	1.0785	0.9788	13	13	12	11
1404	Cardiac M<31.15	1.7805	1.5048	1.3640	1.2379	17	16	15	14
1501	Pulmonary M>49.25	1.0089	0.8543	0.7888	0.7436	10	9	9	8
1502	Pulmonary M>39.05 and M<49.25	1.2746	1.0793	0.9966	0.9394	11	11	11	10
1503	Pulmonary M>29.15 and M<39.05	1.5543	1.3162	1.2153	1.1456	15	14	12	12
1504	Pulmonary M<29.15	1.9370	1.6402	1.5145	1.4276	19	17	15	14
1601	Pain syndrome M>37.15	0.9889	0.8933	0.8321	0.7677	9	9	10	9
1602	Pain syndrome M>26.75 and M<37.15	1.2901	1.1654	1.0855	1.0015	12	13	12	12
1603	Pain syndrome M<26.75	1.6155	1.4592	1.3592	1.2540	13	17	15	14
1701	Major multiple trauma without brain or spinal cord injury M>39.25	1.1345	0.9258	0.8520	0.7671	16	10	10	10
1702	Major multiple trauma without brain or spinal cord injury M>31.05 and M<39.25	1.4253	1.1631	1.0704	0.9637	13	14	13	12
1703	Major multiple trauma without brain or spinal cord	1.6987	1.3862	1.2758	1.1486	16	15	15	14

CMG	CMG Description (M=motor, C=cognitive, A=age)	Relative Weight				Average Length of Stay			
	injury M>25.55 and M<31.05								
1704	Major multiple trauma without brain or spinal cord injury M<25.55	2.1821	1.7806	1.6387	1.4753	22	19	18	17
1801	Major multiple trauma with brain or spinal cord injury M>40.85	1.2932	1.0595	0.9203	0.8254	14	13	12	10
1802	Major multiple trauma with brain or spinal cord injury M>23.05 and M<40.85	1.8234	1.4939	1.2976	1.1639	17	17	15	14
1803	Major multiple trauma with brain or spinal cord injury M<23.05	2.8692	2.3507	2.0419	1.8314	31	27	21	20
1901	Guillian Barre M>35.95	1.2267	1.0516	0.9270	0.9134	14	13	11	11
1902	Guillian Barre M>18.05 and M<35.95	2.2288	1.9106	1.6843	1.6595	20	22	19	19
1903	Guillian Barre M<18.05	3.6684	3.1447	2.7722	2.7315	52	31	32	30
2001	Miscellaneous M>49.15	0.9225	0.7562	0.6942	0.6285	9	9	8	8
2002	Miscellaneous M>38.75 and M<49.15	1.2097	0.9916	0.9104	0.8241	12	11	11	10
2003	Miscellaneous M>27.85 and M<38.75	1.5124	1.2397	1.1381	1.0303	14	14	13	12
2004	Miscellaneous M<27.85	1.9412	1.5912	1.4608	1.3224	19	17	16	15
2101	Burns M>0	1.6899	1.6899	1.5061	1.3813	24	18	16	17
5001	Short-stay cases, length of stay is 3 days or fewer				0.1585				2

CMG	CMG Description (M=motor, C=cognitive, A=age)	Relative Weight				Average Length of Stay			
5101	Expired, orthopedic, length of stay is 13 days or fewer				0.6785				7
5102	Expired, orthopedic, length of stay is 14 days or more				1.6606				16
5103	Expired, not orthopedic, length of stay is 15 days or fewer				0.8002				8
5104	Expired, not orthopedic, length of stay is 16 days or more				2.1200				21

Generally, updates to the CMG relative weights result in some increases and some decreases to the CMG relative weight values. Table 2 shows how we estimate that the application of the revisions for FY 2017 would affect particular CMG relative weight values, which would affect the overall distribution of payments within CMGs and tiers. Note that, because we proposed to implement the CMG relative weight revisions in a budget-neutral manner (as previously described), total estimated aggregate payments to IRFs for FY 2017 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 Changes to the CMG Relative Weights (FY 2016 Values Compared with FY 2017 Values)

Percentage Change	Number of Cases Affected	Percentage of Cases Affected
Increased by 15% or more	0	0.0%
Increased by between 5% and 15%	540	0.1%
Changed by less than 5%	395,897	99.7%
Decreased by between 5% and 15%	761	0.2%
Decreased by 15% or more	41	0.0%

As Table 2 shows, 99.7 percent of all IRF cases are in CMGs and tiers that would experience less than a 5 percent change (either increase or decrease) in the CMG relative weight value as a result of the revisions for FY 2017. The largest estimated increase in the CMG relative weight values that affects the largest number of IRF discharges would be a 0.7 percent change in the CMG relative weight value for CMG 0604--Neurological, with a motor score less than 25.85-in the “no comorbidity” tier. In the FY 2015 claims data, 8,572 IRF discharges (2.2 percent of all IRF discharges) were classified into this CMG and tier.

The largest decrease in a CMG relative weight value affecting the largest number of IRF cases would be a 1.4 percent decrease in the CMG relative weight for CMG 0110 – Stroke, with a motor score less than 22.35 and age less than 84.5 -in the “no comorbidity” tier. In the FY 2015 IRF claims data, this change would have affected 13,739 cases (3.5 percent of all IRF cases).

The proposed changes in the average length of stay values for FY 2017, compared with the FY 2016 average length of stay values, are small and do not show any particular trends in IRF length of stay patterns.

We received 3 comments on the proposed update to the CMG relative weights and average length of stay values for FY 2017, which are summarized below.

Comment: Commenters, while supportive of the methodology used to calculate the weights, requested that we provide more detail about the use of the CCR data in the CMG relative weight calculations. Additionally, the commenters requested that we outline the methodology used to calculate the average length of stay values in the FY 2017 IRF PPS proposed rule.

Response: As we discussed, most recently, in the FY 2016 IRF PPS final rule (80 FR 47036, 47045), a key variable used to calculate the CMG relative weights is a facility's average cost per case, which is obtained by averaging the estimated cost per case for every patient discharged from the facility in a given fiscal year. To obtain the estimated cost per case for a given IRF patient, we start by pulling the appropriate charges from the Medicare claim for that patient. Then, we calculate the appropriate CCRs from the Medicare cost report submitted by the facility. The CCRs are then multiplied by the charges from the Medicare claim to obtain the estimated IRF cost for the case. This variable is used as the dependent variable in the regression analysis to estimate the CMG relative weights.

As we also discussed in the FY 2016 IRF PPS final rule (80 FR 47036, 47045), the methodology for calculating the average length of stay values is available for download from the IRF PPS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Research.html>.

Final Decision: After careful consideration of the public comments, we are finalizing our proposal to update the CMG relative weight and average length of stay values for FY 2017, as shown in Table 1 of this final rule. These updates are effective October 1, 2016.

V. Facility-Level Adjustment Factors

Section 1886(j)(3)(A)(v) of the Act confers broad authority upon the Secretary to adjust

the per unit payment rate by such factors as the Secretary determines are necessary to properly reflect variations in necessary costs of treatment among rehabilitation facilities. Under this authority, we currently adjust the federal prospective payment amount associated with a CMG to account for facility-level characteristics such as an IRF's LIP, teaching status, and location in a rural area, if applicable, as described in §412.624(e).

Based on the substantive changes to the facility-level adjustment factors that were adopted in the FY 2014 final rule (78 FR 47860, 47868 through 47872), in the FY 2015 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 2017, we will continue to hold the adjustment factors at the FY 2014 levels as we continue to monitor the most current IRF claims data available and continue to evaluate and monitor the effects of the FY 2014 changes.

VI. FY 2017 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 covered IRF services, which is referred to as a market basket index. According to section 1886(j)(3)(A)(i) of the Act, the increase factor shall be used to update the IRF federal prospective payment rates for each FY. Section 1886(j)(3)(C)(ii)(I) of the Act requires the application of a productivity adjustment, as described below. 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 2017. Thus, in the FY 2017 IRF PPS proposed rule (81 FR 24178, 24187 through 24188), we proposed to update the IRF PPS

payments for FY 2017 by a market basket increase factor as required by section 1886(j)(3)(C) of the Act, with a productivity adjustment 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.

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

B. FY 2017 Market Basket Update and Productivity Adjustment

For FY 2017, we proposed to use the same methodology described in the FY 2016 IRF PPS final rule (80 FR 47066) to compute the FY 2017 market basket increase factor to update

the IRF PPS base payment rate. Consistent with historical practice, we proposed to estimate the market basket update for the IRF PPS based on IHS Global Insight's forecast using the most recent available data. IHS Global Insight (IGI), Inc. is a nationally recognized economic and financial forecasting firm with which CMS contracts to forecast the components of the market baskets and multifactor productivity (MFP).

Based on IGI's first quarter 2016 forecast with historical data through the fourth quarter of 2015, we proposed that the projected 2012-based IRF market basket increase factor for FY 2017 would be 2.7 percent. We also proposed that if more recent data were subsequently available (for example, a more recent estimate of the market basket update), we would use such data to determine the FY 2017 update in the final rule. Incorporating the most recent data available, based on IGI's second quarter 2016 forecast with historical data through the first quarter of 2016, the projected 2012-based IRF market basket increase factor for FY 2017 is 2.7 percent.

According to section 1886(j)(3)(C)(i) of the Act, the Secretary shall establish an increase factor based on an appropriate percentage increase in a market basket of goods and services. Section 1886(j)(3)(C)(ii) of the Act then requires that, after establishing the increase factor for a FY, the Secretary shall reduce such increase factor for FY 2012 and each subsequent FY, by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1886(b)(3)(B)(xi)(II) of the Act sets forth the definition of this productivity adjustment. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business MFP (as projected by the Secretary for the 10-year period ending with the applicable FY, year, cost reporting period, or other annual period) (the "MFP adjustment"). The BLS publishes the official measure of private nonfarm business

MFP. Please see <http://www.bls.gov/mfp> for the BLS historical published MFP data. A complete description of the MFP projection methodology is available on the CMS Web site at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html>.

Using IGI's first quarter 2016 forecast, the proposed MFP adjustment for FY 2017 (the 10-year moving average of MFP for the period ending FY 2017) was 0.5 percent. We proposed that if more recent data were subsequently available, we would use such data to determine the FY 2017 MFP adjustment in the final rule. Incorporating the most recent data available, based on IGI's second quarter 2016 forecast with historical data through the first quarter of 2016, the projected MFP adjustment for FY 2017 is 0.3 percent.

Thus, in accordance with section 1886(j)(3)(C) of the Act, we proposed to base the FY 2017 market basket update, which is used to determine the applicable percentage increase for the IRF payments, on the most recent estimate of the 2012-based IRF market basket. We proposed to then reduce this percentage increase by the most up-to-date estimate of the MFP adjustment for FY 2017. Following application of the MFP, we proposed to further reduce the applicable percentage increase by 0.75 percentage point, as required by sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(v) of the Act. Therefore, the estimate of the FY 2017 IRF update for the proposed rule was 1.45 percent (2.7 percent market basket update, less 0.5 percentage point MFP adjustment, less 0.75 percentage point legislative adjustment). Incorporating the most recent data, the current estimate of the FY 2017 IRF update is 1.65 percent (2.7 percent market basket update, less 0.3 percentage point MFP adjustment, less 0.75 percentage point legislative adjustment).

For FY 2017, the Medicare Payment Advisory Commission (MedPAC) recommends that

a 0-percent update be applied to IRF PPS payment rates. As discussed, and in accordance with sections 1886(j)(3)(C) and 1886(j)(3)(D) of the Act, the Secretary proposed to update the IRF PPS payment rates for FY 2017 by an adjusted market basket increase factor of 1.45 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 2017. As noted above, incorporating the most recent data, the current estimate of the FY 2017 IRF update is 1.65 percent.

We received 10 comments on the proposed market basket increase update and productivity adjustment, which are summarized below.

Comment: One commenter (MedPAC) stated that it understood that CMS is required to implement this statutory payment update; however, MedPAC noted that after reviewing many factors—including indicators of beneficiary access to rehabilitative services, the supply of providers, and Medicare margins—it determined that Medicare’s current payment rates for IRFs appear to be adequate and therefore recommended no update to IRF payment rates for FY 2017. MedPAC appreciated that CMS cited its recommendation, even while noting that the Secretary does not have the authority to deviate from statutorily mandated updates.

Response: As discussed, and in accordance with sections 1886(j)(3)(C) and 1886(j)(3)(D) of the Act, the Secretary is updating IRF PPS payment rates for FY 2017 by an adjusted market basket increase factor of 1.65 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 2017.

Comment: Several commenters requested that, with respect to the productivity adjustment, CMS remain cognizant of the intensive labor, time and costs required by state and/or federal regulations to which IRFs are bound. These commenters stated that these requirements

may be barriers to IRFs achieving further gains in productivity efficiencies. Further, some commenters stated that successful rehabilitation outcomes require an intense labor component, including the interaction of the full multidisciplinary treatment team, which includes physicians, nurses, physical and occupational therapists, speech language pathologists as well as social workers, psychologists and others. In addition, these commenters indicated that some states have regulations mandating increased professional staffing ratios between health care providers and patients. A few commenters claimed that, since CMS has stated its policy is that the majority of patient therapy should be one-on-one, which is highly labor-intensive, then CMS should not mandate further efficiencies such as productivity adjustments while simultaneously implementing new regulations or interpreting existing regulations in ways that preclude IRFs from adopting clinically appropriate innovations that would allow for greater efficiencies. These commenters requested that the 0.5 percentage point productivity adjustment be “reversed.” In addition, several commenters requested that CMS be mindful of the additional labor costs and quality improvement activities that IRFs will incur as a result of the additional items required in version 1.4 of the IRF PAI beginning on October 1, 2016 as well as the IRF PAI proposed changes relating to the drug regimen measure for which data would start to be collected on October 1, 2018.

Response: Section 1886(j)(3)(C)(ii)(I) of the Act requires the application of a productivity adjustment that must be applied to the IRF PPS market basket update. The statute does not provide the Secretary with the authority to “reverse” the productivity adjustment or apply a different adjustment. We will continue to monitor the impact of the payment updates, including the effects of the productivity adjustment, on IRF provider margins as well as beneficiary access to care.

Comment: One commenter recommended that CMS use the latest data available in estimating the market basket in the final rule.

Response: We agree with the commenter's recommendation, and it is consistent with the proposed rule language stating that the final IRF PPS payment update will be based on the most recent forecast of the market basket update and productivity adjustment. As noted above, the most recent estimate of the 2012-based IRF market basket is based on IGI's second quarter 2016 forecast with historical data through the first quarter of 2016.

Final Decision: Based on careful consideration of the comments, we are finalizing the FY 2017 market basket update for IRF payments of 1.65 percent (2.7 percent market basket update, less 0.3 percentage point MFP adjustment, less 0.75 percentage point legislative adjustment), which is based on the most recent forecasts of the 2012-based IRF market basket update and the MFP adjustment.

C. Labor-Related Share for FY 2017

Section 1886(j)(6) of the Act specifies that the Secretary is to adjust the proportion (as estimated by the Secretary from time to time) of rehabilitation facilities' costs which are attributable to wages and wage-related costs of the prospective payment rates computed under section 1886(j)(3) for area differences in wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the rehabilitation facility compared to the national average wage level for such facilities. The labor-related share is determined by identifying the national average proportion of total costs that are related to, influenced by, or vary with the local labor market. We continue to classify a cost category as labor-related if the costs are labor-intensive and vary with the local labor market.

Based on our definition of the labor-related share and the cost categories in the 2012-

based IRF market basket, we proposed to include in the labor-related share for FY 2017 the sum of the FY 2017 relative importance of Wages and Salaries, Employee Benefits, Professional Fees: Labor- Related, Administrative and Facilities Support Services, Installation, Maintenance, and Repair, All Other: Labor-related Services, and a portion 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 2016 forecast for the 2012-based IRF market basket, the proposed IRF labor-related share for FY 2017 was 71.0 percent. We proposed that if more recent data were subsequently available, we would use such data to determine the FY 2017 IRF labor-related share in the final rule.

Incorporating the most recent estimate of the 2012-based IRF market basket based on IGI's second quarter 2016 forecast with historical data through the first quarter of 2016, the sum of the relative importance for FY 2017 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 67.0 percent. We proposed that the portion of Capital-Related Costs that is influenced by the local labor market is estimated to be 46 percent. Incorporating the most recent estimate of the FY 2017 relative importance of Capital-Related costs from the 2012-based IRF market basket based on IGI's second quarter 2016 forecast with historical data through the first quarter of 2016, which is 8.4 percent, we take 46 percent of 8.4 percent to determine the labor-related share of Capital for FY 2017. As we proposed, we then add this amount (3.9 percent) to the sum of the relative importance for FY 2017 operating costs (67.0 percent) to determine the

total labor-related share for FY 2017 of 70.9 percent.

TABLE 3: IRF Labor-Related Share

	FY 2017 Final Labor-Related Share¹	FY 2016 Final Labor Related Share²
Wages and Salaries	47.7	47.6
Employee Benefits	11.3	11.4
Professional Fees: Labor-related	3.5	3.5
Administrative and Facilities Support Services	0.8	0.8
Installation, Maintenance, and Repair	1.9	2.0
All Other: Labor-related Services	1.8	1.8
Subtotal	67.0	67.1
Labor-related portion of capital (46%)	3.9	3.9
Total Labor-Related Share	70.9	71.0

1. Based on the 2012-based IRF Market Basket, IHS Global Insight, Inc. 2nd quarter 2016 forecast.
2. Federal Register 80 FR 47068.

Final Decision: As we did not receive any comments on the proposed labor-related share for FY 2017, we are finalizing the FY 2017 labor-related share of 70.9 percent.

D. Wage Adjustment

1. Background

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

For FY 2017, we proposed to maintain the policies and methodologies described in the

FY 2016 IRF PPS final rule (80 FR 47036, 47068 through 47075) related to the labor market area definitions and the wage index methodology for areas with wage data. Thus, we proposed to use the CBSA labor market area definitions and the FY 2016 pre-reclassification and pre-floor hospital wage index data. The current statistical areas which were implemented in FY 2016 are based on OMB standards published on February 28, 2013, in OMB Bulletin No. 13–01. For FY 2017, we are continuing to use the new OMB delineations that we adopted beginning with FY 2016. In accordance with section 1886(d)(3)(E) of the Act, the FY 2016 pre-reclassification and pre-floor hospital wage index is based on data submitted for hospital cost reporting periods beginning on or after October 1, 2011, and before October 1, 2012 (that is, FY 2012 cost report data).

The labor market designations made by the OMB include some geographic areas where there are no hospitals and, thus, no hospital wage index data on which to base the calculation of the IRF PPS wage index. We proposed to continue to use the same methodology discussed in the FY 2008 IRF PPS final rule (72 FR 44299) to address those geographic areas where there are no hospitals and, thus, no hospital wage index data on which to base the calculation for the FY 2017 IRF PPS wage index.

We did not receive any comments on these proposals. Therefore, we are finalizing our proposal to use the CBSA labor market area definitions and the FY 2016 pre-reclassification and pre-floor hospital wage index data for areas with wage data. We are also finalizing our proposal to continue to use the same methodology discussed in the FY 2008 IRF PPS final rule (72 FR 44299) to address those geographic areas where there are no hospitals and, thus, no hospital wage index data.

2. Update

The wage index used for the IRF PPS is calculated using the pre-reclassification and pre-floor acute care hospital wage index data and is assigned to the IRF on the basis of the labor market area in which the IRF is geographically located. IRF labor market areas are delineated based on the CBSAs established by the OMB. In the FY 2016 IRF PPS final rule (80 FR 47036, 47068), we established an IRF wage index based on FY 2011 acute care hospital wage data to adjust the FY 2016 IRF payment rates. We also adopted the revised CBSAs set forth by OMB. The current CBSA delineations (which were implemented for the IRF PPS beginning with FY 2016) are based on revised OMB delineations issued on February 28, 2013, in OMB Bulletin No. 13–01. OMB Bulletin No. 13–01 established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas in the United States and Puerto Rico, and provided guidance on the use of the delineations of these statistical areas based on new standards published on June 28, 2010, in the Federal Register (75 FR 37246 through 37252). A copy of this bulletin may be obtained at <http://www.whitehouse.gov/sites/default/files/omb/bulletins/2013/b-13-01.pdf>. For FY 2017, we are continuing to use the new OMB delineations that we adopted beginning with FY 2016 to calculate the area wage indexes and the transition periods, which we discuss below.

3. Transition Period

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. Under that policy, all IRF providers are receiving a blended wage index in FY 2016 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. For FY 2017, we proposed to maintain the policy established in FY 2016 IRF PPS final rule related to

the blended one-year transition wage index (see 80 FR 47036, 47073 through 47074). Thus, the 1-year blended wage index that became effective on October 1, 2015, will expire on September 30, 2016.

We did not receive any comments on the proposal to maintain the policy established in FY 2016 IRF PPS final rule related to the blended one-year transition wage index.

Final decision: As we did not receive any comments on our proposal to maintain the 1-year blended wage index for all IRF providers, we are finalizing the expiration of this policy on September 30, 2016.

For FY 2016, in addition to the blended wage index, we also adopted a 3-year budget neutral phase out of the rural adjustment for IRFs that were rural in FY 2015 and 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. FY 2017 represents the second year of the 3-year phase out of the rural adjustment, in which these same IRFs will receive one-third of the 2015 rural adjustment of 14.9 percent, as finalized in the FY 2016 IRF PPS final rule (80 FR 47036, 47073 through 47074).

For FY 2017, the wage index will be based solely on the previously adopted revised CBSA delineations and their respective wage index (rather than on a blended wage index). Furthermore, we will continue the 3-year phase out of the rural adjustments for IRF providers that changed from rural to urban status that was finalized in the FY 2016 IFR PPS final rule (80 FR 47036, 47073 through 47074).

We received one comment on our proposal to continue the 3-year phase out of the rural adjustments for IRF providers that changed from rural to urban status and that was finalized in the FY 2016 IFR PPS final rule.

Comment: One commenter suggested that we implement a 5-year phase-out of the rural adjustment or allow IRFs that are losing the FY 2015 rural adjustment due to the changes in the CBSA delineations to apply for reclassification back to rural status for a period of 5 years.

Response: The intent of the 3-year phase-out of the rural adjustment is to mitigate potential negative payment effects on rural facilities that are redesignated as urban facilities, effective FY 2016. As described in more detail in the FY 2006 IRF PPS final rule (70 FR 47880), our analysis determined that a 3-year budget-neutral transition policy would best accomplish the goals of mitigating the loss of the rural adjustment for existing IRFs that were rural in FY 2005 and became urban in FY 2006 under the new CBSA designations. For a complete discussion of this policy, we refer readers to the FY 2006 IRF PPS final rule (70 FR 47880, 47921 through 47925). As discussed in the FY 2016 IRF PPS final rule (80 FR 47036, 47074), we continue to believe that a 3-year budget-neutral phase-out of the rural adjustment appropriately mitigates the adverse payment impacts for these IRFs while also ensuring that payment rates for all IRFs are set accurately and appropriately.

Final Decision: After careful consideration, we are finalizing the continuation of the 3-year phase-out of the rural adjustment for IRFs that were designated as rural in FY 2015 but changed to urban in FY 2016 under the new OMB market area delineations. For FY 2017, these IRFs will receive the full FY 2017 wage index and one-third of the FY 2015 rural adjustment. For FY 2018, these IRFs will receive the full FY 2018 wage index with no rural adjustment.

For a full discussion of our implementation of the new OMB labor market area delineations for the FY 2016 wage index, please refer to the FY 2016 IRF PPS final rule (80 FR 47036, 47068 through 47076). While conducting analysis for the FY 2017 IRF PPS final rule, an additional IRF provider was identified as being eligible for the 3-year phase out of the rural adjustments for IRF providers that changed from rural to urban status. The original 19 providers were identified in FY 2014 claims data for the FY 2016 IRF PPS proposed and final rules. This newly eligible provider was new in FY 2015 and thus had no claims data in FY 2014. An analysis of the FY 2015 claims determined that this provider should have received two-thirds of the rural adjustment in FY 2016. This provider will be added to the group of providers receiving two-thirds of the rural adjustment in FY 2016 and one-third of the rural adjustment in FY 2017. For FY 2017, 20 IRFs that were designated as rural in FY 2015 and became designated as urban in FY 2016 will receive the FY 2017 wage index (based solely on the revised CBSA delineations) and one-third of the FY 2015 rural adjustment of 14.9 percent (80 FR 47036, 47073 through 47076). The wage index applicable to FY 2017 is available on the CMS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Data-Files.html>. Table A is for urban areas, and Table B is for rural areas.

To calculate the wage-adjusted facility payment for the payment rates set forth in this final rule, we multiply the unadjusted federal payment rate for IRFs by the FY 2017 labor-related share based on the 2012-based IRF market basket (70.9 percent) to determine the labor-related portion of the standard payment amount. A full discussion of the calculation of the labor-related share is located in section VI.C of this final rule. We then multiply the labor-related portion by the applicable IRF wage index from the tables in the addendum to this final rule. These tables

are available through the Internet on the CMS Web site at

<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Data-Files.html>.

Adjustments or updates to the IRF wage index made under section 1886(j)(6) of the Act must be made in a budget-neutral manner. We proposed to calculate a budget-neutral wage adjustment factor as established in the FY 2004 IRF PPS final rule (68 FR 45689), codified at §412.624(e)(1), as described in the steps below. We proposed to use the listed steps to ensure that the FY 2017 IRF standard payment conversion factor reflects the update to the wage indexes (based on the FY 2012 hospital cost report data) and the labor-related share in a budget-neutral manner:

Step 1. Determine the total amount of the estimated FY 2016 IRF PPS payments, using the FY 2016 standard payment conversion factor and the labor-related share and the wage indexes from FY 2016 (as published in the FY 2016 IRF PPS final rule (80 FR 47036)).

Step 2. Calculate the total amount of estimated IRF PPS payments using the FY 2017 standard payment conversion factor and the FY 2017 labor-related share and CBSA urban and rural wage indexes.

Step 3. Divide the amount calculated in step 1 by the amount calculated in step 2. The resulting quotient is the FY 2017 budget-neutral wage adjustment factor of 0.9992.

Step 4. Apply the FY 2017 budget-neutral wage adjustment factor from step 3 to the FY 2016 IRF PPS standard payment conversion factor after the application of the adjusted market basket update to determine the FY 2017 standard payment conversion factor.

We discuss the calculation of the standard payment conversion factor for FY 2017 in section VI.E of this final rule.

We did not receive any specific comments on the proposal to calculate a budget-neutral wage adjustment factor.

Final Decision: As we did not receive any comments on the proposal to calculate a budget-natural wage adjustment factor, we are finalizing our calculation of the budget-neutral wage adjustment factor of 0.9992 for FY 2017.

We received 11 public comments on the proposed IRF wage adjustment for FY 2017, which are summarized below.

Comment: Commenters again recommended that we develop a new methodology for the area wage adjustment that eliminates hospital wage index reclassifications for all hospitals and reduces the problems associated with annual fluctuations in wage indices and across geographic boundaries. Until such time as the new methodology may be developed, commenters also recommended that we consider adopting certain wage index policies currently employed under the IPPS, because IRFs compete in a similar labor pool as acute care hospitals. Such comments included requests that CMS grant IRFs the ability to request reclassification and/or establish a rural floor policy. One commenter further recommended that, until a new wage index system is implemented, we institute a “smoothing” variable to the current process to reduce the fluctuations IRFs annually experience.

Response: Consistent with our previous responses to these comments (most recently published in our FY 2016 IRF PPS final rule (80 FR 47036, 47076)), we note that the IRF PPS does not account for geographic reclassification under sections 1886(d)(8) and (d)(10) of the Act, and does not apply the “rural floor” under section 4410 of the BBA. Furthermore, as we do not have an IRF-specific wage index, we are unable to determine at this time the degree, if any, to which a geographic reclassification adjustment or a rural floor policy under the IRF PPS would

be appropriate. The rationale for our current wage index policies is fully described in the FY 2006 IRF PPS final rule (70 FR 47880, 47926 through 47928).

Additionally, while some commenters recommended that we adopt IPPS reclassification and/or floor policies, we note the MedPAC's June 2007 report to the Congress, titled "Report to Congress: Promoting Greater Efficiency in Medicare" (available at <http://www.medpac.gov/documents-/reports>), recommends that Congress "repeal the existing hospital wage index statute, including reclassification and exceptions, and give the Secretary authority to establish new wage index systems." We continue to believe it would not be appropriate at this time to adopt the IPPS wage index policies, such as reclassification and/or floor policies. Therefore, we will continue to use the CBSA labor market area definitions and the pre-reclassification and pre-floor hospital wage index data based on 2012 cost report data as this is the most recent final data available.

With regard to issues mentioned about ensuring that the wage index minimizes fluctuations, matches the costs of labor in the market, and provides for a single wage index policy, we note that section 3137(b) of the Affordable Care Act required us to submit a report to the Congress by December 31, 2011 that includes a plan to reform the hospital wage index system. This report describes the concept of a Commuting Based Wage Index as a potential replacement to the current Medicare wage index methodology. While this report addresses the goals of broad based Medicare wage index reform, no consensus has been achieved regarding how best to implement a replacement system. These concerns will be taken into consideration while CMS continues to explore potential wage index reforms.

The report that we submitted is available online at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Reform.html>.

Comment: Several commenters suggested that CMS use the most current wage data that is available and align the timeframe for the IRF wage index with other post-acute and acute care settings. These commenters indicated that this would position the IRF PPS to be more in line with alternative payment models that are currently being developed and tested.

Response: As we did not propose any changes to the methodology for determining the wage index for IRF providers, these comments are outside the scope of the proposed rule. We appreciate the commenters' suggestions and agree that this issue needs to be considered within the broader context of Medicare post-acute care payment reform efforts. We will consider these suggestions for future analyses.

Final Decision: After careful consideration of the comments, we are finalizing use of the FY 2016 pre-floor, pre-reclassified hospital wage index data to derive the applicable IRF PPS wage index for FY 2017. We are also continuing to implement the 3-year phase-out of the rural adjustment for IRFs that were designated as rural in FY 2015 but changed to urban in FY 2016 under the new OMB market area delineations. For FY 2017, these IRFs will receive the full FY 2017 wage index and one-third of the FY 2015 rural adjustment. For FY 2018, these IRFs will receive the full FY 2018 wage index with no rural adjustment.

E. Description of the IRF Standard Payment Conversion Factor and Payment Rates for FY 2017

To calculate the standard payment conversion factor for FY 2017, as illustrated in Table 4, we begin by applying the adjusted market basket increase factor for FY 2017 that was adjusted in accordance with sections 1886(j)(3)(C) and (D) of the Act, to the standard payment

conversion factor for FY 2016 (\$15,478). Applying the 1.65 percent adjusted market basket increase for FY 2017 to the standard payment conversion factor for FY 2016 of \$15,478 yields a standard payment amount of \$15,733. Then, we apply the budget neutrality factor for the FY 2017 wage index and labor-related share of 0.9992, which results in a standard payment amount of \$15,721. We next apply the budget neutrality factor for the revised CMG relative weights of 0.9992, which results in the standard payment conversion factor of \$15,708 for FY 2017.

TABLE 4: Calculations to Determine the FY 2017 Standard Payment Conversion Factor

Explanation for Adjustment	Calculations
Standard Payment Conversion Factor for FY 2016	\$15,478
Market Basket Increase Factor for FY 2017 (2.7 percent), reduced by 0.3 percentage point for the productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act, and reduced by 0.75 percentage point in accordance with paragraphs 1886(j)(3)(C) and (D) of the Act	x 1.0165
Budget Neutrality Factor for the Wage Index and Labor-Related Share	x 0.9992
Budget Neutrality Factor for the Revisions to the CMG Relative Weights	x 0.9992
FY 2017 Standard Payment Conversion Factor	= \$15,708

We did not receive comments specifically on the proposed FY 2017 standard payment conversion factor. We received comments on how the FY 2016 IRF QRP relates to the proposed FY 2017 standard payment conversion factor, which we have summarized in section IX. of this final rule.

Final Decision: As we did not receive comments specifically on the proposed FY 2017 standard payment conversion factor, we are finalizing the IRF standard payment conversion factor of \$15,708 for FY 2017.

After the application of the proposed CMG relative weights described in section IV of this final rule to the FY 2017 standard payment conversion factor (\$15,708), the resulting unadjusted IRF prospective payment rates for FY 2017 are shown in Table 5.

TABLE 5: FY 2017 Payment Rates

CMG	Payment Rate Tier 1	Payment Rate Tier 2	Payment Rate Tier 3	Payment Rate No Comorbidity
0101	\$12,553.83	\$11,179.38	\$10,227.48	\$9,762.52
0102	\$15,912.20	\$14,168.62	\$12,962.24	\$12,373.19
0103	\$18,591.99	\$16,556.23	\$15,145.65	\$14,457.64
0104	\$19,788.94	\$17,621.23	\$16,121.12	\$15,387.56
0105	\$22,889.70	\$20,382.70	\$18,646.97	\$17,798.73
0106	\$25,597.76	\$22,793.88	\$20,852.37	\$19,903.61
0107	\$28,568.14	\$25,439.11	\$23,271.40	\$22,214.25
0108	\$35,960.32	\$32,022.33	\$29,293.85	\$27,961.81
0109	\$32,333.35	\$28,791.19	\$26,339.17	\$25,140.65
0110	\$42,914.26	\$38,212.85	\$34,958.15	\$33,368.50
0201	\$12,178.41	\$9,960.44	\$8,977.12	\$8,392.78
0202	\$17,192.41	\$14,060.23	\$12,671.64	\$11,846.97
0203	\$19,121.35	\$15,637.31	\$14,094.79	\$13,175.87
0204	\$21,135.11	\$17,283.51	\$15,579.19	\$14,564.46
0205	\$25,484.66	\$20,842.95	\$18,785.20	\$17,563.11
0206	\$30,220.62	\$24,714.97	\$22,277.09	\$20,825.67
0207	\$39,716.11	\$32,481.00	\$29,275.00	\$27,369.62
0301	\$17,944.82	\$14,815.79	\$13,463.33	\$12,569.54
0302	\$22,090.16	\$18,236.99	\$16,573.51	\$15,472.38
0303	\$25,902.49	\$21,384.87	\$19,433.94	\$18,142.74
0304	\$33,514.59	\$27,668.07	\$25,143.80	\$23,474.04
0401	\$15,392.27	\$13,534.01	\$12,483.15	\$11,330.18
0402	\$22,072.88	\$19,410.38	\$17,900.84	\$16,248.36
0403	\$34,816.78	\$30,618.03	\$28,236.70	\$25,629.17
0404	\$60,793.10	\$53,459.04	\$49,302.70	\$44,750.52
0405	\$54,027.67	\$47,510.42	\$43,815.90	\$39,771.09
0501	\$13,389.50	\$10,547.92	\$10,045.27	\$9,033.67
0502	\$18,221.28	\$14,355.54	\$13,670.67	\$12,294.65
0503	\$22,866.14	\$18,015.51	\$17,154.71	\$15,428.40
0504	\$26,840.26	\$21,146.11	\$20,136.09	\$18,109.75
0505	\$30,798.68	\$24,264.15	\$23,104.90	\$20,780.11
0506	\$42,648.79	\$33,600.98	\$31,995.63	\$28,777.06
0601	\$16,260.92	\$12,888.41	\$11,901.95	\$10,899.78
0602	\$20,926.20	\$16,587.65	\$15,316.87	\$14,027.24
0603	\$25,778.40	\$20,432.97	\$18,868.45	\$17,280.37
0604	\$34,168.04	\$27,082.16	\$25,010.28	\$22,903.83
0701	\$15,693.86	\$12,780.03	\$12,200.40	\$11,077.28
0702	\$20,041.84	\$16,320.61	\$15,580.77	\$14,146.62
0703	\$24,163.62	\$19,677.41	\$18,783.63	\$17,055.75
0704	\$31,326.46	\$25,509.79	\$24,352.11	\$22,110.58
0801	\$12,539.70	\$10,120.66	\$9,358.83	\$8,601.70
0802	\$16,231.08	\$13,100.47	\$12,115.58	\$11,135.40
0803	\$21,713.17	\$17,523.84	\$16,205.94	\$14,894.33
0804	\$19,548.61	\$15,777.12	\$14,591.16	\$13,409.92

CMG	Payment Rate Tier 1	Payment Rate Tier 2	Payment Rate Tier 3	Payment Rate No Comorbidity
0805	\$23,257.26	\$18,769.49	\$17,358.91	\$15,954.62
0806	\$28,253.98	\$22,803.30	\$21,087.99	\$19,382.10
0901	\$15,455.10	\$12,472.15	\$11,554.80	\$10,513.36
0902	\$19,765.38	\$15,951.47	\$14,778.09	\$13,446.05
0903	\$24,834.35	\$20,043.41	\$18,568.43	\$16,893.95
0904	\$31,437.99	\$25,373.13	\$23,507.02	\$21,386.44
1001	\$16,831.12	\$14,840.92	\$12,878.99	\$11,623.92
1002	\$21,843.54	\$19,259.58	\$16,714.88	\$15,085.96
1003	\$30,848.94	\$27,201.54	\$23,607.55	\$21,306.33
1101	\$20,769.12	\$18,826.04	\$15,298.02	\$13,889.01
1102	\$29,771.37	\$26,987.91	\$21,929.94	\$19,911.46
1201	\$16,303.33	\$16,086.56	\$14,617.86	\$12,929.25
1202	\$18,945.42	\$18,692.52	\$16,985.06	\$15,023.13
1203	\$24,143.20	\$23,821.18	\$21,645.62	\$19,144.91
1301	\$18,753.78	\$14,754.52	\$13,650.25	\$12,577.40
1302	\$25,756.41	\$20,263.32	\$18,747.50	\$17,274.09
1303	\$31,753.72	\$24,982.00	\$23,114.32	\$21,296.91
1401	\$13,612.55	\$11,504.54	\$10,428.54	\$9,464.07
1402	\$18,551.15	\$15,678.15	\$14,211.03	\$12,897.84
1403	\$22,115.29	\$18,690.95	\$16,941.08	\$15,374.99
1404	\$27,968.09	\$23,637.40	\$21,425.71	\$19,444.93
1501	\$15,847.80	\$13,419.34	\$12,390.47	\$11,680.47
1502	\$20,021.42	\$16,953.64	\$15,654.59	\$14,756.10
1503	\$24,414.94	\$20,674.87	\$19,089.93	\$17,995.08
1504	\$30,426.40	\$25,764.26	\$23,789.77	\$22,424.74
1601	\$15,533.64	\$14,031.96	\$13,070.63	\$12,059.03
1602	\$20,264.89	\$18,306.10	\$17,051.03	\$15,731.56
1603	\$25,376.27	\$22,921.11	\$21,350.31	\$19,697.83
1701	\$17,820.73	\$14,542.47	\$13,383.22	\$12,049.61
1702	\$22,388.61	\$18,269.97	\$16,813.84	\$15,137.80
1703	\$26,683.18	\$21,774.43	\$20,040.27	\$18,042.21
1704	\$34,276.43	\$27,969.66	\$25,740.70	\$23,174.01
1801	\$20,313.59	\$16,642.63	\$14,456.07	\$12,965.38
1802	\$28,641.97	\$23,466.18	\$20,382.70	\$18,282.54
1803	\$45,069.39	\$36,924.80	\$32,074.17	\$28,767.63
1901	\$19,269.00	\$16,518.53	\$14,561.32	\$14,347.69
1902	\$35,009.99	\$30,011.70	\$26,456.98	\$26,067.43
1903	\$57,623.23	\$49,396.95	\$43,545.72	\$42,906.40
2001	\$14,490.63	\$11,878.39	\$10,904.49	\$9,872.48
2002	\$19,001.97	\$15,576.05	\$14,300.56	\$12,944.96
2003	\$23,756.78	\$19,473.21	\$17,877.27	\$16,183.95
2004	\$30,492.37	\$24,994.57	\$22,946.25	\$20,772.26
2101	\$26,544.95	\$26,544.95	\$23,657.82	\$21,697.46
5001				\$2,489.72
5101				\$10,657.88
5102				\$26,084.70

CMG	Payment Rate Tier 1	Payment Rate Tier 2	Payment Rate Tier 3	Payment Rate No Comorbidity
5103				\$12,569.54
5104				\$33,300.96

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

Table 6 illustrates the methodology for adjusting the federal prospective payments (as described in sections VI.A. through VI.F. of this final rule). The following examples are based on two hypothetical Medicare beneficiaries, both classified into CMG 0110 (without comorbidities). The unadjusted federal prospective payment rate for CMG 0110 (without comorbidities) appears in Table 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 0.8297, 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 0.8756, and a teaching status adjustment of 0.0784.

To calculate each IRF's labor and non-labor portion of the federal prospective payment, we begin by taking the unadjusted federal prospective payment rate for CMG 0110 (without comorbidities) from Table 5. Then, we multiply the labor-related share for FY 2017 (70.9 percent) described in section VI.C. of this final rule by the unadjusted federal prospective payment rate. To determine the non-labor portion of the federal prospective payment rate, we subtract the labor portion of the federal payment from the unadjusted federal prospective payment.

To compute the wage-adjusted federal prospective payment, we multiply the labor

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

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

TABLE 6: Example of Computing the IRF FY 2017 Federal Prospective Payment

Steps		Rural Facility A (Spencer Co., IN)	Urban Facility B (Harrison Co., IN)
1	Unadjusted Federal Prospective Payment	\$33,368.50	\$33,368.50
2	Labor Share	X 0.709	X 0.709
3	Labor Portion of Federal Payment	= \$23,658.27	= \$23,658.27
4	CBSA-Based Wage Index (shown in the Addendum, Tables A and B)	X 0.8297	X 0.8756
5	Wage-Adjusted Amount	= \$19,629.27	= \$20,715.18
6	Non-Labor Amount	+ \$9,710.23	+ \$9,710.23
7	Wage-Adjusted Federal Payment	= \$29,339.50	= \$30,425.41
8	Rural Adjustment	X 1.149	X 1.000
9	Wage- and Rural-Adjusted Federal Payment	= \$33,711.09	= \$30,425.41
10	LIP Adjustment	X 1.0156	X 1.0454

Steps		Rural Facility A (Spencer Co., IN)	Urban Facility B (Harrison Co., IN)
11	FY 2017 Wage-, Rural- and LIP-Adjusted Federal Prospective Payment Rate	= \$34,236.98	= \$31,806.72
12	FY 2017 Wage- and Rural-Adjusted Federal Prospective Payment	\$33,711.09	\$30,425.41
13	Teaching Status Adjustment	X 0	X 0.0784
14	Teaching Status Adjustment Amount	= \$0.00	= \$2,385.35
15	FY 2017 Wage-, Rural-, and LIP-Adjusted Federal Prospective Payment Rate	+ \$34,236.98	+ \$31,806.72
16	Total FY 2017 Adjusted Federal Prospective Payment	= \$34,236.98	= \$34,192.08

Thus, the adjusted payment for Facility A would be \$34,236.98 and the adjusted payment for Facility B would be \$34,192.08.

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

A. Update to the Outlier Threshold Amount for FY 2017

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 2016 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, 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 2017, we proposed to use FY 2015 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 2016. 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 2.8 percent in FY 2016. Therefore, we proposed to update the outlier threshold amount from \$8,658 for FY 2016 to \$8,301 for FY 2017 to maintain estimated outlier payments at approximately 3 percent of total estimated aggregate IRF payments for FY 2017.

We note that, as we typically do, we updated our data between the FY 2017 IRF PPS proposed and final rules to ensure that we use the most recent available data in calculating IRF PPS payments. This updated data includes a more complete set of claims for FY 2015. Based on our analysis using this updated data, we now estimate that IRF outlier payments as a percentage of total estimated payments are approximately 2.7 percent in FY 2016. Therefore, we will update the outlier threshold amount from \$8,658 for FY 2016 to \$7,984 for FY 2017 to maintain estimated outlier payments at approximately 3 percent of total estimated aggregate IRF payments for FY 2017.

We received 7 public comments on the proposed update to the FY 2017 outlier threshold amount to maintain estimated outlier payments at approximately 3 percent of total estimated IRF payments, which are summarized below.

Comment: Commenters, while supportive of maintaining estimated payments for outlier payments at approximately 3 percent, suggested that CMS review its methodology for setting the outlier threshold amount and modify as needed so that the full 3 percent is paid as outlier payments. Some commenters suggested implementing a forecast error correction if the full amount of the outlier pool is not paid out.

Response: We will continue to monitor our IRF outlier policies to ensure that they continue to compensate IRFs appropriately for treating unusually high-cost patients and, thereby, promote access to care for patients who are likely to require unusually high-cost care. As we have indicated in previous IRF PPS final rules, we do not make adjustments to IRF PPS payment rates for the sole purpose of accounting for differences between projected and actual outlier payments. We use the best available data at the time to establish an outlier threshold for IRF PPS payments prior to the beginning of each fiscal year to help ensure that estimated outlier

payments for that fiscal year will equal 3 percent of total estimated IRF PPS payments. We analyze expenditures annually, and if there is a difference from our projection, that information is used to make a prospective adjustment to lower or raise the outlier threshold for the upcoming fiscal year. We believe a retrospective adjustment would not be appropriate, given that we do not recoup or make excess payments to hospitals.

If outlier payments for a given year turn out to be greater than projected, we do not recoup money from hospitals; if outlier payments for a given year are lower than projected, we do not make an adjustment to account for the difference. Payments for a given discharge in a given fiscal year are generally intended to reflect or address the prospective average costs of that discharge in that year; that goal would be undermined if we adjusted IRF PPS payments to account for “underpayments” or “overpayments” in IRF outliers in previous years.

Comment: One commenter recommended that we expand the outlier pool from 3 percent to 5 percent in order to ensure that payments are more equitably distributed within the IRF payment system. However, this same commenter noted that such an expansion in the outlier pool could inappropriately reward facilities for inefficiencies. Several other commenters stated that expanding the outlier pool would be inappropriate for this same reason.

Response: We refer readers to the 2002 IRF PPS final rule (66 FR 41316, 41362 through 41363), for a discussion of the rationale for setting the outlier threshold amount for the IRF PPS so that estimated outlier payments would equal 3 percent of total estimated payments. For the 2002 IRF PPS final rule, we analyzed various outlier policies using 3, 4, and 5 percent of the total estimated payments, and we concluded that an outlier policy set at 3 percent of total estimated payments would optimize the extent to which we could reduce the financial risk to IRFs of caring for high-cost patients, while still providing for adequate payments for all other

(non-high cost outlier) cases. We believe that the outlier policy of 3 percent of total estimated payments optimizes the extent to which we can encourage facilities to continue to take patients that are likely to have unusually high costs, while still providing adequate payment for all other cases. Increasing the outlier pool would leave less money available to cover the costs of non-outlier cases, due to the fact that we would implement such a change in a budget-neutral manner. We believe that our current outlier policy, to set outlier payments at 3 percent of total payments, is consistent with the statute and the goals of the prospective payment system.

Comment: Several commenters recommended that CMS impose a cap on the amount of outlier payments an individual IRF can receive under the IRF PPS.

Response: Comments regarding the amount of outlier payments an individual IRF can receive are outside the scope of this rule. However, any future consideration given to imposing a limit on outlier payments would have to be carefully analyzed and would need to take into account any effect on access to IRF care it would have for certain high-cost populations.

Final Decision: Having carefully considered the public comments received and also taking into account the most recent available data, we are finalizing the outlier threshold amount of \$7,984 to maintain estimated outlier payments at approximately 3 percent of total estimated aggregate IRF payments for FY 2017. This update is effective October 1, 2016.

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

In accordance with the methodology stated in the FY 2004 IRF PPS final rule (68 FR 45674, 45692 through 45694), we proposed to apply a ceiling to IRFs' CCRs. Using the methodology described in that final rule, we proposed to update the national urban and rural CCRs for IRFs, as well as the national CCR ceiling for FY 2017, based on analysis of the most recent data that is available. We apply the national urban and rural CCRs in the following

situations:

- New IRFs that have not yet submitted their first Medicare cost report.
- IRFs whose overall CCR is in excess of the national CCR ceiling for FY 2017, as

discussed below.

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

Specifically, for FY 2017, we proposed to estimate a national average CCR of 0.562 for rural IRFs, which we calculated by taking an average of the CCRs for all rural IRFs using their most recently submitted cost report data. Similarly, we proposed to estimate a national average CCR of 0.435 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. We used FY 2013 IRF cost report data for the proposed rule. (Please note that we erroneously stated in the proposed rule that we used FY 2014 cost report data.) For this final rule, we have used the most recent available cost report data (FY 2014). This includes all IRFs whose cost reporting periods begin on or after October 1, 2013, and before October 1, 2014. If, for any IRF, the FY 2014 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 2013) settled cost report for that IRF. We do not use cost report data from before FY 2004 for any IRF because changes in IRF utilization since FY 2004 resulting from the 60 percent rule and IRF medical review activities suggest that these older data do not adequately reflect the current cost of care. Using the updated FY 2014 cost report data for this final rule, we estimate a national average CCR of 0.522 for rural IRFs, and a national average CCR of 0.421 for urban IRFs.

In accordance with past practice, we proposed to set the national CCR ceiling at 3 standard deviations above the mean CCR. Using this method, we proposed a national CCR ceiling of 1.36 for FY 2017. This means that, if an individual IRF's CCR were to exceed this proposed ceiling of 1.36 for FY 2017, we would replace the IRF's CCR with the appropriate proposed national average CCR (either rural or urban, depending on the geographic location of the IRF). We calculated the proposed national CCR ceiling by:

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

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

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

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

Using the updated FY 2014 cost report data for this final rule, we estimate a national average CCR ceiling of 1.29, using this same methodology.

We did not receive any comments on the proposed update to the IRF CCR ceiling and the urban/rural averages for FY 2017.

Final Decision: As we did not receive any comments on the proposed updates to the IRF CCR ceiling and the urban/rural averages for FY 2017, we are finalizing the national average urban CCR at 0.421, the national average rural CCR at 0.522, and the national CCR ceiling at 1.29 for FY 2017. These updates are effective October 1, 2016.

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

A. Background and Statutory Authority

We seek to promote higher quality and more efficient health care for Medicare beneficiaries, and our efforts are furthered by QRPs coupled with public reporting of that information. Section 3004(b) of the Affordable Care Act amended section 1886(j)(7) of the Act, 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 (CAHs). Beginning with the FY 2014 payment determination and subsequent years, 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 payment determination and subsequent years, 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).

The Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) imposed new data reporting requirements for certain PAC providers, including IRFs. For information on the statutory background of the IMPACT Act, please refer to the FY 2016 IRF PPS final rule (80 FR 47080 through 47083).

In the FY 2016 IRF PPS final rule, we reviewed general activities and finalized the general timeline and sequencing of such activities that will occur under the IRF QRP. For further information, please refer to the FY 2016 IRF PPS final rule (80 FR 40708 through 47128). In addition, we established our approach for identifying cross-cutting measures and

process for the adoption of measures, including the application and purpose of the Measures Application Partnership (MAP) and the notice-and-comment rulemaking process (80 FR 47080 through 47084). For information on these topics, please refer to the FY 2016 IRF PPS final rule (80 FR 47080).

B. General Considerations Used for Selection of Quality, Resource Use, and Other 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 3 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). Overall, we strive to promote high quality and efficiency in the delivery of health care to the beneficiaries we serve. Performance improvement leading to the highest-quality health care requires continuous evaluation to identify and address performance gaps and reduce the unintended consequences that may arise in treating a large, vulnerable, and aging population. QRPs, coupled with public reporting of quality information, are critical to the advancement of health care quality improvement efforts. Valid, reliable, relevant quality measures are fundamental to the effectiveness of our QRPs. Therefore, selection of quality measures is a priority for us in all of our QRPs.

In the IRF PPS FY 2017 proposed rule (81 FR 24178), we proposed to adopt for the IRF QRP one measure that we are specifying under section 1899B(c)(1) of the Act to meet the Medication Reconciliation domain, that is, Drug Regimen Review Conducted with Follow-Up

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>

for Identified Issues-Post Acute Care Inpatient Rehabilitation Facility Quality Reporting Program. Further, we proposed to adopt for the IRF QRP three measures to meet the resource use and other measure domains identified in section 1899B(d)(1) of the Act. These measures include: (1) Total Estimated Medicare Spending per Beneficiary: Medicare Spending Per Beneficiary-Post Acute Care Inpatient Rehabilitation Facility Quality Reporting Program; (2) Discharge to Community: Discharge to Community-Post Acute Care Inpatient Rehabilitation Facility Quality Reporting Program, and (3) Potentially Preventable 30-Day Post-Discharge Readmission Measure for Inpatient Rehabilitation Facility Quality Reporting Program. We also proposed an additional measure, which is not required under the IMPACT Act: (4) Potentially Preventable Within Stay Readmission Measure for Inpatient Rehabilitation Facilities.

In our development and specification of measures, we employed a transparent process in which we seek input from stakeholders and national experts and engage in a process that allows for pre-rulemaking input on each measure, as required by section 1890A of the Act. To meet this requirement, we provided the following opportunities for stakeholder input: Our measure development contractor convened technical expert panels (TEPs) that included stakeholder experts and patient representatives on July 29, 2015, for the Drug Regimen Review Conducted with Follow-Up for Identified Issues measures; on August 25, 2015, September 25, 2015, and October 5, 2015, for the Discharge to Community measures; on August 12 and 13, 2015, and October 14, 2015, for the Potentially Preventable 30-Day Post-Discharge Readmission Measures and Potentially Preventable Within Stay Readmission Measure for IRFs; and on October 29 and 30, 2015, for the Medicare Spending per Beneficiary (MSPB) measures. In addition, we released draft quality measure specifications for public comment for the Drug Regimen Review Conducted with Follow-Up for Identified Issues measures from September 18, 2015, to October

6, 2015; for the Discharge to Community measures from November 9, 2015, to December 8, 2015; for the Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRFs and Potentially Preventable Within Stay Readmission Measure for IRFs from November 2, 2015 to December 1, 2015; and for the MSPB measures from January 13, 2016 to February 5, 2016. We implemented a public mailbox, PACQualityInitiative@cms.hhs.gov, for the submission of public comments. This PAC mailbox is accessible on our post-acute care quality initiatives Web site at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-of-2014-Data-Standardization-and-Cross-Setting-MeasuresMeasures.html>.

Additionally, we sought public input from the NQF-convened MAP Post-Acute Care, Long-Term Care Workgroup during the annual in-person meeting held December 14 and 15, 2015. The MAP, composed of multi-stakeholder groups, is tasked to provide input on the selection of quality and efficiency measures described in section 1890(b)(7)(B) of the Act.

The MAP reviewed each IMPACT Act-related measure, as well as other quality measures proposed in this rule for use in the IRF QRP. For more information on the MAP's recommendations, please refer to the MAP 2016 Final Recommendations to HHS and CMS public report at

http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx.

For measures that do not have NQF endorsement, or which are not fully supported by the MAP for use in the IRF QRP, we proposed for the IRF QRP for the purposes of satisfying the measure domains required under the IMPACT Act, measures that closely align with the national priorities identified in the National Quality Strategy (<http://www.ahrq.gov/workingforquality/>)

and for which the MAP supports the measure concept. Further discussion as to the importance and high-priority status of these proposed measures in the IRF setting is included under each quality measure in this final rule.

Although we did not solicit feedback on General Considerations Used for Selection of Quality, Resource Use, and Other Measures for the IRF QRP, we received a number of comments, which are summarized with our responses below.

Comment: One commenter supported CMS's intention to select measures that are already incorporated in various quality reporting programs to minimize burden. One commenter commented that CMS should recognize burden of data collection and focus on measures that are the most clinically relevant and actionable to the facility and patients. Additionally, the commenter recommended that CMS use minimum standards in the development of new measures so that they are as clear and consistent across facilities as possible.

Response: We appreciate the commenters' support of CMS's intention to select measures that are already incorporated in the various quality reporting programs to minimize burden. In addition, we note that we strive to strike a balance between minimizing burden and addressing gaps in quality of care as we continue to expand the IRF QRP. We interpret the commenter's suggestion that CMS apply minimum standards in its measure development to suggest that we simplify our approach to quality measure development itself. We will take these recommendations into consideration in our future measure development.

We also received several comments related to the proposed measures, the IMPACT Act, NQF endorsement, the NQF MAP review process, and the use of TEPs, which are addressed below.

Comment: We received several comments supporting the goals of the IMPACT Act and the implementation of cross-setting measures across PAC settings as required by the IMPACT Act. One commenter appreciated the use of TEPs and input of stakeholders. These commenters noted the importance of functional status measures and recommended that CMS include additional functional status measures in future iterations. Also, one of the commenters indicated that achieving standardized and interoperable patient assessment data will allow for better cross-setting comparisons of quality and will support the development of better quality measures with uniform risk standardization.

Response: We believe that standardizing patient assessment data will allow for the exchange of data among PAC providers in order to facilitate care coordination and improve patient outcomes. We appreciate the importance of functional status measures and will consider inclusion of additional measures. As with our measure development process, we will continue to use TEPs, public comments, open door forums, and the pre-rulemaking process in order to gather stakeholder input on all measures under development.

Comment: One commenter recommended that CMS seek an increased level of patient engagement in order to discern what quality measures are of greatest value to patients.

Response: We value the patient perspective in the measure development process. We have employed a transparent process in which we seek input from stakeholders, as described earlier. We have also have taken several steps to engage stakeholders, including patients, in all TEPs, public comments, and special open door forums. In addition, a summary of the IMPACT Act measure TEP proceedings, public comments, and special open door forums is available on the PAC Quality Initiatives Downloads and Videos 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](https://www.cms.gov/Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html)

Patient engagement is a priority for CMS, and we will continue to take steps to include the patient perspective, especially with regard to assembling TEP, which review and comment on our measure development activities.

Comment: Several commenters recommended that CMS delay implementation of proposed measures until NQF has completed its review and has endorsed measures that are appropriate for the specific characteristics of the IRF patient population. A few commenters suggested that CMS seek NQF's formal consensus development process instead of a time-limited endorsement, as it was perceived that the time-limited endorsement was not sufficient.

Response: We received several comments regarding the NQF endorsement status for the proposed measures, and acknowledge the commenters' recommendation to submit the measures to the NQF prior to implementation. We consider and propose appropriate measures that have been endorsed by the NQF whenever possible. However, when this is not feasible because there is no NQF-endorsed measure, we utilize our statutory authority that allows the Secretary to specify a measure for the IRF QRP that is not NQF-endorsed where, as in the case for the proposed measures, we have not been able to identify other measures that are endorsed or adopted by a consensus organization. While we appreciate the importance of consensus endorsement and intend to seek such endorsement, we must balance the need to address gaps in quality and adhere to statutorily required timelines as in the case of the quality and resource use measures that we proposed to address the IMPACT Act. In regard to the comments surrounding time-limited endorsement, NQF uses time-limited endorsement for measures that meet all of the NQF's endorsement criteria with the exception of field testing and are critical to advancing quality improvement. When measures are granted this two-year endorsement rather than the

traditional three-year period, measure developers must test the measure and return results to NQF within the two-year window to maintain the endorsement. We wish to clarify that we have not yet sought endorsement of the proposed measures, time-limited or otherwise.

Comment: Several commenters stated the NQF MAP committee did not endorse the proposed measures; instead, the commenters recommended that CMS delay measure implementation until the measures are fully developed and tested and brought back to the NQF for further consideration. One commenter further stated that TEP members and other stakeholders who provided feedback in the measure development process did not support measures moving forward without further testing.

Response: We interpret this comment to address the activities of the Measures Application Partnership, a multi-stakeholder partnership convened by NQF that provides input to the U.S. Department of Health and Human Services (HHS) on its selection of measures for certain Medicare programs. We would like to clarify that the MAP “encouraged continued development” for the proposed measures. According to the MAP, the term “encourage continued development” is applied when a measure addresses a critical program objective or promotes alignment, but is in an earlier stage of development. In contrast, the MAP uses the phrase “do not support” when it does not support the measure at all.

Since the MAP recommendation of “encourage continued development” for the proposed measures during the December 2015 NQF-convened PAC LTC MAP meeting, further refinement of measure specifications and testing of measure validity and reliability have been performed. These efforts have included: a pilot test in 12 post-acute care settings, including IRFs, to determine the feasibility of assessment items for use in calculation of the Drug Regimen Review Conducted with Follow-Up for Identified Issues measure, and further development of

the risk-adjusted models for the Discharge to Community, Medicare Spending per Beneficiary, Potentially Preventable Readmissions, and Potentially Preventable Within Stay Readmissions Measure for Inpatient Rehabilitation Facilities measures. Additional information regarding testing is further described in the specific measure sections. Additional information regarding testing that was performed since the MAP Meeting, TEP meetings, and public comment periods is further described below in our responses to comments on individual proposed measures.

For these reasons, we believe that the measures have been fully and robustly developed, and believe they are appropriate for implementation and should not be delayed.

Comment: Several commenters, including MedPAC, expressed concern regarding the standardization and interoperability of the proposed measures as they perceived the measures to have different inclusion/exclusion criteria, episode constructions and risk factors, and therefore do not meet the mandate of the IMPACT Act. The commenters expressed further concern about future implications of such variations and recommend delaying implementation until measures are standardized and interoperable across PAC settings. One commenter further indicated that the measure names were different for each setting, pointing out the words “IRF QRP” or “Inpatient Rehabilitation Facility” were included in the measures’ titles to designate a difference in the measure in each setting. One commenter stated implementing the quality measures in an unstandardized fashion would result in additional costs in the future for aligning measures between PAC providers.

MedPAC suggested that the measures use uniform definitions, specifications, and risk-adjustment methods, conveying that findings from their work on a unified PAC payment system suggest overlap or similar care provided for Medicare beneficiaries with similar needs across PAC settings. As a result of this work, MedPAC recommended that the IMPACT Act measures

be standardized to facilitate quality comparison across PAC settings to inform Medicare beneficiary choice and provide an opportunity for CMS to evaluate the value of PAC services, noting that differences in rates should reflect differences in quality of care rather than differences in the way rates are constructed.

Response: We wish to clarify that the IMPACT Act requires that the patient assessment instruments be modified to enable the submission of standardized data, for purposes such as interoperability. However, measures themselves are not “interoperable.”

CMS, in collaboration with our measure contractors, developed the proposed measures with the intent to standardize the measure methodology so that we are able to detect variation among PAC providers in order to be able to assess differences in quality of care. For example, the proposed patient assessment-based quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC IRF QRP, was developed across PAC settings with uniform definitions and specifications. This measure is not risk adjusted. The standardized development of this assessment-based measure follows the mandate of the IMPACT Act to develop standardized patient assessment-based measures for the four PAC settings (section 1899B(c)(1) of the Act). The resource use and other measures, Discharge to the Community-PAC IRF QRP and All-Condition Risk-Adjusted Potentially Preventable Hospital Readmissions Rates –PAC IRF QRP were developed to be uniform across the PAC settings in terms of their definitions, measure calculations, and risk-adjustment approach where applicable. However, there is variation in each measure primarily due to the data sources for each PAC setting. Further, the risk-adjustment approach for the resource use and other IMPACT Act measures is aligned, but is tailored to each measure based on measure testing results. Adjusting for relevant case-mix characteristics in each setting improves the validity and explanatory power of risk

adjustment models, and helps ensure that any differences in measure performance reflect differences in the care provided rather than differences in patient case-mix. We employ this approach to measure development to enable appropriate cross-setting comparisons in PAC settings and to maximize measure reliability and validity. It should be noted that sections 1899B(c)(3)(B) and 1899B(d)(3)(B) of the Act require that quality measures and resource use and other measures be risk adjusted, as determined appropriate by the Secretary.

Comment: Several commenters expressed concerns regarding the validity and reliability of IMPACT Act measures and encouraged CMS to conduct further analysis of data to ensure comparability across post-acute care settings, prior to implementation and public reporting of data.

Response: We have tested for validity and reliability all of the IMPACT Act measures, and the results of that testing is available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html>.

We intend to continue to monitor the reliability and validity of the IRF QRP measures, including whether the measures are reliable and valid for cross-setting purposes.

Comment: A few commenters voiced concern regarding the burden of implementing the proposed measures in the IRF setting. One commenter requested that CMS proceed cautiously to ensure new measures are associated with minimal administrative and data collection burden. One commenter expressed concern that the new measures increase provider burden by increasing the time providers are ensuring data accuracy and move the focus away from patient-centered care towards a more metric-based focus.

Response: We appreciate the importance of avoiding undue burden on providers and will continue to evaluate and consider any unnecessary burden associated with the implementation of the IRF QRP. We wish to note that the three proposed resource measures are claims-based, and will require no additional data collection by providers and thus result in minimal increases in burden. The measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues, is calculated using assessment data and requires the addition of three items to the IRF-PAI, also requiring minimal additional burden. We address the issue of burden further under section XI.B. of this final rule.

Comment: Several commenters recommended that CMS engage in several activities which would afford greater transparency with stakeholders regarding proposed measure development. These commenters also requested that measures undergo field testing with providers prior to implementation. Commenters also requested that more detailed measure specifications be posted in order to enable providers to evaluate measure design decisions. Commenters requested that IRF providers be provided with confidential preview reports as a part of a “dry run” process as this would enable providers to review data and provide CMS with feedback on potential technical issues with proposed measure. Finally, the commenters requested that measure data be provided to IRFs on a patient level on a quarterly basis, similar to other quality reporting programs, in order to make effective use of the data and improve performance.

Response: With regard to the testing and analytic results provided for this measure, since the December 2015 MAP meeting, further refinement of measure specifications and testing of measure validity and reliability have been performed.

We direct readers to the Measure Specifications for Measures Adopted in the FY 2017 IRF QRP final rule are available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient->

Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html, which include detailed information regarding measure specifications, including results of the final risk adjustment models for the resource use measures. For resource use measures, our testing results are within range for similar outcome measures finalized in public reporting and value-based purchasing programs, including the All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from IRFs (NQF #2502), previously adopted into the IRF QRP.

We appreciate the comment requesting that we provide performance data on IRF QRP measures on a more frequent, such as quarterly, basis in order to promote quality improvement. We wish to note that the proposed claims-based measures are based on 2 consecutive years of data in order to ensure a sufficient sample size to reliably assess IRFs' performance. However, we will investigate the feasibility and usability of providing IRFs with information more frequently, such as unadjusted counts of PPRs and discharge data. We also appreciate the commenters' suggestions related to the implementation of dry run activities, such as confidential reports, for the purposes of identifying any technical issues prior to public reporting, as was successfully provided in the fall of 2015 for the All Cause Unplanned Readmission Measure for 30 Days Post Discharge from IRFs (NQF#2502). We wish to note that we intend to provide confidential feedback reports beginning in October, 2017, as described in section VIII.O of this final rule, and we believe that the reports could serve as an opportunity for providers to extend to us any technical issues they may discover. We note that, as described in section VIII.P of this final rule, we are unable at this time to provide patient-level information for the claims-based measure, for example, the readmission measures, because such data comes from a separate

entity. Finally, we wish to note that we intend to continue refining specifications, and we will consider pilot testing in addition to the performance testing that we currently conduct.

C. Policy for Retention of IRF QRP Measures Adopted for Previous Payment Determinations

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 was actively removed, suspended, or replaced, when we initially adopt a measure for the IRF QRP for a payment determination. For the purpose of streamlining the rulemaking process, when we initially adopt a measure for the IRF QRP for a payment determination, this measure will also be adopted for all subsequent years or until we remove, suspend, or replace the measure. 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 did not propose any changes to the policy for retaining IRF QRP measures adopted for previous payment determinations.

D. Policy for Adopting Changes to IRF QRP Measures

In the CY 2013 OPPS/ASC final rule (77 FR 68500 through 68507), we adopted a subregulatory process to incorporate NQF 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 nonsubstantive change and the subregulatory process for nonsubstantive changes, please refer to the CY 2013 OPPS/ASC final rule (77 FR 68500). We did not propose any changes to the policy for adopting changes to IRF QRP measures.

E. Quality Measures Previously Finalized for and Currently Used in the IRF QRP

A history of the IRF QRP quality measures adopted for the FY 2014 payment determinations and subsequent years is presented in Table 7. The year in which each quality measure was first adopted and implemented, and then subsequently re-proposed or revised, if applicable, is displayed. The initial and subsequent annual payment determination years are also shown in Table 7. For more information on a particular measure, please refer to the IRF PPS final rule and associated page numbers referenced in Table 7.

Although we did not solicit feedback, we received a number of comments about previously finalized measures for and currently used in the IRF QRP. These comments are summarized and addressed below.

Comment: One commenter was generally supportive of implementing additional quality measures in post-acute care, especially those that are cross-setting, but recommended that CMS take steps to validate data and assess provider experience during the first several months of reporting. One commenter supported the retention of the NHSN measures.

With regard to the measure, Pressure Ulcers that are New or Worsened (Short-Stay) (NQF #0678), several commenters recommended that future updates to the measure include clinical guidance that is consistent with the most current evidence-based processes.

We received several comments about the NHSN Facility-Wide Inpatient Hospital-Onset Clostridium difficile Infection (CDI) Outcome Measure (NQF #1717). Several commenters recommended that CMS revise the measure so that it is only reported at the first site of discovery, to avoid penalizing IRFs for the presence of the infection that started in a previous care setting.

With regard to the measure, Application of Percent of Residents Experiencing One or More Falls with Major Injury (NQF #0674), one commenter had concerns that the nature of IRF

treatment could lead to a frequency of falls higher than other settings. The commenter was concerned that including assisted falls in the definition of falls for this quality measure was inappropriate and confusing and recommended that CMS revisit the definition and include only falls with major injury.

Response: With regard to the measure Pressure Ulcers that are New or Worsened (Short-Stay) (NQF #0678), we intend to continue our ongoing measure development and refinement activities to inform the ongoing evaluation of this measure, to ensure that the measure remains valid and reliable to inform quality improvement within and across each PAC setting, and to fulfill the public reporting goals of quality reporting programs, including the IRF QRP. Reviewing the most current evidence-based clinical guidance is part of that process.

With regard to the comments about the NHSN Facility-Wide Inpatient Hospital-Onset CDI Outcome Measure (NQF #1717), the scope of NQF#1717 extends to acute care hospitals, long-term care hospitals, inpatient rehabilitation facilities, and cancer hospitals. The same measure specifications are used by all these facility types to report Clostridium difficile Laboratory Identified events to NHSN, and these measure specifications differentiate between community-onset events, which include events that had their onset at another healthcare facility, from healthcare-associated events, which are attributed to the facility reporting the event. CDC reports only incident healthcare-associated events on behalf of healthcare facilities to CMS. To limit Clostridium difficile Laboratory Identified event reporting to the first site of discovery offers opportunity for missed “true” healthcare-associated events (those recognized on or after hospital day 4) and would require additional data collection and investigation burden to users.

The measure specifications for NQF#1717, by design, align with the NHSN LabID Event protocol, which was developed to require minimal investigation on the part of facilities and to

provide a proxy measure of infection. Dates of admission and specimen collection are required and can easily be collected via electronic methods and identified as healthcare-associated (HO) or community-onset (CO). To require a facility to determine if a CDI LabID Event had been identified in another facility would call for manual review of medical records and potential communication with transferring facilities. In accordance with protocol guidelines, IRF-based events are categorized as “incident” (first non-duplicate event for the IRF) in addition to a CO/HO categorization. IRF facilities are analyzed independently of any other reporting facility, that is, are viewed as separate reporting facilities.

With regard to the measure, An Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674), we would like to clarify that the quality measure adopted for the IRF QRP includes only falls with a major injury, satisfying the IMPACT Act domain, Incidence of Major Falls. Thus, falls with no injury, such as those that may be considered near-falls, are not included in the measure.

Additionally, we received a number of comments specifically regarding quality measures that were finalized into the IRF QRP in the FY 2016 IRF PPS final rule.

Comment: Many commenters indicated they had concerns about the use of CARE items or the use of the CARE Tool. Several commenters were concerned that the CARE items added to the IRF-PAI would be duplicative and confusing to clinicians because they are similar to the FIM® items. One commenter suggested the FIM® items be removed from the IRF-PAI. Other commenters supported continued use of the FIM® instrument, and recommended a delay in implementing the CARE items. The commenters also had concerns about the precision of the CARE items and the patient types with which it was tested, the timeframe and six-point scale, as well as NQF-endorsement of CARE items in all settings. Commenters noted that the FIM®

instrument has demonstrated increased efficiency and decreased length of stay, and allows for comparison of functional gains across patients with similar debility levels. Commenters had concerns about lack of credentialing of staff for CARE items, as this is currently required for the FIM® instrument to ensure consistent scoring.

Several commenters were concerned about the training, data submission specifications, and support CMS has provided for items being required on the IRF-PAI Version 1.4, effective October 1, 2016. Several commenters were concerned that the data were collected for research purposes. One commenter indicated there was a discrepancy between the IRF-PAI Training Manual and the data submission specifications. Many commenters had concerns about the need for further clarification about the patient's usual status, and another commenter requested clarification about the use of a dash to indicate that an item was not assessed.

Response: As we did not propose any changes to the quality measures finalized in the FY 2016 IRF PPS final rule, these comments are outside the scope of the proposed rule. However, we would like to clarify that we are not implementing the CARE Tool for the IRF QRP to meet the mandate of the IMPACT Act. To meet the mandate, and to standardize quality measures and data items, we retained the use of the IRF-PAI as the collection instrument for all IRF settings. We incorporated items from the CARE Tool into new section GG: Functional Abilities and Goals of the IRF-PAI Version 1.4 in order to calculate the 5 function quality measures that were adopted into the IRF QRP in the IRF PPS FY 2016 Final Rule (80 FR 47100 through 47120). The items were not added to the IRF-PAI for research purposes.

We refer the readers to the FY 2016 final rule (80 FR 47100 through 47120) for discussion about the testing, including the rating scale, reliability, validity and sensitivity of the function items that were added to the IRF-PAI, as well as plans for ongoing evaluation of these

items, and concerns related to FIM® item duplication. With regard to training and provider support, we agree with the importance of thorough and comprehensive training. Information about and materials from each IRF QRP training are posted on the IRF-QRP Training Web site at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/Training.html>. With regard to the comments related to the data specifications, we post data specifications and errata on the CMS Web site as soon as we are able so that vendors and providers are able to review and understand the valid data codes for all items and the associated requirements: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Software.html>.

TABLE 7: Quality Measures Previously Finalized for and Currently Used in the IRF Quality Reporting Program

Measure Title	Final Rule	Data Collection Start Date	Annual Payment Determination: Initial and Subsequent APU Years
National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138)	Adopted an application of the measure in FY 2012 IRF PPS Final Rule (76 FR 47874 through 47886)	October 1, 2012	FY 2014 and subsequent years
	Adopted the NQF-endorsed version and expanded measure (with standardized infection ratio) in CY 2013 OPPS/ASC Final Rule (77 FR 68504 through 68505)	January 1, 2013	FY 2015 and subsequent years
Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678)	Adopted application of measure in FY 2012 IRF PPS final rule (76 FR 47876 through 47878)	October 1, 2012	FY 2014 and subsequent years
	Adopted a non-risk-adjusted application of the NQF-endorsed version in CY 2013 OPPS/ASC Final Rule (77 FR 68500 through 68507)	January 1, 2013	FY 2015 and subsequent years
	Adopted the risk adjusted, NQF-endorsed version in FY 2014 IRF PPS Final Rule (78 FR 47911 through 47912)	October 1, 2014	FY 2017 and subsequent years
	Adopted in the FY 2016	October 1, 2015	FY 2018 and subsequent years

Measure Title	Final Rule	Data Collection Start Date	Annual Payment Determination: Initial and Subsequent APU Years
	IRF PPS final rule (80 FR 47089 through 47096) to fulfill IMPACT Act requirements		
Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680)	Adopted in FY 2014 IRF PPS final rule (78 FR 47906 through 47911)	October 1, 2014	FY 2017 and subsequent years
Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431)	Adopted in FY 2014 IRF PPS final rule (78 FR 47905 through 47906)	October 1, 2014	FY 2016 and subsequent years
All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from Inpatient Rehabilitation Facilities (NQF #2502)	Adopted in FY 2014 IRF PPS final rule (78 FR 47906 through 47910)	N/A	FY 2017 and subsequent years
	Adopted the NQF-endorsed version in FY 2016 IRF PPS final rule (80 FR 47087 through 47089)	N/A	FY 2018 and subsequent years
National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure (NQF #1716)	Adopted in the FY 2015 IRF PPS final rule (79 FR 45911 through 45913)	January 1, 2015	FY 2017 and subsequent years
National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset Clostridium difficile Infection (CDI) Outcome Measure (NQF #1717)	Adopted in the FY 2015 IRF PPS final rule (79 FR 45913 through 45914)	January 1, 2015	FY 2017 and subsequent years

Measure Title	Final Rule	Data Collection Start Date	Annual Payment Determination: Initial and Subsequent APU Years
Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674)	Adopted an application of the measure in FY 2016 IRF PPS Final Rule (80 FR 47096 through 47100)	October 1, 2016	FY 2018 and subsequent years
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)	Adopted an application of the measure in the FY 2016 IRF PPS final rule (80 FR 47100 through 47111)	October 1, 2016	FY 2018 and subsequent years
IRF Functional Outcome Measure: Change in Self-Care for Medical Rehabilitation Patients (NQF #2633)*	Adopted in the FY 2016 IRF PPS final rule (80 FR 47111 through 47117)	October 1, 2016	FY 2018 and subsequent years
IRF Functional outcome Measure: Change in Mobility Score for Medical Rehabilitation (NQF #2634)*	Adopted in the FY 2016 IRF PPS final rule (80 FR 47117 through 47118)	October 1, 2016	FY 2018 and subsequent years
IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (NQF #2635)	Adopted in the FY 2016 IRF PPS final rule (80 FR 47118 through 47119)	October 1, 2016	FY 2018 and subsequent years
IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (NQF #2636)	Adopted in the FY 2016 IRF PPS final rule (80 FR 47119 through 47120)	October 1, 2016	FY 2018 and subsequent years

* These measures were under review at NQF when they were finalized for use in the IRF QRP. These measures are now NQF-endorsed.

F. IRF QRP Quality, Resource Use and Other Measures Finalized for the FY 2018 Payment

Determination and Subsequent Years

For the FY 2018 payment determinations and subsequent years, in addition to the quality measures we are retaining under our policy described in section VIII.C. of this final rule, we proposed four new measures. Three of these measures were developed to meet the requirements of IMPACT Act. They are:

- (1) MSPB -PAC IRF QRP,
- (2) Discharge to Community-PAC IRF QRP, and
- (3) Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP.

The fourth measure is: (4) Potentially Preventable Within Stay Readmission Measure for IRFs. The measures are described in more detail below.

For the risk-adjustment of the resource use and other measures, we understand the important role that sociodemographic status plays in the care of patients. However, we continue to have concerns about holding providers to different standards for the outcomes of their patients of diverse sociodemographic status because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We routinely monitor the impact of sociodemographic status on providers' results for our measures.

The NQF is currently undertaking a two-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate. For 2 years, NQF will conduct a trial of temporarily allowing inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will issue recommendations on future permanent inclusion of sociodemographic factors. During the trial, measure developers are expected to submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model.

Furthermore, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) is conducting research to examine the impact of sociodemographic status on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act. We will closely examine the findings of the ASPE reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

We received several comments on the impact of sociodemographic status on quality measures, resource use, and other measures, which are summarized with our responses below.

Comment: Several commenters indicated their support for the inclusion of sociodemographic status adjustment in quality measures, resource use, and other measures. Commenters suggested that failure to account for patient characteristics could penalize IRFs for providing care to a more medically-complex and socioeconomically disadvantaged patient population and affect provider performance. Some commenters expressed concerns about standardization and interoperability of the measures as it pertain to risk-adjusting, particularly for SDS characteristics. Many commenters recommended incorporating socioeconomic factors as risk-adjustors for the measures, and several commenters suggested conducting additional testing and NQF-endorsement prior to implementation of these measures. In addition, many commenters recommended including functionality as an additional risk-adjustment factor, and several commenters suggested risk-adjustment for cognitive impairment.

A few commenters, including MedPAC, did not support risk-adjustment of measures by socioeconomic status (SES) or SDS status. One commenter did not support risk-adjustment, stating that it can hide disparities and create different standards of care for IRFs based on the demographics in the facility. MedPAC reiterated that risk adjustment can hide disparities in care

and suggested that risk-adjustment reduces pressure on providers to improve quality of care for low-income Medicare beneficiaries. Instead, MedPAC supported peer provider group comparisons with providers of similar low-income beneficiary populations. Another commenter stated that SDS factors should not be included in measures that examine the patient during an IRF stay, but should only be considered for measures evaluating care after the IRF discharge.

Response: We appreciate the considerations and suggestions conveyed in relation to the measures and the importance in balancing appropriate risk adjustment along with ensuring access to high-quality care. We note that in the measures that are risk adjusted, we do take into account characteristics associated with medical complexity, as well as factors such as age where appropriate to do so. For those cross-setting post-acute measures, such as those intended to satisfy the IMPACT Act domains that use the patient assessment-based data elements for risk adjustment, we have either made such items standardized, or intend to do so as feasible. With regard to the incorporation of additional factors, such as function, we have and will continue to take such factors into account, which would include further testing as part of our ongoing measure development monitoring activities. As discussed previously, we intend to seek NQF endorsement for our measures.

We also received suggestions pertaining to the incorporation of socioeconomic factors as risk-adjustors for the measures, including in those measures that pertain to after the patient was discharged from the IRF, additional testing and/or NQF endorsement prior to implementation of these measures, and comments that pertain to potential consequences associated with such risk adjustors and alternative approaches to grouping comparative data. We wish to reiterate that as previously discussed, NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for

sociodemographic factors is appropriate. This trial entails temporarily allowing inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will issue recommendations on future permanent inclusion of sociodemographic factors. During the trial, measure developers are encouraged to submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model. Several measures developed by CMS have been brought to NQF since the beginning of the trial. CMS, in compliance with NQF's guidance, has tested sociodemographic factors in the measures' risk models and made recommendations about whether or not to include these factors in the endorsed measure. We intend to continue engaging in the NQF process as we consider the appropriateness of adjusting for sociodemographic factors in our outcome measures.

Furthermore, the Office of the ASPE is conducting research to examine the impact of sociodemographic status on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act. We will closely examine the findings of the ASPE reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

1. Measure to Address the IMPACT Act Domain of Resource Use and Other Measures:

Total Estimated MSPB-PAC IRF QRP

We proposed an MSPB-PAC IRF QRP measure for inclusion in the IRF QRP for the FY 2018 payment determination and subsequent years. Section 1899B(d)(1)(A) of the Act requires the Secretary to specify resource use measures, including total estimated MSPB, on which PAC providers consisting of Skilled Nursing Facilities (SNFs), IRFs, Long-Term Care Hospitals

(LTCHs), and Home Health Agencies (HHAs) are required to submit necessary data specified by the Secretary.

Rising Medicare expenditures for post-acute care as well as wide variation in spending for these services underlines the importance of measuring resource use for providers rendering these services. Between 2001 and 2013, Medicare PAC spending grew at an annual rate of 6.1 percent and doubled to \$59.4 billion, while payments to inpatient hospitals grew at an annual rate of 1.7 percent over this same period.³ A study commissioned by the Institute of Medicine discovered that variation in PAC spending explains 73 percent of variation in total Medicare spending across the United States.⁴

We reviewed the NQF's consensus-endorsed measures and were unable to identify any NQF-endorsed resource use measures for PAC settings. As such, we proposed this MSPB-PAC IRF QRP measure under the Secretary's authority to specify non-NQF-endorsed measures under section 1899B(e)(2)(B) of the Act. Given the current lack of resource use measures for PAC settings, our MSPB-PAC IRF QRP measure will provide valuable information to IRF providers on their relative Medicare spending in delivering services to approximately 338,000 Medicare beneficiaries.⁵

The MSPB-PAC IRF QRP episode-based measure will provide actionable and transparent information to support IRF providers' efforts to promote care coordination and deliver high quality care at a lower cost to Medicare. The MSPB-PAC IRF QRP measure holds IRF providers accountable for the Medicare payments within an "episode of care" (episode), which includes the period during which a patient is directly under the IRF's care, as well as a

³ MedPAC, "A Data Book: Health Care Spending and the Medicare Program," (2015). 114

⁴ Institute of Medicine, "Variation in Health Care Spending: Target Decision Making, Not Geography," (Washington, DC: National Academies 2013). 2

⁵ Figures for 2013. MedPAC, "Medicare Payment Policy," Report to the Congress (2015). xvii-xviii

defined period after the end of the IRF treatment, which may be reflective of and influenced by the services furnished by the IRF. MSPB-PAC IRF QRP episodes, constructed according to the methodology described below, have high levels of Medicare spending with substantial variation. In FY 2013 and FY 2014, Medicare FFS beneficiaries experienced 613,089 MSPB-PAC IRF QRP episodes triggered by admission to an IRF. The mean payment-standardized, risk-adjusted episode spending for these episodes is \$30,370. There is substantial variation in the Medicare payments for these MSPB-PAC IRF QRP episodes - ranging from approximately \$15,059 at the 5th percentile to approximately \$55,912 at the 95th percentile. This variation is partially driven by variation in payments occurring following IRF treatment.

Evaluating Medicare payments during an episode creates a continuum of accountability between providers that should improve post-treatment care planning and coordination. While some stakeholders throughout the measure development process supported the MSPB-PAC measures and believed that measuring Medicare spending was critical for improving efficiency, others believed that resource use measures did not reflect quality of care in that they do not take into account patient outcomes or experience beyond those observable in claims data. However, IRFs involved in the provision of high quality PAC care as well as appropriate discharge planning and post-discharge care coordination would be expected to perform well on this measure since beneficiaries would likely experience fewer costly adverse events (for example, avoidable hospitalizations, infections, and emergency room usage). Further, it is important that the cost of care be explicitly measured so that, in conjunction with other quality measures, we can publicly report which IRFs provide high quality care at lower cost.

We developed an MSPB-PAC measure for each of the four PAC settings. We proposed an LTCH-specific MSPB-PAC measure in the FY 2017 IPPS/LTCH proposed rule (81 FR 25216

through 25220), an IRF-specific MSBP-PAC measure in the FY 2017 IRF PPS proposed rule (81 FR 24197 through 24201), a SNF-specific MSPB-PAC measure in the FY 2017 SNF proposed rule (81 FR 24258 through 24262), and a HHA-specific MSBP-PAC measure in the CY 2017 HH proposed rule (81 FR 43760 through 43764). The four setting-specific MSPB-PAC measures are closely aligned in terms of episode construction and measure calculation. Each of the MSPB-PAC measures assess Medicare Part A and Part B spending during an episode, and the numerator and denominator are defined similarly for each of the MSPB-PAC measures. However, setting-specific measures allow us to account for differences between settings in payment policy, the types of data available, and the underlying health characteristics of beneficiaries. For example, we use the IRF setting-specific rehabilitation impairment categories (RICs) in the MSPB-PAC IRF QRP risk adjustment model, as detailed below.

The MSPB-PAC measures mirror the general construction of the inpatient prospective payment system (IPPS) hospital MSPB measure, which was adopted for the Hospital IQR Program beginning with the FY 2014 program, and was implemented in the Hospital VBP Program beginning with the FY 2015 program. The measure was endorsed by the NQF on December 6, 2013 (NQF #2158).⁶ The hospital MSPB measure evaluates hospitals' Medicare spending relative to the Medicare spending for the national median hospital during a hospital MSPB episode. It assesses Medicare Part A and Part B payments for services performed by hospitals and other healthcare providers during a hospital MSPB episode, which is comprised of the periods immediately prior to, during, and following a patient's hospital stay.^{7,8} Similarly, the MSPB-PAC measures assess all Medicare Part A and Part B payments for FFS claims with a

⁶ QualityNet, "Measure Methodology Reports: Medicare Spending Per Beneficiary (MSPB) Measure," (2015).

<http://www.qualitynet.org/dcs/ContentServer?pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772053996>

⁷ QualityNet, "Measure Methodology Reports: Medicare Spending Per Beneficiary (MSPB) Measure," (2015).

<http://www.qualitynet.org/dcs/ContentServer?pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772053996>

⁸ FY 2012 IPPS/LTCH PPS final rule (76 FR 51619)

start date during the episode window (which, as discussed in this section, is the time period during which Medicare FFS Part A and Part B services are counted towards the MSPB-PAC IRF QRP episode). There are differences between the MSPB-PAC measures and the hospital MSPB measure to reflect differences in payment policies and the nature of care provided in each PAC setting. For example, the MSPB-PAC measures exclude a limited set of services (for example, clinically unrelated services) provided to a beneficiary during the episode window, while the hospital MSPB measure does not exclude any services.⁹

MSPB-PAC episodes may begin within 30 days of discharge from an inpatient hospital as part of a patient's trajectory from an acute to a PAC setting. An IRF stay beginning within 30 days of discharge from an inpatient hospital would therefore be included once in the hospital's MSPB measure, and once in the IRF provider's MSPB-PAC measure. Aligning the hospital MSPB and MSPB-PAC measures in this way creates continuous accountability and aligns incentives to improve care planning and coordination across inpatient and PAC settings.

We sought and considered the input of stakeholders throughout the measure development process for the MSPB-PAC measures. We convened a TEP consisting of 12 panelists with combined expertise in all of the PAC settings on October 29 and 30, 2015 in Baltimore, Maryland. A follow-up email survey was sent to TEP members on November 18, 2015 to which seven responses were received by December 8, 2015. The MSPB-PAC TEP Summary Report is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Technical-Expert-Panel-on-Medicare-Spending-Per-Beneficiary.pdf>. The measures were also presented to the MAP Post-Acute Care/Long-Term Care (PAC/LTC) Workgroup on December 15, 2015. As the MSPB-

PAC measures were under development, there were three voting options for members: encourage continued development, do not encourage further consideration, and insufficient information.¹⁰ The MAP PAC/LTC workgroup voted to “encourage continued development” for each of the MSPB-PAC measures.¹¹ The MAP PAC/LTC workgroup’s vote of “encourage continued development” was affirmed by the MAP Coordinating Committee on January 26, 2016.¹² The MAP’s concerns about the MSPB-PAC measures, as outlined in their final report “MAP 2016 Considerations for Implementing Measures in Federal Programs: Post-Acute Care and Long-Term Care” and Spreadsheet of Final Recommendations, were taken into consideration during the measure development process and are discussed as part of our responses to public comments, described below.^{13,14}

Since the MAP’s review and recommendation of continued development, CMS continued to refine risk adjustment models and conduct measure testing for the IMPACT Act measures in compliance with the MAP’s recommendations. The IMPACT Act measures are consistent with the information submitted to the MAP and support the scientific acceptability of these measures for use in quality reporting programs.

In addition, a public comment period, accompanied by draft measures specifications, was open from January 13 to 27, 2016 and extended to February 5. A total of 45 comments on the

¹⁰ National Quality Forum, Measure Applications Partnership, “Process and Approach for MAP Pre-Rulemaking Deliberations, 2015-2016” (February 2016) <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81693>

¹¹ National Quality Forum, Measure Applications Partnership Post-Acute Care/Long-Term Care Workgroup, “Meeting Transcript - Day 2 of 2” (December 15, 2015) 104-106 <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81470>

¹² National Quality Forum, Measure Applications Partnership, “Meeting Transcript – Day 1 of 2” (January 26, 2016) 231-232 <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81637>

¹³ National Quality Forum, Measure Applications Partnership, “MAP 2016 Considerations for Implementing Measures in Federal Programs: Post-Acute Care and Long-Term Care” Final Report, (February 2016) http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx

¹⁴ National Quality Forum, Measure Applications Partnership, “Spreadsheet of MAP 2016 Final Recommendations” (February 1, 2016) <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593>

MSPB-PAC measures were received during this 3.5 week period. The comments received also covered each of the MAP's concerns as outlined in their Final Recommendations.¹⁵ The MSPB-PAC Public Comment Summary Report is available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/2016_03_24_mspb_pac_public_comment_summary_report.pdf and the MSPB-PAC Public Comment Supplementary Materials are available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/2016_03_24_mspb_pac_public_comment_summary_report_supplementary_materials.pdf: these documents contain the public comments, along with our responses including statistical analyses. The MSPB-PAC IRF QRP measure, along with the other MSPB-PAC measures, as applicable, will be submitted for NQF endorsement when feasible.

To calculate the MSPB-PAC IRF QRP measure for each IRF provider, we first defined the construction of the MSPB-PAC IRF QRP episode, including the length of the episode window as well as the services included in the episode. Next, we apply the methodology for the measure calculation. The specifications are discussed further in this section. More detailed specifications for the MSPB-PAC measures, including the MSPB-PAC IRF QRP measure, are available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html>.

a. Episode Construction

¹⁵ National Quality Forum, Measure Applications Partnership, "Spreadsheet of MAP 2016 Final Recommendations" (February 1, 2016) <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593>

An MSPB-PAC IRF QRP episode begins at the episode trigger, which is defined as the patient's admission to an IRF. The admitting facility is the attributed provider, for whom the MSPB-PAC IRF QRP measure is calculated. The episode window is the time period during which Medicare FFS Part A and Part B services are counted towards the MSPB-PAC IRF QRP episode. Because Medicare FFS claims are already reported to the Medicare program for payment purposes, IRF providers would not be required to report any additional data to CMS for calculation of this measure. Thus, there would be no additional data collection burden from the implementation of this measure.

The episode window is comprised of a treatment period and an associated services period. The treatment period begins at the trigger (that is, on the day of admission to the IRF) and ends on the day of discharge from that IRF. Readmissions to the same facility occurring within 7 or fewer days do not trigger a new episode, and instead are included in the treatment period of the original episode. When two sequential stays at the same IRF occur within 7 or fewer days of one another, the treatment period ends on the day of discharge for the latest IRF stay. The treatment period includes those services that are provided directly or reasonably managed by the IRF provider that are directly related to the beneficiary's care plan. The associated services period is the time during which Medicare Part A and Part B services (with certain exclusions) are counted towards the episode. The associated services period begins at the episode trigger and ends 30 days after the end of the treatment period. The distinction between the treatment period and the associated services period is important because clinical exclusions of services may differ for each period. Certain services are excluded from the MSPB-PAC IRF QRP episodes because they are clinically unrelated to IRF care, and/or because IRF providers may have limited influence over certain Medicare services delivered by other providers during

the episode window. These limited service-level exclusions are not counted towards a given IRF provider's Medicare spending to ensure that beneficiaries with certain conditions and complex care needs receive the necessary care. Certain services that are determined to be outside of the control of an IRF provider include planned hospital admissions, management of certain preexisting chronic conditions (for example, dialysis for end-stage renal disease (ESRD), and enzyme treatments for genetic conditions), treatment for preexisting cancers, organ transplants, and preventive screenings (for example, colonoscopy and mammograms). Exclusion of such services from the MSPB-PAC IRF QRP episode ensures that facilities do not have disincentives to treat patients with certain conditions or complex care needs.

An MSPB-PAC episode may begin during the associated services period of an MSPB-PAC IRF QRP episode in the 30 days post-treatment. One possible scenario occurs where an IRF provider discharges a beneficiary who is then admitted to an LTCH within 30 days. The LTCH claim will be included once as an associated service for the attributed provider of the first MSPB-PAC IRF QRP episode and once as a treatment service for the attributed provider of the second MSPB-PAC LTCH QRP episode. As in the case of overlap between hospital and PAC episodes discussed earlier, this overlap is necessary to ensure continuous accountability between providers throughout a beneficiary's trajectory of care, as both providers share incentives to deliver high quality care at a lower cost to Medicare. Even within the IRF setting, one MSPB-PAC IRF QRP episode may begin in the associated services period of another MSPB-PAC IRF QRP episode in the 30 days post-treatment. The second IRF claim would be included once as an associated service for the attributed IRF provider of the first MSPB-PAC IRF QRP episode and once as a treatment service for the attributed IRF provider of the second MSPB-PAC IRF QRP episode. Again, this ensures that IRF providers have the same incentives throughout both

MSPB-PAC IRF QRP episodes to deliver quality care and engage in patient-focused care planning and coordination. If the second MSPB-PAC IRF QRP episode were excluded from the second IRF provider's MSPB-PAC IRF QRP measure, that provider would not share the same incentives as the first IRF provider of the first MSPB-PAC IRF QRP episode. The MSPB-PAC IRF QRP measure was designed to benchmark the resource use of each attributed provider against what their spending is expected to be as predicted through risk adjustment. As discussed further in this section, the measure takes the ratio of observed spending to expected spending for each episode and then takes the average of those ratios across all of the attributed provider's episodes. The measure is not a simple sum of all costs across a provider's episodes, thus mitigating concerns about double counting.

b. Measure Calculation

Medicare payments for Part A and Part B claims for services included in MSPB-PAC IRF QRP episodes, defined according to the methodology previously discussed, are used to calculate the MSPB-PAC IRF QRP measure. Measure calculation involves determination of the episode exclusions, the approach for standardizing payments for geographic payment differences, the methodology for risk adjustment of episode spending to account for differences in patient case mix, and the specifications for the measure numerator and denominator.

(1) Exclusion Criteria

In addition to service-level exclusions that remove some payments from individual episodes, we exclude certain episodes in their entirety from the MSPB-PAC IRF QRP measure to ensure that the MSPB-PAC IRF QRP measure accurately reflects resource use and facilitates fair and meaningful comparisons between IRF providers. The episode-level exclusions are as follows:

- Any episode that is triggered by an IRF claim outside the 50 states, D.C., Puerto Rico, and U.S. Territories.
- Any episode where the claim(s) constituting the attributed IRF provider's treatment have a standard allowed amount of zero or where the standard allowed amount cannot be calculated.
- Any episode in which a beneficiary is not enrolled in Medicare FFS for the entirety of a 90-day lookback period (that is, a 90-day period prior to the episode trigger) plus episode window (including where a beneficiary dies), or is enrolled in Part C for any part of the lookback period plus episode window.
- Any episode in which a beneficiary has a primary payer other than Medicare for any part of the 90-day lookback period plus episode window.
- Any episode where the claim(s) constituting the attributed IRF provider's treatment include at least one related condition code indicating that it is not a prospective payment system bill.

(2) Standardization and Risk Adjustment

Section 1899B(d)(2)(C) of the Act requires that the MSPB-PAC measures are adjusted for the factors described under section 1886(o)(2)(B)(ii) of the Act, which include adjustment for factors such as age, sex, race, severity of illness, and other factors that the Secretary determines appropriate. Medicare payments included in the MSPB-PAC IRF QRP measure are payment-standardized and risk-adjusted. Payment standardization removes sources of payment variation not directly related to clinical decisions and facilitates comparisons of resource use across geographic areas. We proposed to use the same payment standardization methodology that was used in the NQF-endorsed hospital MSPB measure. This methodology removes

geographic payment differences, such as wage index and geographic practice cost index (GPCI), incentive payment adjustments, and other add-on payments that support broader Medicare program goals including indirect graduate medical education (IME) and hospitals serving a disproportionate share of uninsured patients (DSH).¹⁶

Risk adjustment uses patient claims history to account for case-mix variation and other factors that affect resource use but are beyond the influence of the attributed IRF provider. To assist with risk adjustment, we created mutually exclusive and exhaustive clinical case mix categories using the most recent institutional claim in the 60 days prior to the start of the MSPB-PAC IRF QRP episode. The beneficiaries in these clinical case mix categories have a greater degree of clinical similarity than the overall IRF patient population, and allow us to more accurately estimate Medicare spending. Our MSPB-PAC IRF QRP measure, adapted for the IRF setting from the NQF-endorsed hospital MSPB measure, uses a regression framework with a 90-day hierarchical condition category (HCC) lookback period and covariates including the clinical case mix categories, HCC indicators, age brackets, indicators for originally disabled, ESRD enrollment, and long-term care status, and selected interactions of these covariates where sample size and predictive ability make them appropriate. We sought and considered public comment regarding the treatment of hospice services occurring within the MSPB-PAC IRF QRP episode window. Given the comments received, we proposed to include the Medicare spending for hospice services but risk adjust for them, such that MSPB-PAC IRF QRP episodes with hospice services are compared to a benchmark reflecting other MSPB-PAC IRF QRP episodes with hospice services. We believe this strikes a balance between the measure's intent of evaluating

¹⁶ QualityNet, "CMS Price (Payment) Standardization – Detailed Methods" (Revised May 2015)
<https://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228772057350>

Medicare spending and ensuring that providers do not have incentives against the appropriate use of hospice services in a patient-centered continuum of care.

We proposed to use RICs in response to commenters' concerns about the risk adjustment approach for the MSPB-PAC IRF QRP measure. Commenters suggested the use of case mix groups (CMGs); however, we believed that the use of RICs may be more appropriate given that the other covariates incorporated in the model partially account for factors in CMGs (for example, age and certain HCC indicators). RICs do not account for functional status as CMGs do, as the functional status information in CMGs is based on the IRF-PAI. Given the move toward standardized data that was mandated by the IMPACT Act, we have chosen to defer risk adjustment for functional status until standardized data become available. We sought comments on whether the use of CMGs would be appropriate to include in the MSPB-PAC IRF QRP risk adjustment model.

We understand the important role that sociodemographic factors, beyond age, play in the care of patients. However, we continue to have concerns about holding providers to different standards for the outcomes of their patients of diverse sociodemographic status because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We will monitor the impact of sociodemographic status on providers' results on our measures.

The NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate. For 2 years, NQF will conduct a trial of temporarily allowing inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will issue recommendations on

future permanent inclusion of sociodemographic factors. During the trial, measure developers are expected to submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model.

Furthermore, ASPE is conducting research to examine the impact of sociodemographic status on quality measures, resource use, and other measures under the Medicare program as required under the IMPACT Act. We will closely examine the findings of the ASPE reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

While we conducted analyses on the impact of age by sex on the performance of the MSPB-PAC IRF QRP risk-adjustment model, we did not propose to adjust the MSPB-PAC IRF QRP measure for socioeconomic factors. As this MSPB-PAC IRF QRP measure would be submitted for NQF endorsement, we prefer to await the results of this trial and study before deciding whether to risk adjust for socioeconomic factors. We will monitor the results of the trial, studies, and recommendations. We invited public comment on how socioeconomic and demographic factors should be used in risk adjustment for the MSPB-PAC IRF QRP measure.

(3) Measure Numerator and Denominator

The MPSB-PAC IRF QRP measure is a payment-standardized, risk-adjusted ratio that compares a given IRF provider's Medicare spending against the Medicare spending of other IRF providers within a performance period. Similar to the hospital MSPB measure, the ratio allows for ease of comparison over time as it obviates the need to adjust for inflation or policy changes.

The MSPB-PAC IRF QRP measure is calculated as the ratio of the MSPB-PAC Amount for each IRF provider divided by the episode-weighted median MSPB-PAC Amount across all IRF providers. To calculate the MSPB-PAC Amount for each IRF provider, one calculates the

average of the ratio of the standardized episode spending over the expected episode spending (as predicted in risk adjustment), and then multiplies this quantity by the average episode spending level across all IRF providers nationally. The denominator for an IRF provider's MSPB-PAC IRF QRP measure is the episode-weighted national median of the MSPB-PAC Amounts across all IRF providers. An MSPB-PAC IRF QRP measure of less than 1 indicates that a given IRF provider's Medicare spending is less than that of the national median IRF provider during a performance period. Mathematically, this is represented in equation (A) below:

$$(A) \text{ MSPB-PAC IRF Measure}_j = \frac{\text{MSPB-PAC Amount}_j}{\text{National Median MSPB-PAC Amount}} =$$

$$\frac{\left(\frac{1}{n_j} \sum_{i \in \{I_j\}} \frac{Y_{ij}}{\widehat{Y}_{ij}}\right) \left(\frac{1}{n} \sum_j \sum_{i \in \{I_j\}} Y_{ij}\right)}{\text{Episode-Weighted Median of IRF Providers' MSPB-PAC Amount}}$$

where

- Y_{ij} = attributed standardized spending for episode i and provider j
- \widehat{Y}_{ij} = expected standardized spending for episode i and provider j , as predicted from risk adjustment
- n_j = number of episodes for provider j
- n = total number of episodes nationally
- $i \in \{I_j\}$ = all episodes i in the set of episodes attributed to provider j .

c. Data Sources

The MSPB-PAC IRF QRP resource use measure is an administrative claims-based measure. It uses Medicare Part A and Part B claims from FFS beneficiaries and Medicare eligibility files.

d. Cohort

The measure cohort includes Medicare FFS beneficiaries with an IRF treatment period ending during the data collection period.

e. Reporting

We intend to provide initial confidential feedback to providers, prior to public reporting of this measure, based on Medicare FFS claims data from discharges in CY 2015 and 2016. We intend to publicly report this measure using claims data from discharges in CY 2016 and 2017.

We proposed to use a minimum of 20 episodes for reporting and inclusion in the IRF QRP. For the reliability calculation, as described in the measure specifications for which a link has been provided above, we used 2 years of data (FY 2013 and FY 2014) to increase the statistical reliability of this measure. The reliability results support the 20 episode case minimum, and 99.74 percent of IRF providers had moderate or high reliability (above 0.4).

We invited public comment on our proposal to adopt the MSPB-PAC IRF QRP measure for the IRF QRP. The comments we received, with our responses, appear below.

Comment: Several commenters expressed concern about the lack of NQF endorsement for proposed measures; some believed that the measure should not be finalized until NQF endorsement is obtained.

Response: Regarding the lack of NQF endorsement, refer to section VIII.B. of this final rule where we also discuss this topic.

Comment: Some commenters recommended the use of uniform single MSPB-PAC measure that could be used to compare providers' resource use across settings, but the commenters also recognized that we do not have a uniform PPS for all the PAC settings currently. In the absence of a single PAC PPS, the commenters recommended a single MSPB-PAC measure for each setting that could be used to compare providers within a setting. Under a

single measure, the episode definitions, service inclusions/exclusions, and risk adjustment methods would be the same across all PAC settings.

Response: The four separate MSPB-PAC measures reflect the unique characteristics of each PAC setting and the population it serves. The four setting-specific MSPB-PAC measures are defined as consistently as possible across settings given the differences in the payment systems for each setting, and types of patients served in each setting. We have taken into consideration these differences and aligned the specifications, such as episode definitions, service inclusions/exclusions and risk adjustment methods for each setting, to the extent possible while ensuring the accuracy of the measures in each PAC setting.

Each of the measures assess Medicare Part A and Part B spending during the episode window which begins upon admission to the provider's care and ends 30 days after the end of the treatment period. The service-level exclusions are harmonized across settings. The definition of the numerator and denominator is the same across settings. However, specifications differ between settings when necessary to ensure that the measures accurately reflect patient care and align with each setting's payment system. For example, Medicare pays LTCHs and IRFs a stay-level payment based on the assigned MS-LTC-DRG and CMG, respectively, while SNFs are paid a daily rate based on the RUG level, and HHA providers are reimbursed based on a fixed 60-day period for standard home health claims. While the definition of the episode window is consistent across settings and is based on the period of time that a beneficiary is under a given provider's care, the duration of the treatment period varies to reflect how providers are reimbursed under the PPS that applies to each setting. The length of the post-treatment period is consistent between settings. There are also differences in services covered under the PPS that applies to each setting: for example, durable medical equipment, prosthetics, orthotics, and

supplies (DMEPOS) claims are covered LTCH, IRF, and SNF services but are not covered HHA services. This affects the way certain first-day service exclusions are defined for each measure.

We recognize that beneficiaries may receive similar services as part of their overall treatment plan in different PAC settings, but believe that there are some important differences in beneficiaries' care profiles that are difficult to capture in a single measure that compares resource use across settings.

Also, the risk adjustment models for the MSPB-PAC measures share the same covariates to the greatest extent possible to account for patient case mix. However, the measures also incorporate additional setting-specific information where available to increase the predictive power of the risk adjustment models. For example, the MSPB-PAC LTCH QRP risk adjustment model uses MS-LTC-DRGs and Major Diagnostic Categories (MDCs) and the MSPB-PAC IRF QRP model includes Rehabilitation Impairment Categories (RICs). The HH and SNF settings do not have analogous variables that directly reflect a patient's clinical profile.

We will continue to work towards a more uniform measure across settings as we gain experience with these measures, and we plan to conduct further research and analyses about comparability of resource use measures across settings for clinically similar patients, different treatment periods and windows, risk adjustment, service exclusions, and other factors.

Comment: A few commenters noted that the MSPB-PAC measures are resource use measures that are not a standalone indicator of quality.

Response: We appreciate the comment regarding the proposed MSPB-PAC measures as resource use measures. The MSPB-PAC IRF QRP measure is one of five QRP measures that were proposed in the FY 2017 IRF PPS proposed rule for inclusion in the IRF QRP: in addition to the MSPB-PAC IRF QRP measure, these proposed measures were the Discharge to

Community – PAC IRF QRP measure (81 FR 24201 through 24204), the Potentially Preventable 30-day Post-Discharge Readmission Measure for IRF QRP (81 FR 24204 through 24206), the Potentially Preventable Within Stay Readmission Measure for IRFs (81 FR 242096 through 24207), and the Drug Regimen Review Conducted with Follow-Up for Identified Issues – PAC IRF QRP measure (81 FR 24207 through 24209). As part of the IRF QRP, the MSPB-PAC IRF QRP measure will be paired with quality measures; we direct readers to section VIII.E. of this final for a discussion of quality measures previously finalized for use in the IRF QRP. We believe it is important that the cost of care be explicitly measured so that, in conjunction with other quality measures, we can publicly report which IRF providers are involved in the provision of high quality care at lower cost.

Comment: One commenter recommended that proposed quality measures obtain the support of a TEP including IRF representatives to ensure the applicability of the measures to the IRF setting.

Response: We thank the commenter for their recommendation. As discussed in the proposed rule (81 FR 24198), we convened a TEP consisting of 12 panelists with combined expertise in PAC settings, including IRFs, on October 29 and 30, 2015, in Baltimore, Maryland. TEPs do not formally support or endorse measures. However, their feedback on risk adjustment, episode windows, exclusions, and other key elements of measure construction were incorporated into measure development. The MSPB-PAC TEP Summary Report website is listed above in this section.

Comment: Several commenters recommended that the risk adjustment model for the MSPB-PAC IRF QRP measure include variables for SES/SDS factors. A commenter recommended that a "fairer" approach than using SES/SDS factors as risk adjustment variables

would be to compare resource use levels that have not been adjusted for SES/SDS factors across peer providers (that is, providers with similar shares of beneficiaries with similar SES characteristics).

Response: With regard to the suggestions that the model include sociodemographic factors and the suggestion pertaining to an approach with which to convey data comparisons, we refer readers to section VIII.F of this final rule where we also discuss these topics.

Comment: Some commenters recommended that additional variables be included in risk adjustment to better capture clinical complexity. A few commenters suggested the inclusion of functional and cognitive status, other patient assessment data and patient-reported data. Commenters recommended that additional variables should include obesity, amputations, CVAs (hemiplegia/paresis), ventilator status, and discharged against medical advice.

Response: We thank the commenters for their suggestions. HCC indicators that are already included in the risk adjustment model account for amputations, hemiplegia, and paresis. We believe that the other risk adjustment variables adequately adjust for ventilator dependency and obesity by accounting for HCCs, clinical case mix categories, and prior inpatient and ICU length of stay. Excluding patients who are discharged against medical advice may create incentives for providers to use this discharge status code to remove high-cost patients from their MSPB-PAC measure calculation. Patient-reported data is not currently available on Medicare FFS claims. The addition of such data would likely be burdensome on IRF providers and the reliability of the data would need to be thoroughly tested before use in Medicare programs.

We recognize the importance of accounting for beneficiaries' functional and cognitive status in the calculation of predicted episode spending. We considered the potential use of functional status information in the risk adjustment models for the MSPB-PAC measures.

However, we decided not to include this information derived from current setting-specific assessment instruments given the move towards standardized data as mandated by the IMPACT Act. We will revisit the inclusion of functional status in these measures' risk adjustment models in the future when the standardized functional status data mandated by the IMPACT Act become available. Once they are available, we will take a gradual and systematic approach in evaluating how they might be incorporated. We intend to implement any changes if appropriate based on testing.

Comment: A few commenters expressed concern that the measures will give incentive to IRFs to avoid admitting medically complex patients, which would result in unintended consequences.

Response: To mitigate the risk of creating incentives for IRFs to avoid admitting medically complex patients, who may be at higher risk for poor outcomes and higher costs, we have included factors related to medical complexity in the risk adjustment methodology for the MSPB-PAC IRF QRP measure. We also intend to conduct ongoing monitoring to assess for potential unintended consequences associated with the implementation of these measures.

Comment: Several commenters recommended that IRF interrupted stays be excluded as those patients would appear more expensive for receiving necessary care outside of the control of the IRF (that is, during the interruption).

Response: We believe that IRFs are in a position to influence a patient's experience and outcomes after the initial discharge from the IRF, including the likelihood and intensity of IRF readmissions. As noted in the proposed rule (81 FR 24197), the proposed MSPB-PAC IRF QRP measure will support IRF providers' efforts to promote care coordination.

Comment: Several commenters expressed concerns over the inclusion of spending that occurs within the thirty day post-discharge timeframe in the measure, believing that providers do not have sufficient control over the patient in the post-treatment period.

Response: We believe that the post-treatment period may be reflective of and influenced by the services furnished by the PAC provider, therefore, including the 30-day post-treatment period in the MSPB-PAC IRF QRP measure creates a continuum of accountability between providers and may incentivize improvements in post-treatment care planning and coordination. The MSPB-PAC measures complement the NQF-endorsed hospital MSPB measure: as they all include a period during which post-treatment spending is attributed to the provider, this accountability incentivizes acute and PAC providers to engage in appropriate discharge planning and post-treatment care coordination to minimize the likelihood of costly adverse events, such as avoidable hospitalizations.

Comment: Several commenters recommended first day service exclusions for IRFs that are the same as other PAC settings, such as SNFs.

Response: As discussed in the MSPB-PAC Measure Specifications, the website that is listed above in this section, treatment services occurring on the first day of MSPB-PAC episodes are subject to exclusions related to prior institutional care such as discharge care services. IRFs provide more intense hospital-level care and have physicians or midlevel practitioners evaluate patients upon admission, which enables the facility to influence many services delivered on the first day of the PAC stay. As such, only a limited number of discharge care services are excluded. Moreover, the NQF-endorsed hospital MSPB measure includes a period during which post-treatment spending is attributed to the provider; this accountability incentivizes acute and PAC providers to engage in appropriate discharge planning and post-treatment care coordination

Comment: Several commenters recommended that short stays be excluded from the MSPB-PAC IRF QRP measure as these patients are identified as not being suitable for IRF care.

Response: We believe that including short stay discharges in the measure promotes timely and accurate pre-admission screening, as well as discharge planning and post-discharge care coordination. Including IRF short stays maintains consistency across the MSPB-PAC measures to the greatest extent possible. Short stays constitute a very small share of IRF stays nationally; in FY 2014, approximately 1.8 percent of IRF stays were short stay discharges. Moreover, the MSPB-PAC IRF QRP measure's methodology excludes outlier episodes. Therefore, we do not believe that inclusion of short stays in the MSPB-PAC IRF QRP measure will unfairly disadvantage or advantage an IRF provider in their performance on the measure. Moreover, including short stay discharges incentivizes providers to maintain beneficiaries under their care for the appropriate length of time, and will not incentivize IRFs to prematurely discharge their beneficiaries. We are finalizing the MSPB-PAC IRF QRP measure to include short stay discharges after careful consideration of the commenter's input.

Comment: Several commenters recommended the use of CMGs for risk adjustment instead of RICs to more fully and accurately account for and explain variances in resource utilization and case mix in the IRF setting. Commenters noted that CMGs incorporate functional status and are weighted to account for patients' predicted resource requirements, while RICs only indicate patients' overall medical condition; as such there can be wide variation of reimbursement within a single RIC.

Response: We have carefully considered the commenters feedback and are proceeding to finalize the measure as proposed. We believe the beneficiary's principal diagnosis or impairment as provided by the RIC currently supports the accurate estimation of Medicare

spending while also reflecting clinical information that is accurately and consistently coded on IRF claims. The inclusion of RICs as variables in the MSPB-PAC IRF QRP risk adjustment model maintains consistency between MSPB-PAC resource use measures for each setting to the greatest extent possible, in that the other settings' MSPB-PAC measures do not incorporate variables reflecting the beneficiaries' functional status information. We may reconsider how to consistently incorporate functional status into the risk adjustment models for the MSPB-PAC measures once standardized data mandated by the IMPACT Act become available in the future. Furthermore, the covariates incorporated in the MSPB-PAC IRF QRP risk adjustment model partially account for two factors in CMGs – age and co-morbidities. For co-morbidities, the risk adjustment specifications use flags for Hierarchical Condition Categories (HCCs) defined by scanning inpatient, Part B physician/carrier, and outpatient claims during a 90-day lookback period. We appreciate commenters' thoughtful input and thank them for their engagement with this measure through the rulemaking process.

Comment: A few commenters suggested that descriptive statistics on the measure score by provider-level characteristics (for example, urban/rural status and bed size) would be useful to evaluate measure design decisions.

Response: Table 8 shows the MSPB-PAC IRF provider scores by provider characteristics, calculated using FY 2013 and FY 2014 data.

TABLE 8. MSPB-PAC IRF Scores by Provider Characteristics

[illegible]

Provider Characteristic	Number of Providers	Mean Score	Score Percentile						
			1st	10th	25th	50th	75th	90th	99th
For profit	345	1.01	0.82	0.91	0.97	1.01	1.06	1.10	1.24
Non-profit	569	0.97	0.76	0.87	0.91	0.97	1.02	1.07	1.28
Government	142	0.98	0.81	0.88	0.93	0.98	1.02	1.08	1.23
Unknown	113	0.97	0.77	0.88	0.91	0.96	1.02	1.06	1.31
Census Division									
New England	36	1.03	0.86	0.92	0.97	1.03	1.08	1.12	1.16
Middle Atlantic	153	0.99	0.79	0.89	0.93	0.98	1.05	1.09	1.30
East North Central	210	0.96	0.79	0.87	0.91	0.97	1.01	1.04	1.10
West North Central	103	0.94	0.76	0.83	0.90	0.94	0.99	1.03	1.14
South Atlantic	162	1.00	0.80	0.90	0.95	1.00	1.05	1.09	1.24
East South Central	78	1.00	0.87	0.92	0.96	0.99	1.04	1.08	1.11
West South Central	226	1.01	0.85	0.91	0.95	1.02	1.05	1.12	1.24
Mountain	91	1.00	0.79	0.88	0.93	0.98	1.05	1.12	1.99
Pacific	106	0.96	0.74	0.83	0.89	0.95	1.02	1.08	1.32
Other	4	0.88	0.74	0.74	0.79	0.90	0.97	0.98	0.98
Bed Count									
0 - 49	114	1.01	0.79	0.91	0.96	1.01	1.04	1.12	1.25
50 - 99	188	1.01	0.80	0.91	0.96	1.00	1.06	1.09	1.30
100 - 199	231	0.98	0.79	0.87	0.92	0.98	1.04	1.10	1.24
200 - 299	184	0.97	0.77	0.87	0.91	0.97	1.01	1.07	1.44
300 +	452	0.98	0.77	0.88	0.92	0.97	1.03	1.08	1.24
No. of Episodes									
0 - 99	108	1.00	0.74	0.81	0.89	0.97	1.07	1.16	1.83
100 - 249	344	0.97	0.76	0.86	0.90	0.96	1.03	1.08	1.31
250 - 499	327	0.98	0.82	0.88	0.92	0.97	1.03	1.08	1.23
500 - 1000	216	0.99	0.83	0.92	0.95	0.99	1.03	1.07	1.17
1000 +	174	1.01	0.89	0.94	0.97	1.02	1.06	1.08	1.15
Teaching									
Non-teaching	1,059	0.98	0.77	0.88	0.93	0.98	1.03	1.08	1.24
Patient to ADC less than 10%	63	0.99	0.83	0.90	0.93	0.98	1.04	1.08	1.30
Patient to ADC 10% -- 20%	36	1.02	0.83	0.89	0.95	1.00	1.06	1.11	1.83
Patient to ADC greater than 20%	11	1.00	0.88	0.90	0.91	1.03	1.06	1.07	1.08

Comment: One commenter recommended that a geographic-specific (for example, state or regional) median should be used instead of the national median, citing differences in cost, patient population, and regulation.

Response: As noted in the proposed rule (81 FR 24199), we proposed to use the same payment standardization methodology that used in the NQF-endorsed hospital MSPB measure to account for variation in Medicare spending. This methodology removes geographic payment differences, such as wage index and geographic practice cost index (GPCI), incentive payment adjustments, and other add-on payments that support broader Medicare program goals including indirect graduate medical education (IME) and hospitals serving a disproportionate share of uninsured patients (DSH). We believe that this approach accounts for the differences that the commenter raises while also maintaining consistency with the NQF-endorsed hospital MSPB measure's methodology for addressing regional variation through payment standardization.

Comment: Some commenters recommended that the measure be tested for reliability and validity prior to finalization.

Response: The MSPB-PAC IRF QRP measure has been tested for reliability using 2 years of data (FY 2013 and FY 2014). The reliability results support the 20 episode case minimum, and 99.74 percent of IRF providers had moderate or high reliability (above 0.4). Further details on the reliability calculation are provided in the MSPB-PAC Measure Specifications website that is listed above in this section.

Comment: Some commenters recommended an initial confidential data preview period for providers, prior to public reporting.

Response: Providers will receive a confidential preview report with 30 days for review in advance of their data and information being publically displayed.

Comment: A few commenters believed that the measure is a burden for providers.

Response: We appreciate the importance of avoiding undue burden on providers. The MSPB-PAC IRF QRP measure relies on Medicare FFS claims, which are already reported to the

Medicare program for payment purposes. PAC providers will not be required to report additional data to CMS for calculation of this measure

Comment: One commenter requested that if the measures are finalized after a trial, that the same FIM Rating system be used to eliminate confusion and ensure that providers are submitting accurate information.

Response: The MSPB-PAC IRF QRP Measure focuses on comparing resource use among providers within a given PAC setting and does not measure clinical outcomes such as severity of disability.

In summary, after consideration of the public comments we received, we are finalizing the specifications of the MSPB-PAC IRF QRP resource use measure, as proposed. A website for the measure specifications has been provided above in this section.

Specifically, we are finalizing the definition of an MSPB-PAC IRF QRP episode, beginning from episode trigger. An episode window comprises a treatment period beginning at the trigger and ended upon discharge, and associated services period beginning at the trigger and ending 30 days after the end of the treatment period. Readmissions to the same IRF within 7 or fewer days do not trigger a new episode and are instead included in the treatment period of the first episode.

We exclude certain services that are clinically unrelated to IRF care and/or because IRF providers may have limited influence over certain Medicare services delivered by other providers during the episode window. We also exclude certain episodes in their entirety from the MSPB-PAC IRF QRP measure, such as where a beneficiary is not enrolled in Medicare FFS for the entirety of the lookback period plus episode window.

We finalize the inclusion of Medicare payments for Part A and Part B claims for services included in the MSPB-PAC IRF QRP episodes to calculate the MSPB-PAC IRF QRP measure.

We are finalizing our proposal to risk adjust using covariates including age brackets, HCC indicators, prior inpatient stay length, ICU stay length, clinical case mix categories, and indicators for originally disabled, ESRD enrollment, long-term care status, and hospice claim in episode window. The measure also adjusts for geographic payment differences such as wage index and GPCI, and adjust for Medicare payment differences resulting from IME and DSH.

We calculate the individual providers' MSPB-PAC Amount which is inclusive of MSPB-PAC IRF QRP observed episode spending over the expected episode spending as predicted through risk adjustment. Individual IRF providers' scores are calculated as their individual MSPB-PAC Amount divided by the median MSPB-PAC amount across all IRFs.

2. Measure to Address the IMPACT Act Domain of Resource Use and Other Measures:

Discharge to Community-Post Acute Care (PAC) Inpatient Rehabilitation Facility (IRF) Quality Reporting Program (QRP)

Sections 1899B(d)(1)(B) and 1899B(a)(2)(E)(ii) of the Act require the Secretary to specify a measure to address the domain of discharge to community by SNFs, LTCHs, and IRFs by October 1, 2016, and HHAs by January 1, 2017. We proposed to adopt the measure, Discharge to Community-PAC IRF QRP, for the IRF QRP for the FY 2018 payment determination and subsequent years as a Medicare FFS claims-based measure to meet this requirement.

This measure 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. Specifically, this measure reports an IRF's risk-

standardized rate of Medicare FFS patients who are discharged to the community following an IRF stay, and do not have an unplanned readmission to an acute care hospital or LTCH in the 31 days following discharge to community, and who remain alive during the 31 days following discharge to community. The term “community”, for this measure, is defined as home or self care, with or without home health services, based on Patient Discharge Status Codes 01, 06, 81, and 86 on the Medicare FFS claim.^{17,18} This measure is conceptualized uniformly across the PAC settings, in terms of the definition of the discharge to community outcome, the approach to risk adjustment, and the measure calculation.

Discharge to a community setting is an important health care outcome for many patients for whom the overall goals of post-acute care include optimizing functional improvement, returning to a previous level of independence, and avoiding institutionalization. Returning to the community is also an important outcome for many patients who are not expected to make functional improvement during their IRF stay, and for patients who may be expected to decline functionally due to their medical condition. The discharge to community outcome offers a multi-dimensional view of preparation for community life, including the cognitive, physical, and psychosocial elements involved in a discharge to the community.^{19,20}

In addition to being an important outcome from a patient and family perspective, patients discharged to community settings, on average, incur lower costs over the recovery episode,

¹⁷ National Uniform Billing Committee Official UB-04 Data Specifications Manual 2017, Version 11, July 2016, Copyright 2016, American Hospital Association.

¹⁸ This definition is not intended to suggest that board and care homes, assisted living facilities, or other settings included in the definition of “community” for the purpose of this measure are the most integrated setting for any particular individual or group of individuals under the Americans with Disabilities Act (ADA) and Section 504.

¹⁹ El-Solh AA, Saltzman SK, Ramadan FH, Naughton BJ. Validity of an artificial neural network in predicting discharge destination from a postacute geriatric rehabilitation unit. Archives of physical medicine and rehabilitation. 2000;81(10):1388-1393.

²⁰ Tanwir S, Montgomery K, Chari V, Nesathurai S. Stroke rehabilitation: availability of a family member as caregiver and discharge destination. European journal of physical and rehabilitation medicine. 2014;50(3):355-362.

compared with those discharged to institutional settings.^{21,22} Given the high costs of care in institutional settings, encouraging IRFs to prepare patients for discharge to community, when clinically appropriate, may have cost-saving implications for the Medicare program.²³ Also, providers have discovered that successful discharge to community was a major driver of their ability to achieve savings, where capitated payments for post-acute care were in place.²⁴ For patients who require long-term care due to persistent disability, discharge to community could result in lower long-term care costs for Medicaid and for patients' out-of-pocket expenditures.²⁵

Analyses conducted for ASPE on PAC episodes, using a 5 percent sample of 2006 Medicare claims, revealed that relatively high average, unadjusted Medicare payments are associated with discharge to institutional settings from IRFs, SNFs, LTCHs or HHAs, as compared with payments associated with discharge to community settings.²⁶ Average, unadjusted Medicare payments associated with discharge to community settings ranged from \$0 to \$4,017 for IRF discharges, \$0 to \$3,544 for SNF discharges, \$0 to \$4,706 for LTCH discharges, and \$0 to \$992 for HHA discharges. In contrast, payments associated with discharge to non-community settings were considerably higher, ranging from \$11,847 to \$25,364 for IRF discharges, \$9,305 to \$29,118 for SNF discharges, \$12,465 to \$18,205 for LTCH discharges, and \$7,981 to \$35,192 for HHA discharges.²⁷

²¹ Dobrez D, Heinemann AW, Deutsch A, Manheim L, Mallinson T. Impact of Medicare's prospective payment system for inpatient rehabilitation facilities on stroke patient outcomes. American journal of physical medicine & rehabilitation / Association of Academic Physiatrists. 2010;89(3):198-204.

²² Gage B, Morley M, Spain P, Ingber M. Examining Post Acute Care Relationships in an Integrated Hospital System. Final Report. RTI International;2009.

²³ Ibid.

²⁴ Doran JP, Zabinski SJ. Bundled payment initiatives for Medicare and non-Medicare total joint arthroplasty patients at a community hospital: bundles in the real world. The journal of arthroplasty. 2015;30(3):353-355.

²⁵ Newcomer RJ, Ko M, Kang T, Harrington C, Hulett D, Bindman AB. Health Care Expenditures After Initiating Long-term Services and Supports in the Community Versus in a Nursing Facility. Medical Care. 2016;54(3):221-228.

²⁶ Gage B, Morley M, Spain P, Ingber M. Examining Post Acute Care Relationships in an Integrated Hospital System. Final Report. RTI International;2009.

²⁷ Ibid.

Measuring and comparing facility-level discharge to community rates is expected to help differentiate among facilities with varying performance in this important domain, and to help avoid disparities in care across patient groups. Variation in discharge to community rates has been reported within and across post-acute settings; across a variety of facility-level characteristics, such as geographic location (for example, regional location, urban or rural location), ownership (for example, for-profit or nonprofit), and freestanding or hospital-based units; and across patient-level characteristics, such as race and gender.^{28,29,30,31,32,33} Discharge to community rates in the IRF setting have been reported to range from about 60 to 80 percent.^{34,35,36,37,38,39} Longer-term studies show that rates of discharge to community from IRFs have decreased over time as IRF length of stay has decreased.^{40,41} In the IRF Medicare FFS

²⁸ Reistetter TA, Karmarkar AM, Graham JE, et al. Regional variation in stroke rehabilitation outcomes. Archives of physical medicine and rehabilitation. 2014;95(1):29-38.

²⁹ El-Solh AA, Saltzman SK, Ramadan FH, Naughton BJ. Validity of an artificial neural network in predicting discharge destination from a postacute geriatric rehabilitation unit. Archives of physical medicine and rehabilitation. 2000;81(10):1388-1393.

³⁰ March 2015 Report to the Congress: Medicare Payment Policy. Medicare Payment Advisory Commission;2015.

³¹ Bhandari VK, Kushel M, Price L, Schillinger D. Racial disparities in outcomes of inpatient stroke rehabilitation. Archives of physical medicine and rehabilitation. 2005;86(11):2081-2086.

³² Chang PF, Ostir GV, Kuo YF, Granger CV, Ottenbacher KJ. Ethnic differences in discharge destination among older patients with traumatic brain injury. Archives of physical medicine and rehabilitation. 2008;89(2):231-236.

³³ Berges IM, Kuo YF, Ostir GV, Granger CV, Graham JE, Ottenbacher KJ. Gender and ethnic differences in rehabilitation outcomes after hip-replacement surgery. American journal of physical medicine & rehabilitation / Association of Academic Physiatrists. 2008;87(7):567-572.

³⁴ Galloway RV, Granger CV, Karmarkar AM, et al. The Uniform Data System for Medical Rehabilitation: report of patients with debility discharged from inpatient rehabilitation programs in 2000-2010. American journal of physical medicine & rehabilitation / Association of Academic Physiatrists. 2013;92(1):14-27.

³⁵ Morley MA, Coots LA, Forgues AL, Gage BJ. Inpatient rehabilitation utilization for Medicare beneficiaries with multiple sclerosis. Archives of physical medicine and rehabilitation. 2012;93(8):1377-1383.

³⁶ Reistetter TA, Graham JE, Deutsch A, Granger CV, Markello S, Ottenbacher KJ. Utility of functional status for classifying community versus institutional discharges after inpatient rehabilitation for stroke. Archives of physical medicine and rehabilitation. 2010;91(3):345-350.

³⁷ Gagnon D, Nadeau S, Tam V. Clinical and administrative outcomes during publicly-funded inpatient stroke rehabilitation based on a case-mix group classification model. Journal of rehabilitation medicine. 2005;37(1):45-52.

³⁸ DaVanzo J, El-Gamil A, Li J, Shimer M, Manolov N, Dobson A. Assessment of patient outcomes of rehabilitative care provided in inpatient rehabilitation facilities (IRFs) and after discharge. Vienna, VA: Dobson DaVanzo & Associates, LLC;2014.

³⁹ Kushner DS, Peters KM, Johnson-Greene D. Evaluating Siebens Domain Management Model for Inpatient Rehabilitation to Increase Functional Independence and Discharge Rate to Home in Geriatric Patients. Archives of physical medicine and rehabilitation. 2015;96(7):1310-1318.

⁴⁰ Galloway RV, Granger CV, Karmarkar AM, et al. The Uniform Data System for Medical Rehabilitation: report of patients with debility discharged from inpatient rehabilitation programs in 2000-2010. American journal of physical medicine & rehabilitation / Association of Academic Physiatrists. 2013;92(1):14-27.

population, using CY 2013 national claims data, we discovered that approximately 69 percent of patients were discharged to the community. Greater variation in discharge to community rates is seen in the SNF setting, with rates ranging from 31 to 65 percent.^{42,43,44,45} A multi-center study of 23 LTCHs demonstrated that 28.8 percent of 1,061 patients who were ventilator-dependent on admission were discharged to home.⁴⁶ A single-center study revealed that 31 percent of LTCH hemodialysis patients were discharged to home.⁴⁷ One study noted that 64 percent of beneficiaries who were discharged from the home health episode did not use any other acute or post-acute services paid by Medicare in the 30 days after discharge.⁴⁸ However, significant numbers of patients were admitted to hospitals (29 percent) and lesser numbers to SNFs (7.6 percent), IRFs (1.5 percent), home health (7.2 percent) or hospice (3.3 percent).⁴⁹

Discharge to community is an actionable health care outcome, as targeted interventions have been shown to successfully increase discharge to community rates in a variety of post-acute settings.^{50,51,52,53} Many of these interventions involve discharge planning or specific

⁴¹ Mallinson T, Deutsch A, Bateman J, et al. Comparison of discharge functional status after rehabilitation in skilled nursing, home health, and medical rehabilitation settings for patients after hip fracture repair. Archives of physical medicine and rehabilitation. 2014;95(2):209-217.

⁴² El-Solh AA, Saltzman SK, Ramadan FH, Naughton BJ. Validity of an artificial neural network in predicting discharge destination from a postacute geriatric rehabilitation unit. Archives of physical medicine and rehabilitation. 2000;81(10):1388-1393.

⁴³ Hall RK, Toles M, Massing M, et al. Utilization of acute care among patients with ESRD discharged home from skilled nursing facilities. Clinical journal of the American Society of Nephrology : CJASN. 2015;10(3):428-434.

⁴⁴ Stearns SC, Dalton K, Holmes GM, Seagrave SM. Using propensity stratification to compare patient outcomes in hospital-based versus freestanding skilled-nursing facilities. Medical care research and review : MCRR. 2006;63(5):599-622.

⁴⁵ Wodchis WP, Teare GF, Naglie G, et al. Skilled nursing facility rehabilitation and discharge to home after stroke. Archives of physical medicine and rehabilitation. 2005;86(3):442-448.

⁴⁶ Scheinhorn DJ, Hassenpflug MS, Votto JJ, et al. Post-ICU mechanical ventilation at 23 long-term care hospitals: a multicenter outcomes study. Chest. 2007;131(1):85-93.

⁴⁷ Thakar CV, Quate-Operacz M, Leonard AC, Eckman MH. Outcomes of hemodialysis patients in a long-term care hospital setting: a single-center study. American journal of kidney diseases: the official journal of the National Kidney Foundation. 2010;55(2):300-306.

⁴⁸ Wolff JL, Meadow A, Weiss CO, Boyd CM, Leff B. Medicare home health patients' transitions through acute and post-acute care settings. Medical care. 2008;46(11):1188-1193.

⁴⁹ Ibid.

⁵⁰ Kushner DS, Peters KM, Johnson-Greene D. Evaluating Siebens Domain Management Model for Inpatient Rehabilitation to Increase Functional Independence and Discharge Rate to Home in Geriatric Patients. Archives of physical medicine and rehabilitation. 2015;96(7):1310-1318.

rehabilitation strategies, such as addressing discharge barriers and improving medical and functional status.^{54,55,56,57} The effectiveness of these interventions suggests that improvement in discharge to community rates among post-acute care patients is possible through modifying provider-led processes and interventions.

A TEP convened by our measure development contractor was strongly supportive of the importance of measuring discharge to community outcomes, and implementing the measure, Discharge to Community-PAC IRF QRP in the IRF QRP. The panel provided input on the technical specifications of this measure, including the feasibility of implementing the measure, as well as the overall measure reliability and validity. A summary of the TEP proceedings is available on the PAC Quality Initiatives Downloads and Videos 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>.

We also solicited stakeholder feedback on the development of this measure through a public comment period held from November 9, 2015, through December 8, 2015. Several stakeholders and organizations, including the MedPAC, among others, supported this measure for implementation. The public comment summary report for the measure is available on our

⁵¹ Wodchis WP, Teare GF, Naglie G, et al. Skilled nursing facility rehabilitation and discharge to home after stroke. Archives of physical medicine and rehabilitation. 2005;86(3):442-448.

⁵² Berkowitz RE, Jones RN, Rieder R, et al. Improving disposition outcomes for patients in a geriatric skilled nursing facility. Journal of the American Geriatrics Society. 2011;59(6):1130-1136.

⁵³ Kushner DS, Peters KM, Johnson-Greene D. Evaluating use of the Siebens Domain Management Model during inpatient rehabilitation to increase functional independence and discharge rate to home in stroke patients. PM & R : the journal of injury, function, and rehabilitation. 2015;7(4):354-364.

⁵⁴ Kushner DS, Peters KM, Johnson-Greene D. Evaluating Siebens Domain Management Model for Inpatient Rehabilitation to Increase Functional Independence and Discharge Rate to Home in Geriatric Patients. Archives of physical medicine and rehabilitation. 2015;96(7):1310-1318.

⁵⁵ Wodchis WP, Teare GF, Naglie G, et al. Skilled nursing facility rehabilitation and discharge to home after stroke. Archives of physical medicine and rehabilitation. 2005;86(3):442-448.

⁵⁶ Berkowitz RE, Jones RN, Rieder R, et al. Improving disposition outcomes for patients in a geriatric skilled nursing facility. Journal of the American Geriatrics Society. 2011;59(6):1130-1136.

⁵⁷ Kushner DS, Peters KM, Johnson-Greene D. Evaluating use of the Siebens Domain Management Model during inpatient rehabilitation to increase functional independence and discharge rate to home in stroke patients. PM & R : the journal of injury, function, and rehabilitation. 2015;7(4):354-364.

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>.

The NQF-convened MAP met on December 14 and 15, 2015, and provided input on the use of this Discharge to Community-PAC IRF QRP measure in the IRF QRP. The MAP encouraged continued development of the measure to meet the mandate of the IMPACT Act. The MAP supported the alignment of this measure across PAC settings, using standardized claims data. More information about the MAP's recommendations for this measure is available at

http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx.

Since the MAP's review and recommendation of continued development, we have continued to refine risk-adjustment models and conduct measure testing for this measure, as recommended by the MAP. This measure is consistent with the information submitted to the MAP, and the original MAP submission and our continued refinements support its scientific acceptability for use in quality reporting programs. As discussed with the MAP, we fully anticipate that additional analyses will continue as we submit this measure to the ongoing measure maintenance process.

We reviewed the NQF's consensus-endorsed measures and were unable to identify any NQF-endorsed resource use or other measures for post-acute care focused on discharge to community. In addition, we are unaware of any other post-acute care measures for discharge to community that have been endorsed or adopted by other consensus organizations. Therefore, we

proposed the measure, Discharge to Community-PAC IRF QRP, under the Secretary's authority to specify non – NQF-endorsed measures under section 1899B(e)(2)(B) of the Act.

We proposed to use data from the Medicare FFS claims and Medicare eligibility files to calculate this measure. We proposed to use data from the “Patient Discharge Status Code” on Medicare FFS claims to determine whether a patient was discharged to a community setting for calculation of this measure. In all PAC settings, we tested the accuracy of determining discharge to a community setting using the “Patient Discharge Status Code” on the PAC claim by examining whether discharge to community coding based on PAC claim data agreed with discharge to community coding based on PAC assessment data. We found excellent agreement between the two data sources in all PAC settings, ranging from 94.6 percent to 98.8 percent. Specifically, in the IRF setting, using 2013 data, we found 98.8 percent agreement in coding of community and non-community discharges when comparing discharge status codes on claims and the Discharge to Living Setting (item 44A) codes on the IRF-PAI. We further examined the accuracy of the “Patient Discharge Status Code” on the PAC claim by assessing how frequently discharges to an acute care hospital were confirmed by follow-up acute care claims. We discovered that 88 percent to 91 percent of IRF, LTCH, and SNF claims with acute care discharge status codes were followed by an acute care claim on the day of, or day after, PAC discharge. We believed these data support the use of the claims “Patient Discharge Status Code” for determining discharge to a community setting for this measure. In addition, this measure can feasibly be implemented in the IRF QRP because all data used for measure calculation are derived from Medicare FFS claims and eligibility files, which are already available to CMS.

Based on the evidence discussed above, we proposed to adopt the measure, Discharge to Community-PAC IRF QRP, for the IRF QRP for FY 2018 payment determination and

subsequent years. This measure is calculated using 2 years of data. We proposed a minimum of 25 eligible stays in a given IRF for public reporting of the measure for that IRF. Since Medicare FFS claims data are already reported to the Medicare program for payment purposes, and Medicare eligibility files are also available, IRFs will not be required to report any additional data to us for calculation of this measure. The measure denominator is the risk-adjusted expected number of discharges to community. The measure numerator is the risk-adjusted estimate of the number of patients who are discharged to the community, do not have an unplanned readmission to an acute care hospital or LTCH in the 31-day post-discharge observation window, and who remain alive during the post-discharge observation window. The measure is risk-adjusted for variables such as age and sex, principal diagnosis, comorbidities, ESRD status, and dialysis, among other variables. For technical information about the proposed measure, including information about the measure calculation, risk adjustment, and denominator exclusions, we referred readers to the document titled, Proposed Measure Specifications for Measures Proposed in the FY 2017 IRF QRP proposed rule, available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html>.

We stated in the proposed rule that we intend to provide initial confidential feedback to IRFs, prior to public reporting of this measure, based on Medicare FFS claims data from discharges in CY 2015 and 2016. We intend to publicly report this measure using claims data from discharges in CY 2016 and 2017. We will submit this measure to the NQF for consideration for endorsement.

In the CY 2013 OPPS/ASC final rule (77 FR 68500), we finalized our policy to use a subregulatory approach to incorporate non-substantive changes to measures adopted in the IRF

QRP, including changes to exclusions. In that rule, we noted that we expect to make this determination on a measure-by-measure basis and that examples of non-substantive changes to measures might include exclusions for a measure. For the proposed Discharge to Community-IRF QRP measure, we have added an exclusion of patients/residents with a hospice benefit in the post-discharge observation window, in response to comments received during measure development and our ongoing analysis and testing. The rationale for the exclusion of patients/residents with a hospice benefit in the post-discharge observation window aligns with the rationale for exclusion of discharges to hospice. Based on testing, we found that patients/residents with a post-discharge hospice benefit have a much higher death rate in the post-discharge observation window compared with patients/residents without a hospice benefit. We determined that the addition of this hospice exclusion enhances the measure by excluding patients/residents with a high likelihood of post-discharge death and improves the national observed discharge to community rate for IRFs by approximately 0.8 percent. With the addition of this hospice exclusion, we do not believe burden is added, nor that the addition of this exclusion is a substantive change to the overall measure. Failure to include this hospice exclusion could lead to unintended consequences and access issues for terminally-ill patients/residents in our PAC populations.

We invited public comment on our proposal to adopt the measure, Discharge to Community-PAC IRF QRP, for the IRF QRP. The comments we received on this topic, with our responses, appear below.

Comment: Multiple commenters, including MedPAC, supported the Discharge to Community-PAC IRF QRP measure, noting that it is a critical measure assessing the ability of PAC providers to avoid patient institutionalization. One commenter noted that measuring the rate

that the various PAC settings discharge patients to the community, without an admission (or readmission) to an acute care hospital within 30 days, is one of the most relevant patient-centered measures that exists in the post-acute care area. One commenter conveyed that successful transitions to the community are expected to decrease potentially preventable readmissions, while another was appreciative that the measure did not place additional data collection burden on facilities. One commenter stated that achieving a standardized and interoperable patient assessment data set and stable quality measures as quickly as possible will allow for better cross-setting comparisons and the evolution of better quality measures with uniform risk standardization.

Response: We thank the commenters for their support of the Discharge to Community-PAC IRF QRP measure, and their recognition of the patient-centeredness of this measure, its potential to decrease post-discharge readmissions, and its lack of data collection burden. We also thank the commenter for their support of standardized and interoperable patient assessment data and quality measures. As mandated by the IMPACT Act, we are moving toward the goal of standardized patient assessment data and quality measures across PAC settings.

Comment: One commenter interpreted our measure proposal language as suggesting that functional improvement is not a requirement, and encouraged that Medicare coverage for maintenance nursing and therapy be ensured and reflected by the measure.

Response: Our intent in the measure proposal was to acknowledge that discharge to community can be an important goal even for patients who may not be able to make functional improvement. This measure does not impact Medicare coverage rules for maintenance nursing and therapy.

Comment: Several commenters expressed concerns regarding the use of the Patient Discharge Status Code variable to define community discharges. Commenters emphasized that it was important to ensure that only home and community based settings were included in the definition of community, and were concerned that Code 01 (Discharge to home or self-care) included institutional settings such as jail or law enforcement. One commenter expressed that many settings included under Code 01 do not satisfy the home and community based settings rule, and may be inconsistent with the integration mandate of the Americans with Disabilities Act. Commenters strongly recommended that CMS either revise Patient Discharge Status Code 01 to exclude non community-based settings, or use alternative variables to capture discharge to community.

Response: We agree with the commenters that the discharge to community measure should only capture discharges to home and community based settings. We believe that the comment referring to the "home and community based settings rule" refers to Medicaid regulations applicable to services authorized under sections 1915(c), 1915(i) and 1915(k) of the Social Security Act (the Act), which are provided through waivers or state plans amendments approved by CMS. We would like to clarify that this measure only captures discharges to home and community based settings, not to institutional settings, and is consistent with both Medicaid regulations requiring home and community based settings to support integration, and also with the Americans with Disabilities Act (ADA), based on Patient Discharge Status Codes 01, 06, 81, and 86 on the Medicare FFS PAC claim.⁵⁸ Discharges to court or law enforcement are not included under Code 01 of the Patient Discharge Status Code; rather these are included under Code 21 (Discharged/transferred to Court/Law Enforcement).

⁵⁸ National Uniform Billing Committee Official UB-04 Data Specifications Manual 2017, Version 11, July 2016, Copyright 2016, American Hospital Association.

We also note that Title II of the ADA requires public entities to administer services, programs, and activities in the most integrated setting appropriate to the needs of qualified individuals with disabilities (28 CFR 35.130(d)). The preamble discussion of the “integration regulation” explains that “the most integrated setting” is one that enables individuals with disabilities to interact with nondisabled persons to the fullest extent possible. Integrated settings are those that provide individuals with disabilities opportunities to live, work, and receive services in the greater community, like individuals without disabilities (28 CFR part 35, app. A (2010) (addressing § 35.130)).

Comment: Several commenters stated that PAC patients/residents discharged to a nursing facility as long-term care residents should not be considered discharges to community, particularly if they were discharged to the nursing facility from the Medicare-certified skilled nursing part of the same nursing home, and even if they resided in a long-term nursing facility at baseline. Commenters emphasized that a nursing home does not represent an individual’s own home in their own community. These commenters interpreted the measure specifications as allowing these discharges to nursing facility to be coded as "group home", "foster care", or "other residential care arrangement" under discharge status code 01. Commenters expressed concern that coding discharges from the SNF to residential/long-term care facility within the same nursing home as discharges to community would unfairly advantage SNFs and artificially inflate their discharge to community rates, would disadvantage other PAC providers, and would miscommunicate a facility’s actual discharge to community performance to the average Medicare beneficiary. One commenter suggested exclusion of patients discharged to a non-Medicare certified residence, such as a “group home” or “foster care” or other arrangement.

Response: We agree with the commenters that discharges to long-term care nursing facilities, or any other institutional settings, should not be coded as discharges to community. We also recognize the differences in required discharge planning processes and resources for discharging a patient/resident to the community compared with discharging to a long-term nursing facility. The discharge to community measure only captures discharges to home and community based settings as discharges to community, based on Patient Discharge Status Codes 01, 06, 81, and 86 on the Medicare FFS PAC claim.⁵⁹ These codes do not include discharges to long-term care nursing facilities or any other institutional setting that may violate the integration mandate of Title II of the ADA. Instead, depending on the nature of the facility to which patients/residents are discharged, such discharges may be coded on the Medicare FFS claim as 04, 64, 84, 92, or another appropriate code for an institutional discharge.

In response to the commenters' concerns that SNFs may be unfairly advantaged by this measure as compared with other PAC providers, we would like to note that, in our measure development samples, the national discharge to community rate for SNFs was 47.26 percent, while this rate for IRFs was considerably higher (69.51 percent). Further, using an MDS-claims linked longitudinal file, we found that of the SNF stays that had a pre-hospitalization non-PPS MDS assessment suggesting prior nursing facility residence, two-thirds had a discharge status code of 30 (still patient), and approximately 18 percent had a discharge status code of 02 (acute hospital). Less than 5 percent of these patients had a Discharge Status Code of 01 (discharge to home or self care). Thus, the commenters' concerns that discharges from SNF to nursing facility are largely coded as Patient Discharge Status Code 01 are not reflected in our data.

⁵⁹ Ibid.

Comment: Some commenters expressed concern that the discharge to community measure fails to distinguish patients/residents who lived in a long-term care nursing facility at baseline and returned to the nursing facility after their PAC stay. Commenters recommended that baseline long-stay nursing facility residents be excluded from the discharge to community measure, as they could not be reasonably expected to discharge back to the community. One commenter noted that these residents have a very different discharge process back to the nursing facility compared with patients discharged to the community. The commenter recommended that different measures be developed for the baseline nursing facility resident population, such as return to prior level of function, improvement in function, prevention of further functional decline, development of pressure ulcers, or accidental falls. The commenter also recognized CMS's current efforts in monitoring transitions of care and quality requirements in long-term care facilities. Commenters suggested that CMS could use longitudinal Minimum Data Set-linkage to identify and exclude baseline nursing facility residents.

Response: We appreciate the commenters' concerns and their recommendation to exclude baseline nursing facility residents from the discharge to community measure, and to distinguish baseline custodial nursing facility residents who are discharged back to the nursing facility after their PAC stay. We recognize that patients/residents who permanently lived in a nursing facility at baseline may not be expected to discharge back to a home and community based setting after their PAC stay. We also recognize that, for baseline nursing facility residents, a discharge back to their nursing facility represents a discharge to their baseline residence. We agree with the commenter about the differences in discharge planning processes when discharging a patient/resident to the community compared with discharging to a long-term nursing facility. However, using Medicare FFS claims alone, we are unable to accurately

identify baseline nursing facility residents. Potential future modifications of the measure could include the assessment of the feasibility and impact of excluding baseline nursing facility residents from the measure through the addition of patient assessment-based data. However, we note that, currently, the IRF-PAI is the only PAC assessment that contains an item related to pre-hospital baseline living setting.

Comment: A few commenters questioned the inclusion of only Medicare FFS patients/residents in the measure, and stated whether the measure would be expanded to include patients/residents with other payers or plan types. One commenter recommended that the patient populations be consistent across IRF measures, and not vary by payer or plan type, stating that consistency in measure populations across IRF measures was important for facilities to understand their quality metrics. Other commenters recommended that the discharge to community measure include other payer populations, and particularly emphasized the importance of including Medicare Advantage patients in the measure, highlighting that Medicare Advantage patients were included in the IRF Drug Regimen Review measure. The commenters noted that the Medicare Advantage population was a rapidly growing Medicare population, warranting their inclusion in quality measures.

Response: We agree that it is important to monitor quality and resource use outcomes of all post-acute care patients/residents, not just Medicare FFS patients/residents. The discharge to community measure is limited to the Medicare FFS population through the use of a Medicare FFS claim, but we will consider the appropriateness and feasibility of including Managed Care patients/residents in future modifications of the measure. We would like to note that further expansion of the measure to include Medicare Managed Care or other payer populations would require standardized data collection across all settings and payer populations.

Comment: MedPAC recommended that CMS confirm discharge to a community setting with the absence of a subsequent claim to a hospital, IRF, SNF, or LTCH, to ensure that discharge to community rates reflect actual facility performance. Other commenters also recommended that CMS assess the reliability and validity of the Patient Discharge Status Code on PAC claims. Commenters cited MedPAC and other studies, noting that Patient Discharge Status Codes often have low reliability, and that this could impact accurate portrayal of measure performance.

Response: We are committed to developing measures based on reliable and valid data. This measure does confirm the absence of hospital or LTCH claims following discharge to a community setting. Unplanned hospital and LTCH readmissions following the discharge to community, including those on the day of IRF discharge, are considered an unfavorable outcome. We will consider verifying the absence of IRF and SNF claims following discharge to a community setting, as we continue to refine this measure. Nonetheless, we would like to note that an ASPE report on post-acute care relationships found that, following discharge to community settings from IRFs, LTCHs, or SNFs in a 5 percent Medicare sample, IRFs or SNFs were very infrequently reported as the next site of post-acute care.⁶⁰

Because the discharge to community measure is a measure of discharge destination from the PAC setting, we have chosen to use the PAC-reported discharge destination (from the Medicare FFS claims) to determine whether a patient/resident was discharged to the community (based on discharge status codes 01, 06, 81, 86). We assessed the reliability of the claims discharge status code(s) by examining agreement between discharge status on claims and assessment instruments in all four PAC settings. We found between 94 and 99 percent

⁶⁰ Gage B, Morley M, Spain P, Ingber M. Examining Post Acute Care Relationships in an Integrated Hospital System Final Report. RTI International; 2009.

agreement in coding of community discharges on matched claims and assessments in each of the PAC settings. We also assessed how frequently discharges to acute care, as indicated on the PAC claim, were confirmed by follow-up acute care claims, and found that 88 percent to 91 percent of IRF, LTCH, and SNF claims indicating acute care discharge were followed by an acute care claim on the day of, or day after, PAC discharge. We believe that these data support the use of the “Patient Discharge Status Code” from the PAC claim for determining discharge to a community setting for this measure.

The use of the claims discharge status code to identify discharges to the community was discussed at length with the TEP convened by our measure development contractor. TEP members did not express significant concerns regarding the accuracy of the claims discharge status code in coding community discharges, nor about our use of the discharge status code for defining this quality measure. A summary of the TEP proceedings is available on the PAC Quality Initiatives Downloads and Videos 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>.

Comment: A few commenters conveyed the importance of ensuring consistency in coding of discharge status codes across PAC settings, and requested a clear definition of community discharge for purposes of this measure.

Response: This measure captures discharges to home and community based settings, with or without home health services. Community, for this measure, is defined as Patient Discharge Status codes 01, 06, 81, and 86 on the PAC claim. Code 01 refers to discharge to home or self care; Code 06 refers to discharge with home health services; Code 81 refers to discharge to home or self care with a planned acute care readmission; and Code 86 refers to

discharge with home health services with a planned acute care readmission. We refer readers to the National Uniform Billing Committee Data Specifications Manual for coding instructions.⁶¹ For further details on measure specifications, including the definition of community, we refer readers to the Measure Specifications for Measures Adopted in the FY 2017 IRF QRP final rule, posted on the CMS IRF QRP Web site at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html>.

Comment: Some commenters were concerned about overlap between the discharge to community and readmissions measures, specifically expressing concern that a single post-discharge readmission would affect a facility's performance on two measures. One commenter expressed that the discharge to community measure essentially functioned as a readmission measure, and that different definitions of readmissions could be confusing for providers and patients, lead to unintended differences in the data CMS receives, and skew the data. One commenter indicated that the IMPACT Act measures overemphasized reducing readmissions and did not adequately address the domains they are meant to measure. This commenter suggested that quality measures should exclude aspects measured by other domains and/or quality measures, and instead should measure unique domains. This commenter further recommended that the Secretary suspend this measure until CMS can evaluate whether the inclusion of readmissions within each quality measure is necessary, and whether it produces duplicative results within the various quality reporting programs.

Response: There are distinct differences between the discharge to community and readmission measures under the IRF QRP. Although there may be some overlap in the outcomes

⁶¹ National Uniform Billing Committee Official UB-04 Data Specifications Manual 2017, Version 11, July 2016, Copyright 2016, American Hospital Association.

captured across the two measures (for example, patients who have a post-discharge readmission also have an unsuccessful discharge to community), the discharge to community and readmission measures each have a distinct purpose, outcome definition, and measure population. For example, the discharge to community measure assesses the rate of successful discharges to the community, defined as discharge to a community setting without post-discharge unplanned readmissions or death, while the readmission measures assess the rate of readmissions for patients discharged to lower levels of care from the IRF.

Our goal is to develop measures that are meaningful to patients and consumers, and assist them in making informed choices when selecting post-acute providers. Since the goal of PAC for most patients and family members is to be discharged to the community and remain in the community, from a patient/consumer perspective, it is important to assess whether a patient remained in the community after discharge and to separately report discharge to community rates. In addition to assessing the success of community discharges, the inclusion of post-discharge readmission and death outcomes in this measure is intended to avoid the potential unintended consequence of inappropriate discharges to the community.

Comment: Several commenters expressed concern that the discharge to community measure holds IRFs accountable for post-discharge adverse outcomes, including unplanned readmissions and death. Commenters expressed that IRFs have little control over patient behavior or adherence once the patient is discharged from the facility, and should not be penalized for post-discharge events. We received recommendations to exclude patients who have been discharged to the community and then expire within the post-discharge window; this recommendation was based on the explanation that the types of patients treated in IRFs greatly

varied and that including post-discharge death in the measure could lead to an inaccurate reflection of the quality of care furnished by the IRF.

Response: We monitor 31-day post-discharge unplanned readmissions and death in the measure to more accurately capture successful discharge to community outcomes, and to avoid the potential unintended consequence of inappropriate discharges to the community. We expect that improved care transitions and care coordination across providers will reduce these post-discharge adverse outcomes. Members of our TEP unanimously believed that the definition of discharge to community should be broader than discharge destination alone, and should incorporate indicators of post-discharge patient outcomes. TEP members agreed with the inclusion of both post-discharge readmissions and death in the discharge to community measure.

We found, through our analyses in our measure development sample, that death in the 31 days following discharge to community is an infrequent event, with only 0.9 percent of IRF Medicare FFS beneficiaries dying during that period. By risk adjusting for prior service use (that is, number of hospitalizations in the past year), our intent is to adjust for patient characteristics, such as access, patient compliance, or sociodemographic and socioeconomic factors that may influence the likelihood of post-discharge readmissions. Additionally, by excluding patients discharged against medical advice from the measure, we are excluding patients who demonstrate non-compliance or non-adherence during the PAC stay.

We would like to note that we do not expect facilities to achieve a 0 percent readmission or death rate in the measure's post-discharge observation window; the focus is to identify facilities with unexpectedly high rates of unplanned readmissions and death for quality monitoring purposes.

Comment: Multiple commenters suggested that the measure include risk adjustment for sociodemographic factors such as home and community caregivers and supports, and socioeconomic factors of patients and communities.

Response: We understand the importance of home and community supports, sociodemographic factors, and socioeconomic factors in ensuring a successful discharge to community outcome. The discharge to community measure is a claims-based measure in its first phase of development. Currently, there are no standardized data on variables such as living status or family and caregiver supports across the four PAC settings. As we refine the measure in the future, we will consider testing and adding additional relevant data sources and standardized items for risk adjustment of this measure. We refer readers to section VIII.F of this final rule for a more detailed discussion of the role of SES/SDS factors in risk adjustment of our measures.

Comment: A few commenters emphasized the relationship between functional gains during the IRF stay and the ability to discharge to the community, stating that functional status measures are important indicators of recovery and achievement of rehabilitation goals and should be more intimately embedded in the proposed discharge to community measure. One commenter stated that return to one's previous home represents part of the goal of care. The commenter noted that, additionally, it is also important that the patient is able to function to the greatest possible extent in the home and community setting and achieve the highest quality of life possible. The commenter recommended that CMS delay adopting this measure until it incorporated metrics that assess whether patients achieved their functional and independence goals based on their plan of care and their specific condition.

Multiple commenters suggested that the measure include risk adjustment for functional status in all settings, as it is closely associated with patients' discharge destination. One

commenter noted that functional status is associated with increased risk of 30-day all-cause hospital readmissions, and since readmissions and discharge to community are closely related, functional status risk adjustment is also important for this measure. One commenter suggested that the SNF and LTCH measures include risk adjustment that is similar to the risk adjustment for CMGs in the IRF setting and Activities of Daily Living in the HHA setting. One commenter interpreted the measure proposal as stating that CMS will not adjust the quality measures, including the discharge to community measure, to account for functional status of beneficiaries until such data are collected under the IMPACT Act.

Response: We agree that it is important to assess various aspects of patient outcomes that are indicative of successful discharge from the IRF setting. We also agree that functional status may be related to discharge to community outcomes, and that it is important to test admission functional status risk adjustment when assessing discharge to community outcomes. The discharge to community measure does include functional status risk adjustment in the IRF setting using CMGs from claims, and in the home health setting using Activities of Daily Living from claims.

As mandated by the IMPACT Act, we are moving toward the goal of collecting standardized patient assessment data for functional status across PAC settings. The IRF QRP includes five NQF-endorsed functional status quality measures, with a data collection start date of October 1, 2016. Two measures are related to mobility functional outcomes, two are related to self-care functional outcomes, and one is a process measure. Once standardized functional status data become available across settings, it is our intent to use these data to assess patients' functional gains during their PAC stay, and to examine the relationship between functional status, discharge destination, and patients' ability to discharge to the community. As we

examine these relationships between functional outcomes and discharge to community outcomes in the future, we will assess the feasibility of leveraging these standardized patient assessment data to incorporate functional outcomes into the discharge to community measure. Standardized cross-setting patient assessment data will also allow us to examine interrelationships between the quality and resource use measures in each PAC setting, and to understand how these measures are correlated.

Comment: One commenter questioned the appropriateness of using HCCs for risk adjustment in the new quality measures proposed for the IRF QRP. The commenters noted that HCCs were initially developed for setting payment benchmarks for the Medicare Advantage program, and broad application of HCCs across quality measures may be beyond the scope of their appropriate use. The commenter cited reports suggesting that the HCC risk model was inaccurate at cost-estimation, and recommended that CMS reconsider the validity and reliability of the HCC risk-adjustment model. The commenter suggested that CMS instead develop a refined model that encompasses the diversity and complexity of PAC patients to a greater extent, and is more sensitive to their levels of resource use.

Response: We agree that comorbidities are important risk adjusters when examining quality and resource use measures. The HCCs were developed to separate clinically-related codes by Medicare utilization implications; they represent diagnosis-based, clinically meaningful clusters of ICD codes that have also been grouped by cost implications. When we apply HCCs for risk adjustment of quality or resources use measures, we do not use the HCC models applied to payment. In our measure development, we typically test individual HCCs that are relevant to the outcome of interest; we estimate the effects of the individual HCCs or clusters on the dependent variable in the particular model and retain those that are significant or meaningful

predictors of outcomes. We believe that risk adjusting for individual HCCs or small clusters provides greater sensitivity than using a single comorbidity index, which is based on selected diagnoses. Our approach accounts for an average effect for each comorbidity or comorbidity group, rather than an overall burden of comorbidities.

The HCCs are more comprehensive than the simpler diagnosis-based systems, such as the Elixhauser Comorbidity Index or Charlson Comorbidity Index, which were targeted for predicting specific outcomes (for example, hospital mortality). We believe that HCCs provide a good representation of health risk, and their use to examine outcomes other than costs is supported in the literature.^{62,63} A study comparing the ability of five comorbidity indices to predict discharge functional status of IRF patients found that HCCs slightly outperformed other comorbidity indices.⁶⁴ The superior performance of HCCs was hypothesized to be related to the inclusion of more medical conditions, and the inclusion of more ICD codes per condition in HCCs, making them a slightly more sensitive index for predicting clinical outcomes compared with other comorbidity indices.⁶⁵

We have successfully used HCCs as risk adjusters in several other quality measures, such as the readmissions and functional status measures for post-acute care. We have found HCCs to be significant and important predictors of outcomes across these quality measures.

Comment: One commenter stated that ventilator use is included as a risk adjuster in the LTCH setting only, but should be used across all settings. This commenter also requested

⁶² Li P, Kim MM, Doshi JA. Comparison of the performance of the CMS Hierarchical Condition Category (CMS-HCC) risk adjuster with the Charlson and Elixhauser comorbidity measures in predicting mortality. *BMC Health Serv Res*. 2010 Aug 20;10:245. doi: 10.1186/1472-6963-10-245.

⁶³ Kumar A, Graham JE, Resnik L, Karmarkar AM, Tan A, Deutsch A, Ottenbacher KJ. Comparing Comorbidity Indices to Predict Post-Acute Rehabilitation Outcomes in Older Adults. *Am J Phys Med Rehabil*. 2016 May 4. [Epub ahead of print]

⁶⁴ Ibid.

⁶⁵ Ibid.

information on the hierarchical logistic regression modeling and variables that will be used for risk adjustment.

Response: We would like to clarify that risk adjustment for ventilator use is included in both LTCH and SNF settings. We investigated the need for risk adjustment for ventilator use in IRFs, but found that less than 0.01 percent of the IRF population (19 patient stays in 2012, and 9 patient stays in 2013) had ventilator use in the IRF. Given the low frequency of ventilator use in IRFs, any associated estimates would not be reliable, and therefore, ventilator use is not included as a risk adjuster in the IRF setting measure. However, we will continue to assess this risk adjuster for inclusion in the IRF model for this measure.

For details on measure specifications, modeling, and calculations, we refer readers to the Measure Specifications for Measures Adopted in the FY 2017 IRF QRP final rule, posted on the CMS IRF QRP webpage at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html>.

Comment: Two commenters requested clarification on the dual status of IRFs as qualifying hospitals for the purposes of the SNF “3-Day Stay” rule, and PAC providers for purposes of the discharge to community measure. Specifically, the commenters questioned whether a discharge from a SNF back to an IRF would count as a readmission under this measure (and thus result in a “failed” community discharge for the SNF), or whether it would only count as a non-community discharge.

Response: For the discharge to community measure, a PAC stay must be preceded by an acute care stay in the past 30 days to be included in the measure. IRF stays are not considered qualifying stays for the purposes of inclusion in the discharge to community measure. When

examining discharge destination from PAC, a discharge to an IRF would be considered a non-community discharge. Additionally, in the current measure specification, if a patient is discharged from PAC to the community and has a subsequent IRF admission in the post-discharge observation window, this IRF admission does not translate into a failed community discharge. In future measure work, we will assess the impact of flagging IRF admissions in the post-discharge window as failed discharges to community.

Comment: One commenter encouraged CMS to provide PAC settings with access to measure performance data as early as possible so providers have time to adequately review these data, and implement strategies to decrease readmissions where necessary.

Response: We intend to provide initial confidential feedback to PAC providers, prior to public reporting of this measure, based on Medicare FFS claims data from discharges in CY 2015 and 2016.

Comment: A few commenters were concerned about potential unintended consequences associated with perceived conflicting incentives of measures within the IRF QRP. One commenter noted that while the discharge to community measure may incentivize IRFs to discharge patients with home health services in order to continue their recovery and function in a safe, lower cost setting, the MSPB measure may create an opposite incentive for IRFs to avoid the use of home health to reduce post-discharge resource utilization. Another commenter conveyed that IRFs may not be incentivized to discharge patients to the community as there is a risk of post-discharge readmissions affecting their measure performance. The commenter expressed that decreased discharge to community rates may result in increased costs.

Response: We expect that, on average, discharges to community settings rather than institutional settings, will result in lower healthcare costs. We choose measures for our quality

reporting programs that reflect patient-centeredness, and assess healthcare outcomes and utilization that may be indicators of poor quality of care or inefficient resource use. As with all our measures, we will monitor for unintended consequences as part of measure monitoring and evaluation to ensure that measures do not reduce quality of care or access for patients.

Comment: Several commenters expressed concern that the discharge to community measure had not been endorsed by the NQF, and had not been fully developed and tested when presented to the NQF MAP. Some commenters recommended that CMS delay measure implementation and seek NQF endorsement before measure adoption, while others recommended that CMS submit the measures for NQF endorsement as soon as feasible after measure adoption. A few commenters suggested that CMS obtain the support of a TEP before deciding whether to implement new quality measures, and that the TEP include IRF setting representatives.

Response: We would like to clarify that the discharge to community measure has been fully developed and tested. We plan to submit the Discharge to Community-PAC IRF QRP measure to the NQF for consideration for endorsement.

As with all measure development, our measure development contractor held three TEP meetings to seek input to guide development of the Discharge to Community measure. The TEP represented members of IRF, LTCH, SNF and home health agency settings. A summary of the TEP proceedings is available on the PAC Quality Initiatives Downloads and Videos 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>. TEP members were very supportive of the discharge to community measure concept across all

PAC settings. We incorporated various TEP member recommendations into the measure specifications.

Final Decision: After careful consideration of the public comments, we are finalizing our proposal to adopt the measure, Discharge to Community-PAC IRF QRP as a Medicare FFS claims-based measure for the FY 2018 payment determination and subsequent years, with the added exclusion of patients with a hospice benefit in the 31-day post-discharge observation window.

For measure specifications, we refer readers to the Measure Specifications for Measures Adopted in the FY 2017 IRF QRP final rule, posted on the CMS IRF QRP Web site at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html>.

3. Measure to Address the IMPACT Act Domain of Resource Use and Other Measures: Potentially Preventable 30-Day Post-Discharge Readmission Measure for Inpatient Rehabilitation Facility Quality Reporting Program.

Sections 1899B(a)(2)(E)(ii) and 1899B(d)(1)(C) of the Act require the Secretary to specify measures to address the domain of all-condition risk-adjusted potentially preventable hospital readmission rates by SNFs, LTCHs, and IRFs by October 1, 2016, and HHAs by January 1, 2017. We proposed the measure Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP as a Medicare FFS claims-based measure to meet this requirement for the FY 2018 payment determination and subsequent years.

The measure assesses the facility-level risk-standardized rate of unplanned, potentially preventable hospital readmissions for Medicare FFS beneficiaries in the 30 days post IRF discharge. The IRF admission must have occurred within up to 30 days of discharge from a prior

proximal hospital stay which is defined as an inpatient admission to an acute care hospital (including IPPS, CAH, or a psychiatric hospital). Hospital readmissions include readmissions to a short-stay acute-care hospital or an LTCH, with a diagnosis considered to be unplanned and potentially preventable. This measure is claims-based, requiring no additional data collection or submission burden for IRFs. Because the measure denominator is based on IRF admissions, each Medicare beneficiary may be included in the measure multiple times within the measurement period. Readmissions counted in this measure are identified by examining Medicare FFS claims data for readmissions to either acute care hospitals (IPPS or CAH) or LTCHs that occur during a 30-day window beginning 2 days after IRF discharge. This measure is conceptualized uniformly across the PAC settings, in terms of the measure definition, the approach to risk adjustment, and the measure calculation. Our approach for defining potentially preventable hospital readmissions is described in more detail below.

Hospital readmissions among the Medicare population, including beneficiaries that utilize PAC, are common, costly, and often preventable.^{66,67} MedPAC and a study by Jencks et al. estimated that 17 to 20 percent of Medicare beneficiaries discharged from the hospital were readmitted within 30 days. MedPAC found that more than 75 percent of 30-day and 15-day readmissions and 84 percent of 7-day readmissions were considered “potentially preventable.”⁶⁸ In addition, MedPAC calculated that annual Medicare spending on potentially preventable readmissions were \$12 billion for 30-day, \$8 billion for 15-day, and \$5 billion for 7-day

⁶⁶ Friedman, B., and Basu, J.: The rate and cost of hospital readmissions for preventable conditions. *Med. Care Res. Rev.* 61(2):225-240, 2004. doi:10.1177/1077558704263799

⁶⁷ Jencks, S.F., Williams, M.V., and Coleman, E.A.: Rehospitalizations among patients in the Medicare Fee-for-Service Program. *N. Engl. J. Med.* 360(14):1418-1428, 2009. doi:10.1016/j.jvs.2009.05.045

⁶⁸ MedPAC: Payment policy for inpatient readmissions, in *Report to the Congress: Promoting Greater Efficiency in Medicare*. Washington, D.C., pp. 103-120, 2007. Available from http://www.medpac.gov/documents/reports/Jun07_EntireReport.pdf

readmissions in 2005.⁶⁹ For hospital readmissions from one post-acute care setting, SNFs, MedPAC deemed 76 percent of these readmissions as “potentially avoidable”—associated with \$12 billion in Medicare expenditures.⁷⁰ Mor et al. analyzed 2006 Medicare claims and SNF assessment data (Minimum Data Set), and reported a 23.5 percent readmission rate from SNFs, associated with \$4.3 billion in expenditures.⁷¹ Fewer studies have investigated potentially preventable readmission rates from the remaining post-acute care settings.

We have addressed the high rates of hospital readmissions in the acute care setting as well as in PAC. For example, we developed the following measure: All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from IRFs (NQF #2502), as well as similar measures for other PAC providers (NQF #2512 for LTCHs and NQF #2510 for SNFs).⁷² These measures are endorsed by the NQF, and the NQF-endorsed IRF measure (NQF #2502) was adopted into the IRF QRP in the FY 2016 IRF PPS final rule (80 FR 47087 through 47089). Note that these NQF-endorsed measures assess all-cause unplanned readmissions.

Several general methods and algorithms have been developed to assess potentially avoidable or preventable hospitalizations and readmissions for the Medicare population. These include the Agency for Healthcare Research and Quality’s (AHRQ’s) Prevention Quality Indicators, approaches developed by MedPAC, and proprietary approaches, such as the 3MTM algorithm for Potentially Preventable Readmissions.^{73, 74, 75} Recent work led by Kramer et al. for

⁶⁹ *ibid.*

⁷⁰ *ibid.*

⁷¹ Mor, V., Intrator, O., Feng, Z., et al.: The revolving door of rehospitalization from skilled nursing facilities. *Health Aff.* 29(1):57-64, 2010. doi:10.1377/hlthaff.2009.0629

⁷² National Quality Forum: *All-Cause Admissions and Readmissions Measures*, pp. 1-319, April 2015. Available from http://www.qualityforum.org/Publications/2015/04/All-Cause_Admissions_and_Readmissions_Measures_-_Final_Report.aspx

⁷³ Goldfield, N.I., McCullough, E.C., Hughes, J.S., et al.: Identifying potentially preventable readmissions. *Health Care Finan. Rev.* 30(1):75-91, 2008. Available from <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4195042/>

⁷⁴ National Quality Forum: *Prevention Quality Indicators Overview*, 2008.

MedPAC identified 13 conditions for which readmissions were deemed as potentially preventable among SNF and IRF populations.^{76, 77} Although much of the existing literature addresses hospital readmissions more broadly and potentially avoidable hospitalizations for specific settings like long-term care, these findings are relevant to the development of potentially preventable readmission measures for PAC.^{78, 79, 80}

Potentially Preventable Readmission Measure Definition: We conducted a comprehensive environmental scan, analyzed claims data, and obtained input from a TEP to develop a definition and list of conditions for which hospital readmissions are potentially preventable. The Ambulatory Care Sensitive Conditions and Prevention Quality Indicators, developed by AHRQ, served as the starting point in this work. For patients in the 30-day post-PAC discharge period, a potentially preventable readmission refers to a readmission for which the probability of occurrence could be minimized with adequately planned, explained, and implemented post-discharge instructions, including the establishment of appropriate follow-up ambulatory care. Our list of PPR conditions is categorized by 3 clinical rationale groupings:

- Inadequate management of chronic conditions;
- Inadequate management of infections; and

⁷⁵ MedPAC: Online Appendix C: Medicare Ambulatory Care Indicators for the Elderly. pp. 1-12, prepared for Chapter 4, 2011. Available from http://www.medpac.gov/documents/reports/Mar11_Ch04_APPENDIX.pdf?sfvrsn=0

⁷⁶ Kramer, A., Lin, M., Fish, R., et al.: Development of Inpatient Rehabilitation Facility Quality Measures: Potentially Avoidable Readmissions, Community Discharge, and Functional Improvement. pp. 1-42, 2015. Available from <http://www.medpac.gov/documents/contractor-reports/development-of-inpatient-rehabilitation-facility-quality-measures-potentially-avoidable-readmissions-community-discharge-and-functional-improvement.pdf?sfvrsn=0>

⁷⁷ Kramer, A., Lin, M., Fish, R., et al.: Development of Potentially Avoidable Readmission and Functional Outcome SNF Quality Measures. pp. 1-75, 2014. Available from http://www.medpac.gov/documents/contractor-reports/mar14_snfqualitymeasures_contractor.pdf?sfvrsn=0

⁷⁸ Allaudeen, N., Vidyarthi, A., Maselli, J., et al.: Redefining readmission risk factors for general medicine patients. *J. Hosp. Med.* 6(2):54-60, 2011. doi:10.1002/jhm.805

⁷⁹ ⁴ Gao, J., Moran, E., Li, Y.-F., et al.: Predicting potentially avoidable hospitalizations. *Med. Care* 52(2):164-171, 2014. doi:10.1097/MLR.0000000000000041

⁸⁰ Walsh, E.G., Wiener, J.M., Haber, S., et al.: Potentially avoidable hospitalizations of dually eligible Medicare and Medicaid beneficiaries from nursing facility and home-and community-based services waiver programs. *J. Am. Geriatr. Soc.* 60(5):821-829, 2012. doi:10.1111/j.1532-5415.2012.03920.x

- Inadequate management of other unplanned events.

Additional details regarding the definition for potentially preventable readmissions are available in the document titled, Proposed Measure Specifications for Measures Proposed in the FY 2017 IRF QRP proposed rule, available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html>.

This measure focuses on readmissions that are potentially preventable and also unplanned. Similar to the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from IRFs (NQF #2502), this measure uses the current version of the CMS Planned Readmission Algorithm as the main component for identifying planned readmissions. A complete description of the CMS Planned Readmission Algorithm, which includes lists of planned diagnoses and procedures, can be found on the CMS Web site <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>. In addition to the CMS Planned Readmission Algorithm, this measure incorporates procedures that are considered planned in post-acute care settings, as identified in consultation with TEPs. Full details on the planned readmissions criteria used, including the CMS Planned Readmission Algorithm and additional procedures considered planned for post-acute care, can be found in the document titled, Proposed Measure Specifications for Measures Proposed in the FY 2017 IRF QRP proposed rule, available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html>.

The measure, Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP, assesses potentially preventable readmission rates while accounting for patient

demographics, principal diagnosis in the prior hospital stay, comorbidities, and other patient factors. While estimating the predictive power of patient characteristics, the model also estimates a facility-specific effect, common to patients treated in each facility. This measure is calculated for each IRF based on the ratio of the predicted number of risk-adjusted, unplanned, potentially preventable hospital readmissions that occur within 30 days after an IRF discharge, including the estimated facility effect, to the estimated predicted number of risk-adjusted, unplanned inpatient hospital readmissions for the same patients treated at the average IRF. A ratio above 1.0 indicates a higher than expected readmission rate (worse) while a ratio below 1.0 indicates a lower than expected readmission rate (better). This ratio is referred to as the standardized risk ratio (SRR). The SRR is then multiplied by the overall national raw rate of potentially preventable readmissions for all IRF stays. The resulting rate is the risk-standardized readmission rate (RSRR) of potentially preventable readmissions.

An eligible IRF stay is followed until: (1) the 30-day post-discharge period ends; or (2) the patient is readmitted to an acute care hospital (IPPS or CAH) or LTCH. If the readmission is unplanned and potentially preventable, it is counted as a readmission in the measure calculation. If the readmission is planned, the readmission is not counted in the measure rate.

This measure is risk adjusted. The risk adjustment modeling estimates the effects of patient characteristics, comorbidities, and select health care variables on the probability of readmission. More specifically, the risk-adjustment model for IRFs accounts for demographic characteristics (age, sex, original reason for Medicare entitlement), principal diagnosis during the prior proximal hospital stay, body system specific surgical indicators, IRF case-mix groups which capture motor function, comorbidities, and number of acute care hospitalizations in the preceding 365 days.

The measure is calculated using 2 consecutive calendar years of FFS claims data, to ensure the statistical reliability of this measure for facilities. In addition, we proposed a minimum of 25 eligible stays for public reporting of the measure.

A TEP convened by our measure contractor provided recommendations on the technical specifications of this measure, including the development of an approach to define potentially preventable hospital readmission for PAC. Details from the TEP meetings, including TEP members' ratings of conditions proposed as being potentially preventable, are available in the TEP summary report 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>. We also solicited stakeholder feedback on the development of this measure through a public comment period held from November 2 through December 1, 2015. Comments on the measure varied, with some commenters supportive of the measure, while others either were not in favor of the measure, or suggested potential modifications to the measure specifications, such as including standardized function data. A summary of the public comments is also available on our 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>.

The MAP encouraged continued development of the proposed measure. Specifically, the MAP stressed the need to promote shared accountability and ensure effective care transitions. More information about the MAP's recommendations for this measure is available at http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx. At the time, the risk-adjustment model was still under development. Following completion of that development work, we were able to

test for measure validity and reliability as identified in the measure specifications document provided above. Testing results are within range for similar outcome measures finalized in public reporting and value-based purchasing programs, including the All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from IRFs (NQF #2502) adopted into the IRF QRP.

We reviewed the NQF's consensus endorsed measures and were unable to identify any NQF-endorsed measures focused on potentially preventable hospital readmissions. We are unaware of any other measures for this IMPACT Act domain that have been endorsed or adopted by other consensus organizations. Therefore, we proposed the Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP, under the Secretary's authority to specify non-NQF-endorsed measures under section 1899B(e)(2)(B) of the Act, for the IRF QRP for the FY 2018 payment determination and subsequent years, given the evidence previously discussed above.

We plan to submit the measure to the NQF for consideration of endorsement. We stated in the proposed rule that we intended to provide initial confidential feedback to providers, prior to public reporting of this measure, based on 2 calendar years of data from discharges in CY 2015 and 2016. We also stated that we intended to publicly report this measure using data from CY 2016 and 2017.

We invited public comment on our proposal to adopt the measure, Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP. We received several comments, which are summarized with our responses below.

Comment: We received several comments in support of the proposed Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP. In particular, MedPAC

supported this measure and believes that IRFs should be held accountable for readmissions in the post-discharge readmission window. Some commenters preferred a potentially preventable readmission measure over an all-cause readmission measure.

Response: We thank commenters for their support of this measure.

Comment: One commenter specifically supported the inclusion of infectious conditions in the inadequate management of infections and inadequate management of other unplanned events categories in the measure's definition of potentially preventable hospital readmissions. Another commenter expressed concern over being "penalized" for readmissions that are clinically unrelated to a patient's original reason for IRF admission. One commenter recommended that CMS continue evaluating and testing the measure to ensure that the codes used for the PPR definition are clinically relevant. Another commenter expressed concern over using DRGs as the basis for defining the reasons for receiving inpatient rehabilitation or the reason for a subsequent hospital readmission given variation in coding practices in acute care hospitals.

Response: As described in the proposed rule, the definition for potentially preventable readmissions for this measure was developed based on existing evidence and was vetted by a TEP, which included clinicians and post-acute care experts. We also conducted a comprehensive environmental scan to identify conditions for which readmissions may be considered potentially preventable. Results of this environmental scan and details of the TEP input received were made available in the PPR TEP summary report 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>. We also solicited stakeholder feedback on the development of this measure through a public

comment period held from November 2 through December 1, 2015. Comments on the measure varied, with some commenters supportive of the proposed measure, while others either were not in favor of the measure, or suggested potential modifications to the measure specifications, such as including standardized function data. A summary of the public comments is also 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>.

Though readmissions may be considered potentially preventable even if they may not appear to be clinically related to the patient's original reason for IRF admission, there is substantial evidence that the conditions included in the definition may be preventable with adequately planned, explained, and implemented post-discharge instructions, including the establishment of appropriate follow-up ambulatory care. Furthermore, this measure is based on Medicare FFS claims data and it may not always be feasible to determine whether a subsequent readmission is or is not clinically related to the reason why the patient was receiving inpatient rehabilitation. We intend to conduct ongoing evaluation and monitoring of this measure, and will take these comments into consideration.

With regard to the comment related to DRGs, we wish to clarify that this measure does not use hospital DRGs to define PPRs or in the risk adjustment. Potentially preventable hospital readmissions are defined by the principal diagnosis on the readmission claim. Our risk-adjustment model uses diagnoses (not DRGs) from the prior hospital claim as risk adjusters. Though there may be variation in coding practices, claims data are the most reliable source to identify potentially preventable hospital readmissions post-IRF discharge. We would also like to

clarify that the reason for receiving inpatient rehabilitation is captured as a risk adjuster by the use of the IRF PPS CMGs which also incorporate the RICs as well as function.

Comment: Several commenters expressed support for the cross-setting standardization of the inclusion and exclusion criteria for the PPR measures. MedPAC and another commenter commented that the measure definition and risk adjustment should be identical across PAC settings so that potentially preventable readmission rates can be compared across settings. One commenter expressed concern over the “nonalignment” specifically between the IRF and SNF versions of the measure, adding that this may lead to confusion. Another commenter suggested a single or harmonized measure to better inform patients, caregivers, and payers. One comment encouraged CMS to assess readmission measures across the agency’s programs to ensure that they promote collaboration and support readmission reduction efforts.

Response: The PPR definition (that is, list of conditions for which readmissions would be considered potentially preventable) is aligned for measures with the same readmission window, regardless of PAC setting. Specifically, the post-PAC discharge PPR measures that were developed for each of the PAC settings contain the same list of PPR conditions. Although there are some minor differences in the specifications across these potentially preventable readmissions measures (for example, years of data used to calculate the measures to ensure reliability and some of the measure exclusions necessary to attribute responsibility to the individual settings), the IMPACT Act PPR measures are standardized. As described for all IMPACT Act measures in section VIII.B in this final rule, the statistical approach for risk adjustment is also aligned across the measures; however, there is variation in the exact risk adjusters. The risk-adjustment models are empirically driven and differ between measures as a consequence of case mix differences, which is necessary to ensure that the estimates are valid.

We appreciate the comment that the readmission measures across our programs be assessed to ensure they promote collaboration and support readmission reduction efforts. As we continually evaluate and monitor the PAC quality reporting and other CMS programs, we will take the commenter's suggestion into consideration.

Comment: Several commenters expressed concern that this measure would capture outcomes that are outside of PAC providers' control, specifically with respect to chronically ill patients, instances of poor patient compliance, unhealthy choices, and various SDS factors, such as lack of resources or limited access to follow up or primary care. One commenter also expressed concern over the added risk of caring for a high volume of transplant patients that other IRFs may choose not to admit. Another commenter noted that even though the risk adjustment will account for some of these circumstances, it is difficult for providers to fully evaluate the risk-adjustment model because the testing and risk-adjustment coefficients have not been finalized. A few commenters recommend these measures be suspended until CMS explains how the measures will treat each of these scenarios.

Response: As noted by one commenter, the measure's comprehensive risk-adjustment approach and exclusion criteria are intended to capture many of these factors. As described above, there is substantial evidence that the conditions included in the definition may be preventable with adequately planned, explained, and implemented post-discharge instructions, including the establishment of appropriate follow-up ambulatory care. We would like to clarify that the focus of the PPR measure is to identify excess PPR rates for the purposes of quality improvement.

We would also like to clarify that the finalized risk-adjustment models and coefficients are included in the measure specifications available at <https://www.cms.gov/Medicare/Quality->

Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.

Comment: Several commenters expressed concern over the overlap between the proposed PPR measure and other IRF QRP measures, including the existing all-cause readmission measure. Commenters expressed concern that public reporting of more than one hospital readmission measure for IRFs may result in confusion among the public; the commenters also noted providers could face confusion over two distinct but similar measures, which could potentially pose challenges for quality improvement efforts. One commenter noted that the proposed PPR measures and the existing all-cause measure are distinct yet overlapping, adding that the PPR measure is a subset of the all-cause readmission measure. Given this overlap, one commenter was concerned that providers who perform poorly on the all-cause readmission measure are likely to do so for the proposed PPR measure as well, and suggested CMS suspend the measure until it could evaluate the necessity of each measure. Some commenters requested that CMS clarify the overlap and intent of these measures, and provide more education to providers and the public on the multiple IRF QRP readmission measures. Another commenter suggested that CMS conduct dry runs of the readmission measures, similar to those conducted for the all-cause measure.

One commenter supported the use of Medicare claims data to calculate these measures because it does not require the submission of additional data by IRFs. Another commenter noted that despite the lack of a data collection burden for providers, multiple readmission measures in the program will create burden on the part of providers to track and improve performance. Another commenter expressed concern that the measures are “extensive” and will place additional financial burden on providers.

Response: The All-Cause Unplanned Hospital Readmission Measure for 30 Days Post-IRF Discharge (NQF #2502) was adopted for the IRF QRP prior to the IMPACT Act. The measure of potentially preventable hospital readmissions was developed in response to the statutory mandate of the IMPACT Act. We would like to clarify that providers are not held financially accountable for their performance on these measures, but only whether they report the necessary data for the IRF QRP.

With regard to overlap with the existing IRF QRP readmission measure, retaining the all-cause measure will allow us to monitor trends in both all-cause and PPR rates in order to assess the extent to which changes in facility performance for one measure are reflected in the other. We are committed to ensuring that measures in the IRF QRP are useful in assessing quality and will continue to evaluate all readmission measures over time.

We thank commenters for their feedback related to provider burden on the measure. We would like to note that the PPR measure uses Medicare claims data and is not collected by means of an assessment instrument. Therefore, the measure does not increase data collection burden on the provider as this data is currently collected by providers. Despite the lack of data collection burden, we appreciate the comments that more education will be required for the public and providers to understand the differences between the readmission measures in the IRF QRP.

Comment: Several commenters raised concerns over the risk-adjustment approach for the PPR measure. One commenter expressed concern that the HCC risk-adjustment method is insufficient at predicting costs for certain patient populations. The commenter suggested CMS research and develop a refined risk-adjustment model that encompasses more of the diversity and complexity of PAC patients and is more sensitive to their levels of resource use. Several commenters expressed concern that the proposed measure is not adjusted for socio-economic

factors, and a couple commenters, including MedPAC, suggested the use of peer group comparisons of performance rates to address this issue.

Another commenter supported the proposed risk-adjustment methodology commenting it will provide a valid assessment of quality of care in preventing unplanned, preventable hospital readmissions. One commenter also suggested that, in addition to the measure exclusion for non-surgical treatment of cancer, that other conditions with similar disease trajectories be excluded from the measure, citing end-stage Multiple Sclerosis (MS), motor neuron disease, and Alzheimer's disease.

Response: We would like to note that the measure is fully developed and the finalized risk-adjustment model and coefficients are included in the measure specifications available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html>.

The HCCs were developed to separate clinically-related codes by Medicare utilization implications; they represent diagnosis-based, clinically meaningful clusters of ICD codes that have also been grouped by cost implications. When we apply HCCs for risk adjustment of quality or resources use measures, we do not use the HCC models applied to payment. In our measure development, we typically test individual HCCs that are relevant to the outcome of interest; we estimate the effects of the individual HCCs or clusters on the dependent variable in the particular model and retain those that are significant or meaningful predictors of outcomes. We believe that risk adjusting for individual HCCs or small clusters provides greater sensitivity than using a single comorbidity index, which is based on selected diagnoses. Our approach accounts for an average effect for each comorbidity or comorbidity group, rather than an overall burden of comorbidities.

The HCCs are more comprehensive than the simpler diagnosis-based systems, such as the Elixhauser Comorbidity Index or Charlson Comorbidity Index, which were targeted for predicting specific outcomes (for example, hospital mortality). We believe that HCCs provide a good representation of health risk, and their use to examine outcomes other than costs is supported in the literature.^{81,82} A study comparing the ability of five comorbidity indices to predict discharge functional status of IRF patients found that HCCs slightly outperformed other comorbidity indices.⁸³ The superior performance of HCCs was hypothesized to be related to the inclusion of more medical conditions in HCCs, and the inclusion of more ICD codes per condition in HCCs, making them a slightly more sensitive index for predicting clinical outcomes compared with other comorbidity indices.⁸⁴

We wish to clarify that the model included in the specifications using HCCs as risk adjusters for comorbidities posted for the proposed rule demonstrated sufficient discrimination power. The model had a c-statistic of 0.74 which is within range, if not higher than, similar readmission measures finalized in public reporting programs, including the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from IRFs (NQF #2502) previously adopted for the IRF QRP.

With regard to the suggestions that the model include sociodemographic factors and the suggestion pertaining to an approach with which to convey data comparisons, we refer the readers to section VIII.F of this final rule where we also discuss these topics. In response to the

81 Kumar A, Graham JE, Resnik L, Karmarkar AM, Tan A, Deutsch A, Ottenbacher KJ. Comparing Comorbidity Indices to Predict Post-Acute Rehabilitation Outcomes in Older Adults. *Am J Phys Med Rehabil*. 2016 May 4. [Epub ahead of print]

82 Li P, Kim MM, Doshi JA. Comparison of the performance of the CMS Hierarchical Condition Category (CMS-HCC) risk adjuster with the Charlson and Elixhauser comorbidity measures in predicting mortality. *BMC Health Serv Res*. 2010 Aug 20;10:245. doi: 10.1186/1472-6963-10-245.

83 Kumar A, Graham JE, Resnik L, Karmarkar AM, Tan A, Deutsch A, Ottenbacher KJ. Comparing Comorbidity Indices to Predict Post-Acute Rehabilitation Outcomes in Older Adults. *Am J Phys Med Rehabil*. 2016 May 4. [Epub ahead of print]

84 Kumar A, Graham JE, Resnik L, Karmarkar AM, Tan A, Deutsch A, Ottenbacher KJ. Comparing Comorbidity Indices to Predict Post-Acute Rehabilitation Outcomes in Older Adults. *Am J Phys Med Rehabil*. 2016 May 4. [Epub ahead of print]

suggestion to include additional conditions from the measure, such as end-stage MS, motor neuron disease, and Alzheimer's disease, we wish to clarify that we risk adjust for these clinical characteristics in our risk-adjustment model. These are low prevalence conditions and the claims data are limited in their ability to identify disease progression. However, we will take this suggestion into consideration.

Comment: Several commenters expressed concern that the measures are not NQF-endorsed, and some had additional concerns over measure testing and development. Some of these commenters recommended that CMS should adopt measures endorsed by the NQF in quality reporting programs or recommended that CMS submit the measures through the NQF endorsement process as soon as feasible.

Response: With regard to NQF endorsement, as noted in the proposed rule, we intend to submit this measure to NQF for consideration of endorsement. In addition, we noted that we reviewed the NQF's consensus endorsed measures and were unable to identify any NQF endorsed measures focused on potentially preventable hospital readmissions. We are unaware of any other measures for this IMPACT Act domain that have been endorsed or adopted by other consensus organizations. Therefore, we proposed the Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP, under the Secretary's authority to specify non-NQF endorsed measures under section 1899B(e)(2)(B) of the Act, for the IRF QRP.

We would also like to clarify that the finalized risk-adjustment models and coefficients are included in the measure specifications available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html>. We will make additional testing results available in the future.

We would like to clarify that the MAP encouraged continued development of the proposed measure. More information about the MAP's recommendations for this measure is available at

http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx.

Comment: Some commenters raised concerns over unintended consequences of the measure. One commenter was concerned that the measure could create an incentive for IRFs to be selective about the types of patients they admit (that is, "cherry pick" their patients) in order to reduce the risk of PPRs. Another comment suggested that IRFs should not be held accountable for IRF patients with planned procedures that are not admitted and treated as observation stays and requested that CMS provide clarification on how these types of patients will be assessed by the measure.

Response: We intend to conduct ongoing monitoring to assess for potential unintended consequences associated with the implementation of this measure and will take these suggestions into account.

In response to the concern regarding holding an IRF accountable for planned procedures that are treated as observation stays instead of planned hospital readmissions, we appreciate the commenter's concern and expect that this is a relatively infrequent occurrence given that most of the planned procedures are invasive surgical procedures. The measure is of hospital readmissions and does not count planned procedures that are treated as observation stays. We will take this issue into consideration for future measure development.

Comment: One commenter expressed concern over using claims data for hospital readmissions, noting that these data may not be accurate.

Response: We appreciate the commenter's concern over the accuracy of claims data. However, we wish to clarify that claims data have been validated for the purposes of assessing hospital readmissions and are used for several NQF-endorsed measures adopted for CMS programs, including the IRF QRP. Multiple studies have been conducted to examine the validity of using Medicare hospital claims to calculate several NQF-endorsed quality measures for public reporting.^{85,86,87} Additionally, although assessment and other data sources may be valuable for risk adjustment, we are not aware of any other data source aside from Medicare claims data that could be used to reliably assess potentially preventable hospital readmissions for this measure.

Final Decision: After careful consideration of the public comments, we are finalizing our proposal to adopt the measure, Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP. Measure Specifications for Measures Adopted in the FY 2017 IRF QRP final rule are available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html>.

4. Potentially Preventable Within Stay Readmission Measure for Inpatient Rehabilitation Facilities

In addition to the measure finalized in section VIII.F.3. of this final rule, Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP, we proposed the Potentially Preventable Within Stay Readmission Measure for IRFs for the FY 2018 payment determination and subsequent years. This measure is similar to the Potentially Preventable 30-

85 Bratzler DW, Normand SL, Wang Y, et al. An administrative claims model for profiling hospital 30-day mortality rates for pneumonia patients. PLoS One 2011;6(4):e17401.

86 Keenan PS, Normand SL, Lin Z, et al. An administrative claims measure suitable for profiling hospital performance on the basis of 30-day all-cause readmission rates among patients with heart failure. Circulation 2008;118(1):29-37.

87 Krumholz HM, Wang Y, Mattera JA, et al. An administrative claims model suitable for profiling hospital performance based on 30-day mortality rates among patients with heart failure. Circulation 2006;113:1693-1701.

Day Post-Discharge Readmission Measure for IRF QRP; however, the readmission window for this measure focuses on potentially preventable hospital readmissions that take place during the IRF stay as opposed to during the 30-day post-discharge period. The two PPR measures are intended to function in tandem, covering readmissions during the IRF stay and for 30 days following discharge from the IRF. Utilizing two PPR measures in the IRF QRP will enable us to assess different aspects of care and care coordination. The within stay measure focuses on the care transition into inpatient rehabilitation as well as the care provided during the IRF stay, whereas the 30-day post-IRF discharge measure focuses on transitions from the IRF into less-intensive levels of care or the community.

Similar to the Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP measure for IRFs, this measure assesses the facility-level risk-standardized rate of unplanned, potentially preventable hospital readmissions during the IRF stay. Hospital readmissions include readmissions to a short-stay acute-care hospital or an LTCH, with a diagnosis considered to be unplanned and potentially preventable. This Medicare FFS measure is claims-based, requiring no additional data collection or submission burden for IRFs. As described in section VIII.F.3. of this final rule, we developed the approach for defining PPR measure based on a comprehensive environmental scan, analysis of claims data, and TEP input. Also, we obtained public comment.

The definition for PPRs differs by readmission window. For the within-IRF stay window, PPRs should be avoidable with sufficient medical monitoring and appropriate patient treatment. The list of PPR conditions for the Potentially Preventable Within Stay Readmission Measure for IRFs are categorized by 4 clinical rationale groupings:

- Inadequate management of chronic conditions;

- Inadequate management of infections;
- Inadequate management of other unplanned events; and
- Inadequate injury prevention.

Additional details regarding the definition for PPRs are available in our document titled, Proposed Measure Specifications for Measures Proposed in the FY 2017 IRF QRP proposed rule available on our Web site at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html>.

Section VIII.F of this final rule discusses the relevant background and details that are also relevant for this measure. This measure defines planned readmissions in the same manner as described in section VIII.F.3 of this final rule, for the Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP. In addition, similar to the Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP measure, this measure uses the same risk-adjustment and statistical approach as described in section VIII.F.3 of this final rule. Note the full methodology is detailed in the document titled, Proposed Measure Specifications for Measures Proposed in the FY 2017 IRF QRP proposed rule, at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html>. This measure is also based on 2 consecutive calendar years of Medicare FFS claims data.

A TEP convened by our measure contractor provided recommendations on the technical specifications of this measure, including the development of an approach to define potentially preventable hospital readmission for PAC. Details from the TEP meetings, including TEP members' ratings of conditions proposed as being potentially preventable, are available in the

TEP Summary Report available on our 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>. We also solicited stakeholder feedback on the development of this measure through a public comment period held from November 2 through December 1, 2015. Comments on this and other PAC measures of PPR measures varied, with some commenters supportive of the proposed measure, while others either were not in favor of the measure, or suggested potential modifications to the measure specifications, such as including standardized function data. A summary of our public comment period is also available on our 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>.

The MAP encouraged continued development of the proposed measure. Specifically, the MAP stressed the need to promote shared accountability and ensure effective care transitions. More information about the MAP's recommendations for this measure is available at http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx. At the time, the risk-adjustment model was still under development. Following completion of that development work, we were able to test for measure validity and reliability as described in the measure specifications document provided above. Testing results are within range for similar outcome measures finalized in public reporting and value-based purchasing programs, including the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from IRFs (NQF #2502) that we previously adopted into the IRF QRP.

We plan to submit the measure to the NQF for consideration of endorsement. We stated in the proposed rule that we intended to provide initial confidential feedback to providers, prior to public reporting of this measure, based on 2 calendar years of claims data from discharges in 2015 and 2016. We proposed a minimum of 25 eligible stays in a given IRF for public reporting of the measure for that IRF. We also stated that we intended to publicly report this measure using claims data from calendar years 2016 and 2017.

We invited public comment on our proposal to adopt this measure, Potentially Preventable Within Stay Readmission Measure for IRFs. We received several comments, which are summarized with our responses below.

Comment: CMS received comments in support of this measure. In particular, MedPAC supported this measure, and further suggested that it should be applied identically across the four PAC settings so that post-discharge rates can be meaningfully compared.

Response: We wish to clarify that this particular measure, developed and proposed for use in the IRF QRP, is unique in that it is a within stay readmission measure. Analogous measures applicable to other PAC settings may be considered in future rulemaking.

Comment: Several commenters expressed concern over cross-setting alignment of measures, some urging CMS to delay implementation of this measure until there are equivalent within stay PPR measures for each PAC setting. Commenters noted this measure is not required by the IMPACT Act and that incongruences between measures in the different PAC settings present concerns for cross-setting comparisons and potential confusion for IRFs about their quality performance. One commenter was particularly concerned about the differences between the IRF within stay measure and the SNF PPR measure proposed for the SNF VBP Program that assess PPRs 30 days after discharge from the prior hospital.

Response: We are clarifying that though this within-stay PPR measure is not required by the IMPACT Act, capturing potentially preventable readmission measures during an IRF stay assesses important aspects of inpatient post-acute care. The measure is a starting point for this work, which is being conducted in phases, and additional measures that calculate PPRs using different readmission windows in other PAC settings will be considered in the future. We will take this comment into consideration.

Comment: Some commenters expressed that IRFs may not be able to control or prevent hospital readmissions that take place during an IRF stay, especially within the first few days of admission, if patients are admitted to IRFs prior to the availability of diagnostic testing results, or if they did not receive adequate acute care. One commenter cited the example of patients with leukemia, who are often readmitted to the hospital for treatment. Another commenter noted that even though the risk adjustment will account for some of these circumstances, it is difficult for providers to fully evaluate the risk-adjustment model because the testing and risk-adjustment coefficients have not been finalized. The commenter recommended these measures be suspended until CMS explains how the measures will treat each of these scenarios. Commenters suggested that the IRF within-stay PPR measure should account for the three-day, short-stay and transfer care policies that exist in the IRF PPS. One commenter expressed concern that the proposed measure's readmission window and IRF payment rules would cause a "double penalty" for short-stay episodes that end in a readmission. Commenters noted that the home health measures account for short-stay payment policies and that the IRF measure should be designed in a similar manner.

Response: We recognize the concerns raised related to potential delays in receiving diagnostic information and or inadequate care provided in the prior acute setting for some

patients. However, we wish to clarify that this measure is intended to address potentially preventable hospital readmissions and does not count all hospital readmissions that take place during the IRF stay. The goal of this measure is to improve care transitions and coordination of care, which is important for all patients. Furthermore, providers assume the responsibility for this outcome for all patients that they admit into their facility, including those with shorter lengths of stay.

We would like to clarify that for the commenter's example regarding patients with leukemia, these patients would most likely be excluded from the measure because non-surgical treatment of cancer is a measure exclusion. Based on analysis of data from 2013, 0.5 percent of the IRF sample was excluded because the prior short-term acute-care stay was for nonsurgical treatment of cancer which includes leukemia. In addition, leukemia and other cancer patients that are not excluded from the measure are more likely being readmitted for planned procedures and treatments; however, this is a measure of potentially preventable hospital readmissions that are also unplanned.

With regard to excluding readmissions during the first three days of an IRF stay, we would like to clarify that the policy cited is for IRF payment determination and is not related to measurement of quality of care. This measure focuses on care transitions and coordination which is relevant to all patients, including those with shorter lengths of stay. Furthermore, excluding readmissions during the first three days of an IRF stay may result in transferring patients back sooner in order to exclude patients from the measure.

We would also like to clarify that the finalized risk-adjustment models and coefficients are included in the measure specifications available at <https://www.cms.gov/Medicare/Quality->

Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.

Comment: Some commenters expressed concern over the “multiplicity” of the IRF QRP’s readmission measures, adding that this may lead to confusion and make it difficult for IRFs to track and improve performance. There was also concern that this IRF within stay PPR measure was not required by the IMPACT Act, nor did it align with a domain in CMS’s National Quality Strategy. Several commenters expressed concern over the overlap between the PPR measure and the existing all-cause readmission measures adopted for the IRF QRP. A few commenters recommended CMS not to adopt this measure, or to postpone implementation, commenting that the purpose and implications of the measure were ambiguous and its introduction was premature. The commenters respectfully recommended CMS not to adopt this measure, and some commenters suggested postponing the implementation of this measure pending further development or use in a cross-setting and standardized manner.

Response: We appreciate the comment related to the potential challenges that may be associated with proposing multiple readmission measures for the program. However, given that each measure focuses on a different aspect of care, we believe that each measure provides value in the program. We are committed to ensuring that measures in the IRF QRP are useful in assessing quality and will evaluate the readmission measures in the future.

In addition, we wish to clarify that though this measure is not required by the IMPACT Act, capturing potentially preventable readmission measures during an IRF stay assesses important aspects of inpatient post-acute care, including care coordination. Like other hospital readmission measures for post-acute care, the measure fits within the National Quality Strategy communication and care coordination priority area. We also wish to clarify that this measure

does not overlap readmission captured in other readmission measures proposed or adopted for the IRF QRP.

We would also like to clarify that the full measure specifications including preliminary results were made available at the time of the proposed rule's display. The measure is fully developed and the final measure specifications, including the finalized risk-adjustment models and descriptive statistics on IRFs' risk-standardized within-stay PPR rates, are available are included in the measure specifications available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html>.

Comment: One commenter specifically supported the inclusion of infectious conditions in the inadequate management of infections and inadequate management of other unplanned events categories in the measure's definition of potentially preventable hospital readmissions. Another commenter expressed support for the inclusion of chronic conditions and infections as conditions for which readmissions would be considered potentially preventable, citing infection prevention and other interventions that are effective in preventing such readmissions. Another commenter expressed appreciation for the focus on preventable readmissions, but recommended that CMS continue evaluating and testing the measure to ensure that the codes used for the PPR definition are clinically relevant. One commenter expressed concern over being "penalized" for readmissions that are clinically unrelated to a patient's original reason for IRF admission.

Response: As described in the proposed rule, the definition for potentially preventable readmissions for this measure was developed based on existing evidence and was vetted by a TEP, which included clinicians and post-acute care experts. We also conducted a comprehensive environmental scan to identify conditions for which readmissions may be considered potentially

preventable. Results of this environmental scan and details of the TEP input received were made available in the PPR TEP summary report 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>.

Though readmissions may be considered potentially preventable even if they may not appear to be clinically related to the patient's original reason for IRF admission, there is substantial evidence that the conditions included in the definition may be preventable with sufficient medical monitoring and appropriate patient treatment. Furthermore, this measure is based on Medicare claims data and it may not always be feasible to determine whether a subsequent readmission is or is not clinically related to the reason why the patient was receiving inpatient rehabilitation. We intend to conduct ongoing evaluation and monitoring of this measure, and will take these comments into consideration.

Comment: One commenter expressed concern that the measure could create an incentive for IRFs to be selective about the types of patients they admit in order to reduce the risk of PPRs (that is, "cherry pick" less complex patients for IRF admission). Another commenter noted this measure could incentivize longer acute hospital stays and delay admission to IRFs, expressing concern over being penalized for brief readmissions for follow-up procedures.

Response: We wish to clarify that this measure does not count planned procedures as these types of readmissions do not reflect quality of care or care transitions. We intend to conduct ongoing monitoring to assess for potential unintended consequences associated with the implementation of this measure, and will take these suggestions into account.

Comment: One commenter raised concerns over the risk-adjustment approach for the within-stay PPR measure. The commenter expressed concern that the HCC risk-adjustment

method is insufficient at predicting costs for certain patient populations. The commenters suggested CMS reconsider the validity and reliability of the HCC risk-adjustment model, and research and develop a refined risk-adjustment model that encompasses more of the diversity and complexity of PAC patients and is more sensitive to their levels of resource use. The commenter also expressed concern that the proposed measure is not adjusted for socio-economic factors.

Response: We appreciate the comment received regarding the risk-adjustment model and will take this comment into consideration. We refer readers to our response on the use of HCCs as described in section VIII.F.3. of this final rule. We wish to clarify that the model included in the specifications using HCCs as risk adjusters for comorbidities posted for the proposed rule demonstrated more than adequate discrimination power. The model had a c-statistic of 0.74 which is within range if not higher for similar readmission measures finalized in public reporting programs, including the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from IRFs (NQF #2502) previously adopted for the IRF QRP. We would also like to clarify that the finalized risk-adjustment models and coefficients are included in the measure specifications available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html>.

With regard to the suggestions that the model include sociodemographic factors and the suggestion pertaining to an approach with which to convey data comparisons, we refer the readers to section VIII.F of this final rule where we also discuss these topics.

Comment: Some commenters expressed concern over provider burden and questioned CMS's intention of applying both all-cause and potentially preventable readmission measures. The commenters also noted that with the finalization of all required measures by the IMPACT

Act, the industry would be subject to significant changes and an increased data reporting burden with regard to the quality reporting program. Some commenters noted that there would not be an additional reporting or data collection burden given the measure is claim-based; however, providers would take on additional burdens, including understanding the measure design, evaluating its implications, and reconciling the CASPER Quality Measure feedback data.

Response: We would like to note that the within-stay PPR measures use a data source of claims data and are not collected by means of an assessment instrument. Therefore, the measure does not increase data collection burden on the provider as this data is currently collected by providers. Despite the lack of data collection burden, we appreciate the comments that more education will be required for the public and providers to understand the differences between the readmission measures in the IRF QRP. We also wish to clarify that the within-stay readmission measure does not overlap any existing readmission measures.

Comment: Several commenters expressed concern that the measures are not NQF-endorsed, some with additional concerns over measure testing and development. Some of these commenters recommended that CMS should adopt measures endorsed by the NQF in quality reporting programs or recommended that CMS submit the measures through the NQF endorsement process as soon as feasible.

Response: With regard to NQF endorsement, as noted in the proposed rule, we intend to submit this measure to NQF for consideration of endorsement. We are unaware of any other measures that assess potentially preventable readmissions during an IRF stay. We appreciate the comments related to the measure's testing. We would also like to clarify that the finalized risk-adjustment models and coefficients are included in the measure specifications available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality->

[Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html](#). We will make results of additional testing and evaluation of the measure beyond those provided in the final measure specifications available in the future.

Final Decision: After careful consideration of the public comments, we are finalizing our proposal to adopt this measure, Potentially Preventable Within Stay Readmission Measure for IRFs. Measure Specifications for Measures Adopted in the FY 2017 IRF QRP Final Rule are available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html>.

G. IRF QRP Quality Measure Finalized for the FY 2020 Payment Determination and Subsequent Years

We proposed to adopt one new quality measure to meet the requirements of the IMPACT Act beginning with the FY 2020 payment determination and subsequent years. The measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC IRF QRP, addresses the IMPACT Act quality domain of Medication Reconciliation.

1. Quality Measure Addressing the IMPACT Act Domain of Medication Reconciliation: Drug Regimen Review Conducted with Follow-Up for Identified Issues-Post Acute Care Inpatient Rehabilitation Facility Quality Reporting Program

Sections 1899B(a)(2)(E)(i)(III) and 1899B(c)(1)(C) of the Act, as added by the IMPACT Act, require the Secretary to specify a quality measure to address the quality domain of medication reconciliation by October 1, 2018 for IRFs, LTCHs and SNFs by January 1, 2017 for HHAs. We proposed to adopt the quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC IRF QRP, for the IRF QRP as a patient-assessment based,

cross-setting quality measure to meet the IMPACT Act requirements with data collection beginning October 1, 2018 for the FY 2020 payment determinations and subsequent years.

This measure assesses whether PAC providers were responsive to potential or actual clinically significant medication issue(s) when such issues were identified. Specifically, the quality measure reports the percentage of patient stays in which a drug regimen review was conducted at the time of admission and timely follow-up with a physician occurred each time potential clinically significant medication issues were identified throughout that stay.

For this quality measure, drug regimen review is defined as the review of all medications or drugs the patient is taking to identify any potential clinically significant medication issues. The quality measure utilizes both the processes of medication reconciliation and a drug regimen review, in the event an actual or potential medication issue occurred. The measure informs whether the PAC facility identified and addressed each clinically significant medication issue and if the facility responded or addressed the medication issue in a timely manner. Of note, drug regimen review in PAC settings is generally considered to include medication reconciliation and review of the patient's drug regimen to identify potential clinically significant medication issues.⁸⁸ This measure is applied uniformly across the PAC settings.

Medication reconciliation is a process of reviewing an individual's complete and current medication list. Medication reconciliation is a recognized process for reducing the occurrence of medication discrepancies that may lead to Adverse Drug Events (ADEs).⁸⁹ Medication discrepancies occur when there is conflicting information documented in the medical records. The World Health Organization regards medication reconciliation as a standard operating protocol necessary to reduce the potential for ADEs that cause harm to patients. Medication

⁸⁸ Institute of Medicine. Preventing Medication Errors. Washington DC: National Academies Press; 2006.

⁸⁹ Ibid

reconciliation is an important patient safety process that addresses medication accuracy during transitions in patient care and in identifying preventable ADEs.⁹⁰ The Joint Commission added medication reconciliation to its list of National Patient Safety Goals (2005), suggesting that medication reconciliation is an integral component of medication safety.⁹¹ The Society of Hospital Medicine published a statement in agreement of the Joint Commission's emphasis and value of medication reconciliation as a patient safety goal.⁹² There is universal agreement that medication reconciliation directly addresses patient safety issues that can result from medication miscommunication and unavailable or incorrect information.^{93,94,95}

The performance of timely medication reconciliation is valuable to the process of drug regimen review. Preventing and responding to ADEs is of critical importance as ADEs account for significant increases in health services utilization and costs^{96,97,98} including subsequent emergency room visits and re-hospitalizations.⁹⁹ Annual health care costs in the United States from ADEs are estimated at \$3.5 billion, resulting in 7,000 deaths annually.^{100,101}

⁹⁰ Leotsakos A., et al. Standardization in patient safety: the WHO High 5s project. *Int J Qual Health Care*. 2014;26(2):109-116.

⁹¹ The Joint Commission. 2016 Long Term Care: National Patient Safety Goals Medicare/Medicaid Certification-based Option. (NPSG.03.06.01).

⁹² Greenwald, J. L., Halasyamani, L., Greene, J., LaCivita, C., et al. (2010). Making inpatient medication reconciliation patient centered, clinically relevant and implementable: a consensus statement on key principles and necessary first steps. *Journal of Hospital Medicine*, 5(8), 477-485.

⁹³ Leotsakos A., et al. Standardization in patient safety: the WHO High 5s project. *Int J Qual Health Care*. 2014;26(2):109-116.

⁹⁴ The Joint Commission. 2016 Long Term Care: National Patient Safety Goals Medicare/Medicaid Certification-based Option. (NPSG.03.06.01).

⁹⁵ IHI. Medication Reconciliation to Prevent Adverse Drug Events [Internet]. Cambridge, MA: Institute for Healthcare Improvement; [cited 2016 Jan 11]. Available from: <http://www.ihl.org/topics/adesmedicationreconciliation/Pages/default.aspx>

⁹⁶ Institute of Medicine. Preventing Medication Errors. Washington DC: National Academies Press; 2006.

⁹⁷ Jha AK, Kuperman GJ, Rittenberg E, et al. Identifying hospital admissions due to adverse drug events using a computer-based monitor. *Pharmacoepidemiol Drug Saf*. 2001;10(2):113-119.

⁹⁸ Hohl CM, Nosyk B, Kuramoto L, et al. Outcomes of emergency department patients presenting with adverse drug events. *Ann Emerg Med*. 2011;58:270-279.

⁹⁹ Kohn LT, Corrigan JM, Donaldson MS. To Err Is Human: Building a Safer Health System Washington, DC: National Academies Press; 1999.

¹⁰⁰ Greenwald, J. L., Halasyamani, L., Greene, J., LaCivita, C., et al. (2010). Making inpatient medication reconciliation patient centered, clinically relevant and implementable: a consensus statement on key principles and necessary first steps. *Journal of Hospital Medicine*, 5(8), 477-485.

¹⁰¹ Phillips, David P.; Christenfeld, Nicholas; and Glynn, Laura M. Increase in US Medication-Error Deaths between 1983 and 1993. *The Lancet*. 351:643-644, 1998.

Medication errors include the duplication of medications, delivery of an incorrect drug, inappropriate drug omissions, or errors in the dosage, route, frequency, and duration of medications. Medication errors are one of the most common types of medical error and can occur at any point in the process of ordering and delivering a medication. Medication errors have the potential to result in an ADE.^{102,103, 104, 105, 106, 107} Inappropriately prescribed medications are also considered a major healthcare concern in the United States for the elderly population, with costs of roughly \$7.2 billion annually.¹⁰⁸

There is strong evidence that medication discrepancies occur during transfers from acute care facilities to post-acute care facilities. Discrepancies occur when there is conflicting information documented in the medial records. Almost one-third of medication discrepancies have the potential to cause patient harm.¹⁰⁹ An estimated 50 percent of patients experienced a clinically important medication error after hospital discharge in an analysis of two tertiary care academic hospitals.¹¹⁰

Medication reconciliation has been identified as an area for improvement during transfer from the acute care facility to the receiving post-acute care facility. PAC facilities report gaps in medication information between the acute care hospital and the receiving post-acute-care setting

¹⁰² Institute of Medicine. To err is human: building a safer health system. Washington, DC: National Academies Press; 2000.

¹⁰³ Lesar TS, Briceland L, Stein DS. Factors related to errors in medication prescribing. JAMA. 1997;277(4): 312-317.

¹⁰⁴ Bond CA, Raehl CL, & Franke T. Clinical pharmacy services, hospital pharmacy staffing, and medication errors in United States hospitals. Pharmacotherapy. 2002;22(2): 134-147.

¹⁰⁵ Bates DW, Cullen DJ, Laird N, Petersen LA, Small SD, et al. Incidence of adverse drug events and potential adverse drug events. Implications for prevention. JAMA. 1995;274(1): 29-34.

¹⁰⁶ Barker KN, Flynn EA, Pepper GA, Bates DW, & Mikeal RL. Medication errors observed in 36 health care facilities. JAMA. 2002; 162(16):1897-1903.

¹⁰⁷ Bates DW, Boyle DL, Vander Vliet MB, Schneider J, & Leape L. Relationship between medication errors and adverse drug events. J Gen Intern Med. 1995;10(4): 199-205.

¹⁰⁸ Fu, Alex Z., et al. "Potentially inappropriate medication use and healthcare expenditures in the US community-dwelling elderly." Medical care 45.5 (2007): 472-476.

¹⁰⁹ Wong, Jacqueline D., et al. "Medication reconciliation at hospital discharge: evaluating discrepancies." Annals of Pharmacotherapy 42.10 (2008): 1373-1379.

¹¹⁰ Kripalani S, Roumie CL, Dalal AK, et al. Effect of a pharmacist intervention on clinically important medication errors after hospital discharge: A randomized controlled trial. Ann Intern Med. 2012;157(1):1-10.

when performing medication reconciliation.^{111,112} Hospital discharge has been identified as a particularly high risk time point, with evidence that medication reconciliation identifies high levels of discrepancy.^{113,114,115,116,117,118} Also, there is evidence that medication reconciliation discrepancies occur throughout the patient stay^{119,120}. For older patients, who may have multiple comorbid conditions and thus multiple medications, transitions between acute and post-acute care settings can be further complicated,¹²¹ and medication reconciliation and patient knowledge (medication literacy) can be inadequate post-discharge.¹²² The quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC IRF QRP, evaluates an important component of care coordination for PAC settings and will affect a large proportion of the Medicare population who transfer from hospitals into PAC services each year. For example, in 2013, 1.7 million Medicare FFS beneficiaries had SNF stays, 338,000 beneficiaries had IRF stays, and 122,000 beneficiaries had LTCH stays.¹²³

¹¹¹ Gandara, Esteban, et al. "Communication and information deficits in patients discharged to rehabilitation facilities: an evaluation of five acute care hospitals." *Journal of Hospital Medicine* 4.8 (2009): E28-E33.

¹¹² Gandara, Esteban, et al. "Deficits in discharge documentation in patients transferred to rehabilitation facilities on anticoagulation: results of a system wide evaluation." *Joint Commission Journal on Quality and Patient Safety* 34.8 (2008): 460-463.

¹¹³ Coleman EA, Smith JD, Raha D, Min SJ. Post hospital medication discrepancies: prevalence and contributing factors. *Arch Intern Med*. 2005 165(16):1842–1847.

¹¹⁴ Wong JD, Bajcar JM, Wong GG, et al. Medication reconciliation at hospital discharge: evaluating discrepancies. *Ann Pharmacother*. 2008 42(10):1373–1379.

¹¹⁵ Hawes EM, Maxwell WD, White SF, Mangun J, Lin FC. Impact of an outpatient pharmacist intervention on medication discrepancies and health care resource utilization in post hospitalization care transitions. *Journal of Primary Care & Community Health*. 2014; 5(1):14-18.

¹¹⁶ Foust JB, Naylor MD, Bixby MB, Ratcliffe SJ. Medication problems occurring at hospital discharge among older adults with heart failure. *Research in Gerontological Nursing*. 2012, 5(1): 25-33.

¹¹⁷ Pherson EC, Shermock KM, Efird LE, et al. Development and implementation of a post discharge home-based medication management service. *Am J Health Syst Pharm*. 2014; 71(18): 1576-1583.

¹¹⁸ Pronovosta P, Weasta B, Swarza M, et al. Medication reconciliation: a practical tool to reduce the risk of medication errors. *J Crit Care*. 2003; 18(4): 201-205.

¹¹⁹ Bates DW, Cullen DJ, Laird N, Petersen LA, Small SD, et al. Incidence of adverse drug events and potential adverse drug events. Implications for prevention. *JAMA*. 1995;274(1): 29-34.

¹²⁰ Himmel, W., M. Tabache, and M. M. Kochen. "What happens to long-term medication when general practice patients are referred to hospital?." *European journal of clinical pharmacology* 50.4 (1996): 253-257.

¹²¹ Chhabra, P. T., et al. (2012). "Medication reconciliation during the transition to and from long-term care settings: a systematic review." *Res Social Adm Pharm* 8(1): 60-75.

¹²² Kripalani S, Roumie CL, Dalal AK, et al. Effect of a pharmacist intervention on clinically important medication errors after hospital discharge: A randomized controlled trial. *Ann Intern Med*. 2012;157(1):1-10.

¹²³ March 2015 Report to the Congress: Medicare Payment Policy. Medicare Payment Advisory Commission; 2015.

A TEP convened by our measure development contractor provided input on the technical specifications of this quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC IRF QRP, including components of reliability, validity, and the feasibility of implementing the measure across PAC settings. The TEP supported the measure's implementation across PAC settings and was supportive of our plans to standardize this measure for cross-setting development. A summary of the TEP proceedings is available on the PAC Quality Initiatives Downloads and Video 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>.

We solicited stakeholder feedback on the development of this measure by means of a public comment period held from September 18 through October 6, 2015. Through public comments submitted by several stakeholders and organizations, we received support for implementation of this measure. The public comment summary report for the 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>.

The NQF-convened MAP met on December 14 and 15, 2015, and provided input on the use of this measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC IRF QRP. The MAP encouraged continued development of the quality measure to meet the mandate added by the IMPACT Act. The MAP agreed with the measure gaps identified by CMS, including medication reconciliation, and stressed that medication reconciliation be present as an ongoing process. More information about the MAP's recommendations for this measure is available at

http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx.

Since the MAP's review and recommendation of continued development, we have continued to refine this measure in compliance with the MAP's recommendations. The measure is consistent with the information submitted to the MAP and supports its scientific acceptability for use in quality reporting programs. Therefore, we proposed this measure for implementation in the IRF QRP as required by the IMPACT Act.

We reviewed the NQF's endorsed measures and identified one NQF-endorsed cross-setting and quality measure related to medication reconciliation, which applies to the SNF, LTCH, IRF, and HHA settings of care: Care for Older Adults (COA), (NQF #0553). The quality measure, Care for Older Adults (COA), (NQF #0553) assesses the percentage of adults 66 years and older who had a medication review. The Care for Older Adults (COA), (NQF #0553) measure requires at least one medication review conducted by a prescribing practitioner or clinical pharmacist during the measurement year and the presence of a medication list in the medical record. This is in contrast to the quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC IRF QRP, which reports the percentage of patient stays in which a drug regimen review was conducted at the time of admission and that timely follow-up with a physician occurred each time one or more potential clinically significant medication issues were identified throughout that stay.

After careful review of both quality measures, we decided to propose the quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC IRF QRP for the following reasons:

- The IMPACT Act requires the implementation of quality measures, using patient assessment data that are standardized and interoperable across PAC settings. The quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC IRF QRP, employs three standardized patient-assessment data elements for each of the four PAC settings so that data are standardized, interoperable, and comparable; whereas, the Care for Older Adults (COA), (NQF #0553) quality measure does not contain data elements that are standardized across all four PAC settings.

- The quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC IRF QRP, requires the identification of potential clinically significant medication issues at the beginning, during, and at the end of the patient's stay to capture data on each patient's complete PAC stay; whereas, the Care for Older Adults (COA), (NQF #0553) quality measure only requires annual documentation in the form of a medication list in the medical record of the target population.

- The quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC IRF QRP, includes identification of the potential clinically significant medication issues and communication with the physician (or physician designee) as well as resolution of the issue(s) within a rapid timeframe (by midnight of the next calendar day); whereas, the Care for Older Adults (COA), (NQF #0553) quality measure does not include any follow-up or timeframe in which the follow-up would need to occur.

- The quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC IRF QRP, does not have age exclusions; whereas, the Care for Older Adults (COA), (NQF #0553) quality measure limits the measure's population to patients aged 66 and older.

- The quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC IRF QRP, will be reported to IRFs quarterly to facilitate internal quality monitoring and quality improvement in areas such as patient safety, care coordination, and patient satisfaction; whereas, the Care for Older Adults (COA), (NQF #0553) quality measure would not enable quarterly quality updates, and thus data comparisons within and across PAC providers would be difficult due to the limited data and scope of the data collected.

Therefore, based on the evidence discussed above, we proposed to adopt the quality measure entitled, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC IRF QRP, for the IRF QRP for FY 2020 payment determination and subsequent years. We plan to submit the quality measure to the NQF for consideration for endorsement.

The calculation of the quality measure is based on the data collection of three standardized items to be included in the IRF-PAI. The collection of data by means of the standardized items will be obtained at admission and discharge. For more information about the data submission required for this measure, we refer readers to section VIII.I.c of this final rule.

The standardized items used to calculate this quality measure do not duplicate existing items currently used for data collection within the IRF-PAI. The measure denominator is the number of patient stays with a discharge assessment during the reporting period. The measure numerator is the number of stays in the denominator where the medical record contains documentation of a drug regimen review conducted at: (1) admission and (2) discharge with a lookback through the entire patient stay with all potential clinically significant medication issues identified during the course of care and followed up with a physician or physician designee by midnight of the next calendar day. This measure is not risk adjusted. For technical information about this measure, including information about the measure calculation and discussion

pertaining to the standardized items used to calculate this measure, we refer readers to the document titled, Proposed Measure Specifications for Measures Proposed in the FY 2017 IRF QRP proposed rule available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html>.

Data for the quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC IRF QRP, will be collected using the IRF-PAI with submission through the Quality Improvement Evaluation System (QIES) Assessment Submission and Processing (ASAP) system.

We invited public comment on our proposal to adopt the quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC IRF QRP for the IRF QRP. We received several comments, which are summarized with our responses below.

Comment: Several commenters, including MedPAC, expressed support for the quality measure. Commenters supported the medication reconciliation concept, and one commenter conveyed that preventing and responding to ADEs that account for increases in health services utilization and cost is critically important. MedPAC further noted that the medication reconciliation and follow-up process can help reduce medication errors that are especially common among patients who have multiple health care providers and multiple comorbidities.

Response: We agree that medication reconciliation is an important patient safety process for addressing medication accuracy during transitions in patient care and identifying preventable ADEs, which may lead to reduced health services utilization and associated costs.

Comment: Several commenters recommended that CMS add an additional response option, to indicate that the item N2003 Medication Follow-up (completed at admission) is not applicable if a patient does not take any medication. Alternatively, commenters suggested that CMS clarify whether this item would be mandatory in the event that a patient is not taking any medications.

Response: We wish to point out that Measure item N2003 has a skip pattern that allows the user to skip over this item if the patient does not take medication. Additional guidance will be included in the IRF- PAI training manual.

Comment: We received several comments regarding concerns about whether the measure has been fully developed and tested. Many commenters noted that the NQF-convened MAP recommended continued development for the measure and requested testing of the measure to ensure that it is appropriate for the IRF setting. Several commenters expressed concern that the measure was not NQF-endorsed.

Response: Since the time of the NQF-convened MAP, with our measure contractor, we tested this measure in a pilot test involving twelve post-acute care facilities (IRF, SNF, LTCH), representing variation across geographic location, size, profit status, and clinical records system. Two clinicians in each facility collected data on a sample of 10 to 20 patients for a total of 298 records (147 qualifying pairs). Analysis of agreement between coders within each participating facility indicated a 71 percent agreement for item DRR-01¹²⁴ Drug Regimen Review (admission); 69 percent agreement for item DRR-02¹²⁵ Medication Follow-up (admission); and

¹²⁴DRR pilot items DRR-01, DRR-02 and DRR-03 are equivalent to the proposed rule DRR PAC instrument items N. 2001, N. 2003 and N. 2005

¹²⁵ DRR pilot items DRR-01, DRR-02 and DRR-03 are equivalent to the proposed rule DRR PAC instrument items N. 2001, N. 2003 and N. 2005

61 percent agreement for DRR-03¹²⁶ Medication Intervention (during stay and discharge).

Overall, pilot testing enabled us to verify feasibility of the measure. Furthermore, measure development included convening a TEP to provide input on the technical specifications of this quality measure, including components of reliability, validity and the feasibility of implementing the measure across PAC settings. The TEP included stakeholders from the IRF setting and was supportive of our plans to standardize this measure for cross-setting development. A summary of the TEP proceedings is available on the PAC Quality Initiatives Downloads and Videos 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>.

As noted above, we plan to conduct further testing on this measure once we have started collecting data from the PAC settings. Once we have completed this additional measure performance testing, we plan to submit the measure to NQF for endorsement.

Comment: We received several comments about guidance and training. One commenter requested clear and consistent information for training staff and resources to meet the requirements of the measure. We received several comments requesting guidance regarding the definition of “clinically significant medication issues.” Several commenters were concerned that the phrase could be interpreted differently by the many providers involved in a patient’s treatment and that this could result in a challenge to collect reliable and accurate data for this quality measure. One commenter further conveyed that there are likely to be variations in measure performance that are not based on differences in care, but rather on differences in data collection. In addition, one commenter requested a specific definition in the measure

¹²⁶ DRR pilot items DRR-01, DRR-02 and DRR-03 are equivalent to the proposed rule DRR PAC instrument items N. 2001, N. 2003 and N. 2005

specifications for the word “potential,” and another commenter requested further guidance on what would be considered an “adequate response” to a clinically significant medication issue.

Response: For this measure, potential clinically significant medication issues are defined as those issues that, in the clinician’s professional judgment, warrant interventions, such as alerting the physician and/or others, and the timely completion of any recommended actions (by midnight of the next calendar day) so as to avoid and mitigate any untoward or adverse outcomes. The definition of “clinically significant” in this measure was conceptualized during the measure development process. For purposes of the measure, the decision regarding whether or not a medication issue is “clinically significant” will need to be made on a case-by-case basis, but we also intend to provide additional guidance and training on this issue.

Comment: We received several comments regarding the patient populations for the measure, specifically conveying concern that the populations are not standardized across PAC settings. For example, many commenters noted that IRF QRP measure includes data collection for Medicare Fee for Service and Medicare Advantage patients, while the SNF QRP measure only includes Medicare Part A patients, and the LTCH QRP includes all patients. Commenters were concerned that this could result in selective sampling of the patient population that would skew the collected data and distort or otherwise invalidate meaningful comparisons across measures and across settings, thereby falling short of the PAC standardization goals of the IMPACT Act. Several commenters suggested that CMS exclude Medicare Advantage patients, while others recommended that they be included for all measures across all PAC settings.

Response: We are working to standardize all measures as mandated by the IMPACT Act to increase data comparability and interoperability. We will take the commenter’s comments and concerns into consideration as we work to standardize the proposed measure.

Comment: We received several comments regarding the time period for the proposed measure. One commenter disagreed with the measure's requirement that a facility must respond to urgent medication issues within one calendar day, noting that some medication issues may need to be resolved much more quickly for the patient's well-being. Another commenter was concerned that the measure tracks medication issues during any point of the patient's stay, citing that medication reconciliation occurs only during transitions of care such as admission, transfer and discharge. Therefore, this commenter had concerns that this drug regimen review process was fundamentally different than a medication reconciliation measure that focused only on care transitions.

Response: We appreciate the challenges in coordinating patient care in IRF settings. However, we chose to set the intervention timeline as midnight of the next calendar day because we believe this timeline is consistent with current standard clinical practice where a clinically significant medication issue arises. The measure evaluates responsiveness to potential or actual clinically significant medication issues when such issues are identified. The measure evaluates responsiveness to potential or actual clinically significant medication issues when such issues are identified. We would like to note that the measure is simply assessing responsiveness to issues and does not prevent clinicians from acting more quickly when an issue is identified.

We agree that medication discrepancies can occur during patient admissions, transfers, and discharges. We wish to clarify that the quality measure requires the identification of potential clinically significant medication issues for each patient's complete IRF stay, from admission to discharge. Medication reconciliation and drug regimen review are interrelated activities; while medication reconciliation is a process that identifies the most accurate and current list of medications, particularly during transitions of care, it also includes the evaluation

of the name, dosage, frequency, and route. Drug regimen review is a process that necessitates and includes the review of all medications for additional purposes such as the identification of potential adverse effects. The process of drug regimen review includes medication reconciliation at the time of patient transitions and throughout the patient's stay.

Comment: We received several comments pertaining to the scope of the measure. Several commenters commented that medication reconciliation and drug regimen review are distinct processes. Several commenters were concerned that the measure does not meet the medication reconciliation domain of the IMPACT Act. Commenters maintained that the services provided as part of drug regimen review are distinctly different from the services provided as part of medication reconciliation, and that they are completed by different members of the care team. These commenters believe that the measure goes beyond the statutory mandate of the medication reconciliation domain of the IMPACT Act. One commenter was also concerned that, according to the definition provided in the Home Health Conditions of Participation, drug regimen review includes taking into consideration a patient's noncompliance with drug therapy, significant side effects, and ineffective drug therapy, which are not feasible for a facility to assess during admission. The commenter conveyed that this was distinct from medication reconciliation. Many commenters were concerned that the measure only evaluates whether the patient's current medications are being reviewed and does not determine whether this review affects the patient's quality of care.

Response: We disagree with the commenters' suggestion that the measure does not meet the requirements of the IMPACT Act. Medication reconciliation and drug regimen review are interrelated activities; while medication reconciliation is a process that identifies the most accurate and current list of medications, particularly during transitions in care, it also includes

the evaluation of the name, dosage, frequency, and route. Drug regimen review is a process that necessitates, and includes the review of all medications for additional purposes, such as the identification of potential adverse effects. The process of drug regimen review includes medication reconciliation at the time of patient transitions and throughout the patient's stay. Therefore, we believe that medication reconciliation and drug regimen review are processes that are appropriate to combine into a single measure for purposes of the IRF QRP. We would also like to note that during the development of the measure, the definitions of medication reconciliation and drug regimen review, as detailed in the State Operations Manual (SOM), which includes the Conditions of Participation, were taken into consideration. We do not believe that the measure's use of the term "clinically significant" overrides or conflicts with the guidance as outlined in the SOM. Further, we wish to clarify that the specification of the measure does not preclude the activities of drug regimen reviews that are consistent with the SOM. The measure encompasses the IMPACT Act's medication reconciliation domain.

Comment: Several commenters were concerned that the measure does not specify which healthcare provider is required to perform the drug regimen review, or the level of clinical training required to do so. The commenters were concerned that this lack of standardization could lead to differences across the PAC settings. Many commenters conveyed that in the IRF setting, medication reconciliation is complicated and time consuming, as IRF patients with multiple clinical needs often arrive from an acute hospital where many physicians, including specialists, have made changes to patients' prescriptions. One commenter noted that patient medications may be adjusted more frequently in an IRF due to the high level of physician supervision and was concerned that the measure would not count the extensive drug regimen review being done if a clinically significant medication issue was not identified during the stay.

However, commenters note that other PAC settings may lack the clinical expertise required to perform such thorough medication reviews. Commenters were concerned that the assessment items proposed do not capture the intense involvement of a pharmacist, physician, and nurse that occurs in complex cases.

Response: We wish to clarify that the measure does not override, supersede or conflict with current CMS guidance or regulations related to drug regimen review. The measure also does not specify what clinical professional is required to perform these activities. We do not prescribe guidance on which clinician may complete patient assessments. We also appreciate concerns about standardization across the PAC settings and acknowledge the complexity of drug regimen review in the IRF settings. While we agree that this measure does not capture every aspect of the drug regimen review process undertaken for each IRF patient, we emphasize that it is intended to assess whether PAC providers were responsive to potential or actual clinically significant medication issue(s) when such issues were identified. As noted in the measure specifications, the measure's assessment items are standardized.

Comment: Many commenters, including MedPAC, encouraged CMS to develop a measure to evaluate medication reconciliation throughout the care continuum. Commenters, including MedPAC, suggested CMS focus on discharge from the PAC setting and evaluate whether the PAC sends a medication list to the patient's primary care physician or to the next PAC provider. One commenter recommended that CMS not proceed with the measure and instead focus on medication reconciliation at discharge.

Response: PAC facilities are expected to document information pertaining to the process of a drug regimen review, which includes medication reconciliation, in the patient's discharge medical record. Further, it is standard practice for patient discharge records to include a

medication list to be transferred to the admitting PAC facility. We appreciate MedPAC and other commenters' recommendation for a quality measure that assesses post-discharge medication communication with primary care providers for patients discharged to home. We will take the recommendation into consideration for future measure development in accordance with the IMPACT Act, which emphasizes the transfer of interoperable patient information across the continuum of care.

Comment: We received a number of comments related to unintended consequences of the measure. One commenter expressed concern that the measure would discourage PAC clinicians from reporting and correcting medication errors. Another commenter was concerned that the measure does not require an IRF to take steps to identify clinically significant medication issues, but instead measures whether steps were taken once an issue was identified, which could be abused by PAC providers who limit the identification of clinically significant medication issues in order to artificially increase their score.

Response: Since it is a professional standard of practice for all providers to address potential clinically significant medication issues before they lead to avoidable harm to the patient, we do not believe that the measure will discourage a clinician from reporting a significant medication issue. We reiterate that the quality measure encourages PAC providers to conduct thorough drug regimen review to identify, address, and follow up for all clinically significant medication errors. The measure was informed by current evidence surrounding medication reconciliation and drug regimen review, as well as a review of best practice and professional standards of care.

Comment: We received multiple comments related to burden and expenses related to this measure. One commenter expressed concern that the requirements required increased resources

without clear benefit or increase in pay to providers for additional expenses. One commenter conveyed concern that providers' existing electronic medical record systems (EMRs) likely do not include data collection and reporting capabilities required by the measure. The commenter conveyed the challenge of collecting the data for this measure manually and had concerns about the cost of doing so, and resulting data inaccuracy.

Response: We are very sensitive to the issue of burden associated with data collection and have proposed only the minimal number of items needed to calculate the quality measures. We emphasize that this measure follows standard clinical practice requirements of ongoing review, documentation, and timely reconciliation of all patient medications, with appropriate follow-up to address all clinically significant medication concerns. While we support the use of EMRs, we do not require that providers use EMRs to populate assessment data.

Comment: One commenter suggested that CMS exclude patients from the measure who were unexpectedly discharged before the medication reconciliation process is completed.

Response: We would like to clarify that this IRF measure includes all Medicare Part A and Medicare Advantage patient stays, including stays where a patient has an unexpected discharge. Data for coding N2005 Medicare Interventions can be obtained from the patient's medical records, so it is feasible to code the measure item when a patient has an unexpected discharge.

Comment: One commenter conveyed concern that drug regimen review occurs differently across the care settings. The commenter specifically expressed that inpatient settings may handle clinically significant medication issues more immediately than home health agencies.

Response: We believe that this comment is immaterial to the intent of the measure. It should be noted that we strive for consistency in the collection and application of the measure across all PAC settings.

Comment: One commenter requested for clarification about whether the measure is intended to include instances where a drug was reviewed for potential adverse effects and drug reactions prior to being ordered. The commenter conveyed that the measure only included medications that have been ordered for the patient but not those that were prevented from being ordered by a drug regimen process.

Response: We appreciate the commenter's concern regarding medications that were prevented from being ordered by the drug regimen review process. If finalized, we would provide guidance on these and other clinical examples as part of the training efforts.

Final Decision: After careful consideration of the public comments, we are finalizing our proposal to adopt the quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC IRF QRP measure for the IRF QRP for FY 2020 payment determination and subsequent years, as described in the Measure Specifications for Measures Adopted in the FY 2017 IRF QRP final rule, available at

<https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/Technical-Information.html>.

H. IRF QRP Quality Measures and Measure Concepts under Consideration for Future Years

We invited comment on the importance, relevance, appropriateness, and applicability of each of the quality measures listed in Table 8 for future years in the IRF QRP. We are developing a measure related to the IMPACT Act domain, "Accurately communicating the existence of and providing for the transfer of health information and care preferences of an

individual to the individual, family caregiver of the individual, and providers of services furnishing items and services to the individual, when the individual transitions.” We considered the possibility of adding quality measures that rely on the patient’s perspective; that is, measures that include patient-reported experience of care and health status data. We recently posted a “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” (80 FR 72725). Also, we are considering a measure focused on pain that relies on the collection of patient-reported pain data. Finally, we are considering a measure related to patient safety, Venous Thromboembolism Prophylaxis.

We received several comments about IRF QRP quality measures under consideration for future years which are summarized with our responses below.

Comment: Commenters had concerns about the current process for seeking stakeholder feedback, noting that seven- and fourteen-day public comment periods are unreasonable for stakeholders. Other commenters did not support the addition of process measures, citing administrative burden and expense, and recommended that CMS focus on outcome measures and postpone any measures outside the requirements of the IMPACT Act.

Many commenters remarked on the limited number of items in the IRF-PAI related to communication, cognition, and swallowing and noted that these domains are important in treating individuals with neurological disorders. One commenter encouraged CMS to adopt a specific screening instrument (Montreal Cognitive Assessment (MoCA)) or similar screening tools and assessment tools (such as the Continuity Assessment Record and Evaluation-Community, or CARE-C) to best meet the needs of Medicare beneficiaries and the intent of the IMPACT Act. Another commenter requested that CMS add a functional cognition assessment

item to the IRF discharge assessment and that this information be provided to the next provider when a patient is transferred. The commenters offered to collaborate with CMS to develop future measures in the area of cognitive function.

Response: We wish to note that several of the measures currently adopted in the IRF QRP are outcome measures, including: Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short-Stay) (NQF #0678), NHSN CAUTI Outcome Measure (NQF #0138), All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from an IRF (NQF #2502), NHSN Facility-wide Inpatient Hospital-onset MRSA Bacteremia Outcome Measure (NQF #1716), and NHSN Facility-wide Inpatient Hospital-onset CDI Outcome Measure (NQF #1717). Measures that have been finalized for implementation October 1, 2016 also include outcome measures: Application of Percent of Residents Experiencing One or More Falls with Major Injury (NQF #0674), IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (NQF #2633), IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634), Discharge Self-Care Score for Medical Rehabilitation Patients (NQF #2635), Discharge Mobility Score for Medical Rehabilitation Patients (NQF #2636) We agree that future development of outcome measures should include other areas of function, such as communication, cognition and swallowing, and are important components of functional assessment and improvement for patients who receive care in PAC settings, including IRFs. We appreciate comments related to the public comment periods during the measure development and stakeholder feedback process, and will continue to engage stakeholders as we develop and implement quality measures to meet the requirements of the IMPACT Act.

Comment: Several commenters supported a Venous Thromboembolism (VTE) Prophylaxis measure but suggested that the measure take into account that not all VTEs can be prevented due to its complexity. Some commenters did not support a process measure, since VTE prophylaxis is already a standard of practice and the measure would add burden, but have no clinical significance. These commenters do support the development of a VTE outcome measure.

Response: We thank the commenters for their comments on the VTE Prophylaxis measure under consideration for future implementation in the IRF QRP and will take into consideration the commenters' recommendations.

Comment: Several commenters recommended that a pain measure take into consideration pain that might be experienced as the result of intense therapy. One commenter suggested that pain management was a more meaningful measure for IRF patients and requested guidance on the definitions of moderate and severe pain.

Response: We will take these suggested quality measure concepts and recommendations regarding measure specifications into consideration in our ongoing measure development and testing efforts.

Comment: We received several comments regarding the patient experience of care measure. Several commenters had concerns about survey fatigue across the continuum of care. Many commenters were concerned that for one episode of care, a patient could receive a survey from each setting which could result in confusion in responses and inaccurate results. Many commenters were concerned that since many IRFs are small units, their data may not be statistically representative or may show high variability. The commenters recommended that CMS take a systems-based approach with patient experience surveys to avoid these problems.

Many commenters supported a patient experience of care measure, and supported accepting proxy response from family members and caregivers to support accurate and reliable results at the facility level. Other commenters supported a measure of patient experience, instead of only patient satisfaction, and recommended that it include several aspects unique to IRF care, including goal setting and discharge planning. Commenters recommended that CMS implement the survey as a voluntary tool prior to requiring it, which would allow IRFs to transition operationally and find a vendor, if needed. Commenters also recommended that the quality measure adjust for factors already in place for existing CAHPS® surveys, including adjusting for mode of survey administration, as well as IRF-specific patient-mix adjustment. The commenter also suggested converting responses to a 0 to 100 linear-scaled score. Several commenters recommended that CMS seek stakeholder input on the development of a patient experience of care measure.

Response: We will take these recommendations regarding measure specifications and survey fatigue across the care continuum into consideration in our ongoing measure development and testing efforts, and will continue to engage stakeholders in the development process.

Comment: We received several comments regarding the transfer of health information and care preferences measure. Many commenters recommended that development efforts for this measure should recognize that there is a large amount of variation in the different health information systems used by different IRFs to record, store, retrieve, and share patient information. The commenter noted that hospitals are already required to transfer health information and care preferences as part of their Medicare Conditions of Participation, and posited that adding such a measure to the IRF QRP would rely on receiving accurate and

complete discharge information from a prior level of care, which may be out of the IRF's control.

Response: As we move through the development of this measure concept, we will consider the variation in health information systems used by different IRFs, as well as the concerns about receiving complete discharge information from a prior level of care for these measure concepts.

TABLE 9: IRF QRP Quality Measures under Consideration for Future Years

IMPACT Act Domain	Accurately communicating the existence of and providing for the transfer of health information and care preferences of an individual to the individual, family caregiver of the individual, and providers of services furnishing items and services to the individual, when the individual transitions
IMPACT Act Measure	<ul style="list-style-type: none"> • Transfer of health information and care preferences when an individual transitions
NQS Priority	Patient- and Caregiver-Centered Care
Measures	<ul style="list-style-type: none"> • Patient Experience of Care • Percent of Patients with Moderate to Severe Pain
NQS Priority	Patient Safety
Measure	<ul style="list-style-type: none"> • Venous Thromboembolism Prophylaxis

I. Form, Manner, and Timing of Quality Data Submission for the FY 2018 Payment

Determination and Subsequent Years

1. Background

Section 1886(j)(7)(C) of the Act requires that, for the FY 2014 payment determination and subsequent years, each IRF submit to the Secretary data on quality measures specified by the Secretary. In addition, section 1886(j)(7)(F) of the Act requires that, for the fiscal year beginning on the specified application date, as defined in section 1899B(a)(2)(E) of the Act, and each subsequent year, each IRF submit to the Secretary data on measures specified by the Secretary under section 1899B of the Act. The data required under section 1886(j)(7)(C) and (F) of the Act must be submitted in a form and manner, and at a time, specified by the Secretary. As required by section 1886(j)(7)(A)(i) of the Act, for any IRF that does not submit data in accordance with section 1886(j)(7)(C) and (F) of the Act for a given fiscal year, the annual increase factor for payments for discharges occurring during the fiscal year must be reduced by 2 percentage points.

a. Timeline for Data Submission Under the IRF QRP for the FY 2018, FY 2019 and Subsequent Year Payment Determinations

Tables 10 through 18 represent our finalized data collection and data submission quarterly reporting periods, as well as the quarterly review and correction periods and submission deadlines for the quality measure data submitted via the IRF-PAI and the CDC/NHSN affecting the FY 2018 and subsequent year payment determinations. We also provide in Table 10 our previously finalized claims-based measures for FY 2018 and subsequent years, although we note that, for claims-based measures, there is no corresponding quarterly-based data collection or submission reporting periods with quarterly-based review and correction deadline periods.

Further, in the FY 2016 IRF PPS final rule (80 FR 47122 through 47123), we established that the IRF-PAI-based measures finalized for adoption into the IRF QRP will transition from reporting based on the fiscal year to an annual schedule consistent with the calendar year, with quarterly reporting periods followed by quarterly review and correction periods and submission deadlines, unless there is a clinical reason for an alternative data collection time frame. The pattern for annual, calendar year-based data reporting, in which we use 4 quarters of data, is illustrated in Table 10 and is in place for all Annual Payment Update (APU) years except for the measure in Table 10 for which the FY 2018 APU determination will be based on 5 calendar year quarters in order to transition this measure from FY to CY reporting. We also wish to clarify that payment determinations for the measures finalized for use in the IRF QRP that use the IRF-PAI or CDC NHSN data sources will subsequently use the quarterly data collection/submission and review, correction and submission deadlines described in Table 10 unless otherwise specified, as is with the measure NQF #0680: Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine. For this measure, we clarify in a subsequent discussion that the data collection and reporting periods, which are based on the

Influenza Season, span 2 consecutive years from July 1 through June 30th and we therefore separately illustrate those collection/submission quarterly reporting periods, review and correction periods, and submission deadlines for FY 2019 and subsequent years in Table 10. We also separately distinguish the reporting periods and data submission timeframes for the finalized measure Influenza Vaccination Coverage among Healthcare Personnel which spans 2 consecutive years, as this measure is based on the Influenza vaccination season, in Table 10.

TABLE 10: Annual QRP CY IRF-PAI & CDC/NHSN Data Collection/submission Reporting Periods and Data Submission/Correction Deadlines Payment Determinations^**

Proposed CY Data Collection Quarter	Data Collection/submission Quarterly Reporting Period	QRP Quarterly Review and Correction Periods Data Submission Deadlines for Payment Determination**	
Quarter 1	January 1- March 31*	April 1- August 15*	Deadline: August 15*
Quarter 2	April 1-June 30	July 1-November 15	Deadline: November 15
Quarter 3	July 1- September 30	October 1- February 15	Deadline: February 15
Quarter 4	October 1- December 31*	January 1- May 15*	Deadline: May 15*

* We refer readers to Table 10 for the annual data collection time frame for the measure, Influenza Vaccination Coverage among Healthcare Personnel

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

^We refer readers to Table 10 for the 12 month (July-June) data collection/submission quarterly reporting periods, review and correction periods and submission deadlines for APU determinations for the measure NQF #0680: Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine

TABLE 11: Summary Details on Data Collection Period and Data Submission Timeline for Previously Adopted Quality Measure Affecting the FY 2018 Payment Determination that will use 5 CY Quarters in order to transition from a FY to a CY reporting cycle

Finalized Measure:			
<ul style="list-style-type: none"> NQF #0678 Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (80 FR 47122) 			
Submission method	Data Collection/ submission Quarterly Reporting Period(s)	Quarterly Review and Correction Periods Data Submission Deadlines for Payment Determination */**	APU determination affected
IRF-PAI/ QIES ASAP System	CY 15 Q4 10/1/15 – 12/31/15	1/1/2016- 5/15/16 deadline	FY 2018
	CY 16 Q1 1/1/16–3/31/16	4/1/2016 - 8/15/16 deadline	
	CY 16 Q2	7/1/16- 11/ 15/16 deadline	

Finalized Measure:			
<ul style="list-style-type: none"> NQF #0678 Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (80 FR 47122) 			
Submission method	Data Collection/ submission Quarterly Reporting Period(s)	Quarterly Review and Correction Periods Data Submission Deadlines for Payment Determination */**	APU determination affected
	4/1/16–6/30/16		
	CY 16 Q3 7/1/16–9/30/16	10/1/16- 2/15/17 deadline	
	CY 16 Q4 10/01/16–12/31/16	1/1/17- 5/15/17 deadline	

*We refer readers to the Table 11 for an illustration of the data collection/submission quarterly reporting periods and correction and submission deadlines

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

TABLE 12: Summary Details on Data Collection Period and Data Submission Timeline for Previously Adopted IRF-PAI Quality Measure, NQF #0680 Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine, Affecting the FY 2018 Payment Determination

Finalized Measure:			
<ul style="list-style-type: none"> NQF #0680 Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (80 FR 47122) 			
Submission method	Data Collection/ submission Quarterly Reporting Period(s)	Quarterly Review and Correction Periods Data Submission Deadlines for Payment Determination *	APU determination affected
IRF-PAI/ QIES ASAP System	CY 15 Q4 10/1/15 – 12/31/15	1/1/2016- 5/15/16 deadline	FY 2018
	CY 16 Q1 1/1/16–3/31/16	4/1/2016 - 8/15/16 deadline	
	CY 16 Q2 4/1/16–6/30/16	7/1/16- 11/15/16 deadline	

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

TABLE 13: Summary Details on Data Collection Period and Data Submission Timeline for Previously Adopted Quality Measures Affecting the FY 2018 Payment Determination that will use only 1 CY quarter of data initially for the purpose of determining provider compliance

Finalized Measures:

- NQF #0674 Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (80 FR 47122)
- NQF #2631 Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (80 FR 47122)
- NQF #2633 IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (80 FR 47122)
- NQF #2634 IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (80 FR 47122)
- NQF #2635 IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (80 FR 47122)
- NQF #2636 IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (80 FR 47122)

Submission method	Data Collection/ submission Quarterly Reporting Period(s)	Quarterly Review and Correction Periods Data Submission Deadlines for Payment Determination */**	APU determination affected
IRF-PAI/ QIES ASAP System	CY 16 Q4 10/1/16 – 12/31/16	1/1/2017- 5/15/17	FY 2018

*We refer readers to the Table 12 for an illustration of the data collection/submission quarterly reporting periods and correction and submission deadlines, which will be followed for the above measures, for all payment determinations subsequent to that of FY 2018.

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

TABLE 14: Summary Details on Data Collection Period and Data Submission Timeline for Previously Adopted CDC/NHSN Quality Measures Affecting the FY 2018 Payment Determination and Subsequent Years that will use 4 CY quarters*

Finalized Measures:

- NQF #0138 NHSN Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (80 FR 47122 through 47123)
- NQF #1716 NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure (80 FR 47122 through 47123)
- NQF #1717 NHSN Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure (79 FR 45917)

Submission method	Data Collection/ submission Quarterly Reporting Period(s)	Quarterly Review and Correction Periods Data Submission Deadlines for Payment Determination	APU determination affected
CDC/NHSN	CY 16 Q1 1/1/16 – 3/31/16 and Q1 of subsequent Calendar Years	4/1/2016 - 8/15/16** and 4/1 – 8/15 of subsequent years	FY 2018 and subsequent years**
	CY 16 Q2 4/1/16 – 6/30/16	7/1/16- 11/ 15/16** and 7/1 – 11/15 of subsequent years	

	and Q2 of subsequent Calendar Years		
	CY 16 Q3 7/1/16 – 9/30/16 and Q3 of subsequent Calendar Years	10/1/16- 2/15/17** and 10/1 – 2/15 of subsequent years	
	CY 16 Q4 10/1/16 – 12/31/16 and Q4 of subsequent Calendar Years	1/1/17- 5/15/17** and 1/1 – 5/15 of subsequent years	

*We refer readers to the Table 14 for an illustration of the data collection/submission quarterly reporting periods and correction and submission deadlines.

** As is illustrated in Table 14: Subsequent years follow the same CY Quarterly Data Collection/submission Quarterly Reporting Periods and Quarterly Review and Correction Periods Deadlines for Payment Determination in which every CY quarter is followed by approximately 135 days for IRFs to review and correct their data until midnight on the final submission deadline dates.

TABLE 15: Summary Details on Data Collection Period and Data Submission Timeline for Previously Adopted IRF-PAI Quality Measures Affecting the FY 2019 Payment Determination and Subsequent Years that will use 4 CY Quarters

Finalized Measures:			
<ul style="list-style-type: none"> • NQF #0678 Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (80 FR 47122) • NQF #0674 Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (80 FR 47122) • NQF #2631 Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (80 FR 47122) • NQF #2633 IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (80 FR 47122) • NQF #2634 IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (80 FR 47122) • NQF #2635 IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (80 FR 47122) • NQF #2636 IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (80 FR 47122) 			
Submission method	Data Collection/ submission Quarterly Reporting Period(s)	Quarterly Review and Correction Periods Data Submission Deadlines for Payment Determination */**	APU determination affected
IRF-PAI/ QIES ASAP System	CY 17 Q1 1/1/17 – 3/31/17 and Q1 of subsequent Calendar Years	4/1/2017 - 8/15/17*** and 4/1 – 8/15 of subsequent years	FY 2019 and subsequent years***

	CY 17 Q2 4/1/17 – 6/30/17 and Q2 of subsequent Calendar Years	7/1/17- 11/15/17*** and 7/1 – 11/15 of subsequent years	
	CY 17 Q3 7/1/17 – 9/30/17 and Q3 of subsequent Calendar Years	10/1/17- 2/15/18*** and 10/1 – 1/15 of subsequent years	
	CY 17 Q4 10/1/17 – 12/31/17 and Q4 of subsequent Calendar Years	1/1/18- 5/15/18*** and 1/1 – 5/15 of subsequent years	

*We refer readers to the Table 15 for an illustration of the data collection/submission quarterly reporting periods and correction and submission deadlines

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

*** As is illustrated in Table 15: Subsequent years follow the same CY Quarterly Data Collection/submission Quarterly Reporting Periods and Quarterly Review and Correction Periods) and Data Submission Deadlines for Payment Determination in which every CY quarter is followed by approximately 135 days for IRFs to review and correct their data until midnight on the final submission deadline dates.

In the FY 2014 IRF PPS final rule, we adopted the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) measure for the FY 2017 payment determination and subsequent years (78 FR 47910 through 47911). In the FY 2014 IRF PPS final rule (78 FR 47917 through 47919), we finalized the data submission timelines and submission deadlines for the measures for FY 2017 payment determination. Refer to the FY 2014 final rule (78 FR 47917 through 47919) for a more detailed discussion of these timelines and deadlines.

We want to clarify that this measure includes all patients in the IRF one or more days during the influenza vaccination season (IVS) (October 1 of any given CY through March 31 of the subsequent CY). This includes, for example, a patient is admitted September 15, 2015, and discharged April 1, 2016 (thus, the patient was in the IRF during the 2015 - 2016 influenza

vaccination season). If a patient's stay did not include one or more days in the IRF during the IVS, IRFs must also complete the influenza items. For example, if a patient was admitted after April 1, 2016, and discharged September 30, 2016, and the patient did not receive the influenza vaccine during the IVS, IRFs should code the reason the patient did not receive the influenza vaccination as "patient was not in the facility during this year's influenza vaccination season."

Further, we wish to clarify that the data submission timeline for this measure includes 4 calendar quarters and is based on the influenza season (July 1 through June 30 of the subsequent year), rather than on the calendar year. For the purposes of APU determination and for public reporting, data calculation and analysis uses data from an influenza vaccination season that is within the influenza season itself. While the influenza vaccination season is October 1 of a given year (or when the vaccine becomes available) through March 31 of the subsequent year, this timeframe rests within a greater time period of the influenza season which spans 12 months—that is July 1 of a given year through June 30 of the subsequent year. Thus for this measure, we utilize data from a timeframe of 12 months that mirrors the influenza season which is July 1 of a given year through June 30th of the subsequent year. Additionally, for the APU determination, we review data that has been submitted beginning on July 1 of the calendar year 2 years prior to the calendar year of the APU effective date and ending June 30 of the subsequent calendar year, one year prior to the calendar year of the APU effective date. For example, and as provided in Table 14 for the FY 2019 (October 1, 2018) APU determination, we review data submission beginning July 1 of 2016 through June 30th of June 2017 for the 2016/2017 influenza vaccination season, so as to capture all data that an IRF will have submitted with regard to the 2016/2017 Influenza season itself. We will use assessment data for that time period as well for public reporting. Further, because we enable the opportunity to review and correct data for all

assessment based IRF-PAI measures within the IRF QRP, we continue to follow quarterly calendar data collection/submission quarterly reporting period(s) and their subsequent quarterly review and correction periods with data submission deadlines for public reporting and payment determinations. However, rather than using CY timeframe, these quarterly data collection/submission periods and their subsequent quarterly review and correction periods and submission deadlines begin with CY quarter 3, July 1, of a given year and end June 30th, CY quarter 2, of the following year. For further information on data collection for this measure, please refer to section 4 of the IRF-PAI training manual, which is available on the CMS IRF QRP Measures Information Web site at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html>, under the downloads section. For further information on data submission of the IRF-PAI, please refer to the IRF-PAI Data Specifications Version 1.12.1 (FINAL) – in effect on October 1, 2015, available for download at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Software.html>.

Refer to Table 16 for details about the quarterly data collection/submission and the review and correction deadlines for FY 2019 and subsequent years for NQF #0680 Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine.

TABLE 16: Summary Details on Data Collection Period and Data Submission Timeline for Previously Adopted IRF-PAI Quality Measure, NQF #0680 Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine, Affecting the FY 2019 Payment Determination and Subsequent Years*

Finalized Measure:			
<ul style="list-style-type: none"> NQF #0680 Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (80 FR 47122) 			
Submission	Data Collection/	Quarterly Review and Correction	APU

method	submission Quarterly Reporting Period(s)	Periods Data Submission Deadlines for Payment Determination **	determination affected
IRF-PAI/ QIES ASAP System	CY 16 Q3 7/1/16 – 9/30/16 and Q3 of subsequent Calendar Years	10/1/16- 2/15/17** and 10/1 – 2/15 of subsequent years	FY 2019 and subsequent years**
	CY 16 Q4 10/1/16 – 12/31/16 and Q4 of subsequent Calendar Years	1/1/17- 5/15/17** and 1/1 – 5/15 of subsequent years	
	CY 17 Q1 1/1/17 – 3/31/17 and Q1 of subsequent Calendar Years	4/1/17 - 8/15/17** and 4/1 – 8/15 of subsequent years	
	CY 17 Q2 4/1/17 – 6/30/17 and Q2 of subsequent Calendar Years	7/1/17- 11/ 15/17** and 7/1 – 11/15 of subsequent years	

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

** As is illustrated in Table 16: Subsequent years follow the same CY Quarterly Data Collection/submission Quarterly Reporting Periods and Quarterly Review and Correction Periods (IRF-PAI) and Data Submission (CDC/NHSN) Deadlines for Payment Determination in which every CY quarter is followed by approximately 135 days for IRFs to review and correct their data until midnight on the final submission deadline dates.

We finalized in the FY 2014 IRF PPS final rule (78 FR 47905 through 47906) that for FY 2016 and subsequent years IRFs will submit data on the quality measure Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) beginning with data submission starting October 1, 2014 (or when the influenza vaccine becomes available). To clarify that while the data collected by IRFs for this measure includes vaccination information for a flu vaccination season that begins October 1 (or when the vaccine becomes available) of a given year through March 31 of the subsequent year, the CDC/NHSN system only allows for the submission of the corresponding data any time between October 1 of a given year until March 31 of the subsequent

year; however, corrections can be made to such data until May 15th of that year. Quality data for this measure are only required to be submitted once per IVS (Oct 1 through March 31), but must be submitted prior to the May 15 deadline for the year in which the IVS ends; quarterly reporting is not required. For example, for FY 2018 payment determinations, while IRFs can begin immunizing their staff when the vaccine is available throughout the influenza vaccination season which ends on March 31, 2016, IRFs can only begin submitting the data for this measure via the CDC/NHSN system starting on October 1, 2015, and may do so up until May 15 of 2016.

TABLE 17: Summary Details on the Data Submission Timeline and Correction Deadline Timeline for the Previously Adopted Influenza Vaccination Coverage among Healthcare Personnel Affecting CY 2018 and Subsequent Years

Influenza Vaccination Coverage Among Healthcare Personnel Data submission Quarters+	Data submission Period	Review and Correction Periods Data Submission (CDC/NHSN) Deadlines for Payment Determination++	
CY QTR 4 through Subsequent CY QTR 1	10/1/15 - 3/31/16 and 10/1 – 3/31 of subsequent years	4/1/16 – 5/15/16 and 4/1 – 5/15 of subsequent years	Deadline: May 15, 2016 and May 15 of subsequent years

+ Data on this measure may be submitted via the CDC/NHSN system from October 1 of a given year through May 15 of the subsequent year.

++ A time period of April 1-May 15th is also allotted for the submission, review, and corrections.

TABLE 18: Finalized IRF QRP Claims-based Measure Affecting FY 2018 and Subsequent Years:

Quality Measure	Data Submission Method	Performance Period
NQF #2502 All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from Inpatient Rehabilitation Facilities (80 FR 47087 through 47089)	Medicare FFS Claims	CY 2013 and 2014 for public reporting in 2016 CY 2014 and 2015 for public reporting in 2017

Although we did not solicit feedback, we received several comments about the previously finalized policy to adopt calendar year data collection time frames, unless there is a clinical

reason for an alternative data collection time frame, which are summarized with our responses below.

Comment: Several commenters supported these data collection timelines to simplify the data collection and reporting process, as summarized in the FY 2016 IRF PPS Final Rule (80 FR 47122 through 47123).

Response: We thank these commenters for their support.

Comment: One commenter generally supported the change to calendar year, but was concerned that the IRF-PAI versions aligned with the fiscal year. Several others also commented that since updates are made to the IRF-PAI on a FY basis, this change would create a discrepancy within a single calendar year's data set. Many commenters were concerned that variations in FY 2018 APU data collection periods placed an increased burden on IRFs to maintain compliance and requested that CMS grant some leniency to an IRF the first time it is not compliant with quality reporting due to the new CY-based deadlines.

Response: When we finalized this change in the FY 2016 IRF PPS final rule (80 FR 47122 through 47123), we posited this change would simplify the data collection and submission time frame under the IRF QRP for IRF providers. It would also eliminate the situation in which data collection during a quarter in the same calendar year can affect 2 different years of annual payment update determination (that is, October 1 to December 31 is the first quarter of data collection for quality measures with a FY-based data collection time frame and the last quarter of data collection for quality measures with a CY-based data collection time frame). This change means that when additional quality measures that use IRF-PAI as the data collection mechanism, such as the measure Drug Regimen Review Conducted with Follow-Up for Identified Issues, are adopted for future use in the IRF QRP, the first data collection time frame for those newly-

adopted measures will be 3 months (October to December) and subsequent data collection time frames would follow a calendar year data collection time frame. This policy only affects IRFs insofar as for these newly adopted measures, compliance determinations for the applicable FY APU will only reflect data collection and submission for Q4 of the CY in which data collection begins. This does not create a discrepancy in the data set, as stated by the commenter, as we would use the following CY of data for APU analysis and public reporting purposes, should state measures be proposed and finalized for public display in the future.

With regard to concerns about increased burden with the change in data collection periods and requests for leniency regarding submission deadlines, we disagree that leniency is warranted, given that there is no discrepancy in the data set and the policy only affects the first quarter of data collection for newly adopted measures. We have ongoing education regarding data submission deadlines, including quarterly email reminders of upcoming deadlines. We also remind the reader of the availability of the reconsideration process, in which IRFs may file for reconsideration if they believe the finding of non-compliance is in error, or they have evidence of the impact of extraordinary circumstances which prevented timely submission of data.

b. Timeline and Data Submission Mechanisms for the FY 2018 Payment Determination and Subsequent Years for the IRF QRP Resource Use and Other Measures Claims-Based Measures

The MSPB PAC IRF QRP measure; Discharge to Community PAC IRF QRP measure; Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP; and Potentially Preventable Within Stay Readmission Measure for IRFs, which we are finalizing in this final rule, are Medicare FFS claims-based measures. Because claims-based measures can be calculated based on data that are already reported to the Medicare program for payment purposes, no additional information collection will be required from IRFs. As discussed in

section VIII.F of this final rule, these measures will use 2 years of claims-based data beginning with CY 2015 and CY 2016 claims to inform confidential feedback reports for IRFs, and CYs 2016 and 2017 claims data for public reporting.

We invited public comments on this proposal. We did not receive comments related to data submission mechanisms for these measures. For comments related to the measures, please see section VIII.F of this final rule. For comments related to the future public display of these measures, please see section VIII.N of this final rule.

We finalize the timeline and data submission mechanisms for FY 2018 payment determination and subsequent years as proposed.

c. Timeline and Data Submission Mechanisms for the IRF QRP Quality Measure for the FY 2020 Payment Determination and Subsequent Years

As discussed in section VIII.F of this final rule, we proposed that the data for the quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues- PAC IRF QRP, affecting FY 2020 payment determination and subsequent years, be collected by completing data elements that will be added to the IRF-PAI with submission through the QIES-ASAP system. Data collection will begin on October 1, 2018. More information on IRF reporting using the QIES-ASAP system is located at the Web site at

<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/IRFPai.html>.

For the FY 2020 payment determinations, we proposed to use CY 2018 4th quarter data, that is, beginning with discharges on October 1, 2018, through discharges on December 31, 2018, to remain consistent with the usual October release schedule for the IRF-PAI, to give IRFs sufficient time to update their systems so that they can comply with the new data reporting

requirements, and to give us sufficient time to determine compliance for the FY 2020 program. The proposed use of 1 quarter of data for the initial year of assessment data reporting in the IRF QRP, to make compliance determinations related to the applicable FY APU, is consistent with the approach we used previously for the SNF, LTCH, and Hospice QRPs.

Table 18 presents the proposed data collection period and data submission timelines for the new IRF QRP quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues- PAC IRF QRP, for the FY 2020 Payment Determination. We invited public comments on this proposal.

TABLE 19: Details on the Proposed Data Collection Period and Data Submission Timeline for Resource Use and Other Measures Affecting the FY 2020 Payment Determination

Quality Measure	Submission method	Data collection period	Data correction deadlines*	APU determination affected
Drug Regimen Review Conducted with Follow-Up for Identified Issues PAC IRF QRP	IRF-PAI/QIES ASAP	CY 2018 Q4 10/1/18–12/31/18; Quarterly for each subsequent calendar year	5/15/19 Quarterly approximately 135 days after the end of each quarter for subsequent years.	FY 2020

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

Following the close of the reporting quarter, October 1, 2018, through December 31, 2018, for the FY 2020 payment determination, IRFs will have the already established additional 4.5 months to correct their quality data and that the final deadline for correcting data for the FY 2020 payment determination will be May 15, 2019 for these measures. We further proposed that for the FY 2021 payment determination and subsequent years, we will collect data using the calendar year reporting cycle as described in section VIII.I.c of this final rule, and illustrated in Table 20. We invited public comments on this proposal.

We did not receive any comments on the proposed data collection periods and data submission timelines for the new proposed IRF QRP quality measure for the FY 2020 and FY 2021 payment determination and subsequent years.

Final Decision: We finalize the timeline and data submission mechanisms for FY 2020 and FY2021 payment determinations and subsequent years as proposed, as described in Table 19. For comments related to the measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues PAC IRF QRP, please see section VIII.G of final rule.

TABLE 20: Proposed Data Collection Period and Data Correction Deadlines* Affecting the FY 2021 Payment Determination and Subsequent Years

Quality Measure	Submission method	Proposed CY Data Collection Quarter	Proposed Data Collection Period	Proposed Quarterly Review and Data Correction Periods* Deadlines for Payment Determination
Drug Regimen Review Conducted with Follow-Up for Identified Issues PAC IRF QRP	IRF-PAI/QIES ASAP	Quarter 1	January 1- March 31	April 1- August 15
		Quarter 2	April 1-June 30	July 1- November 15
		Quarter 3	July 1- September 30	October 1- February 15
		Quarter 4	October 1- December 31	January 1- May 15

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

J. IRF QRP Data Completion Thresholds for the FY 2016 Payment Determination and Subsequent Years

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 payment determination and for each subsequent year, IRFs must meet or exceed two separate data completeness thresholds: one threshold set at 95 percent for completion of quality measures data collected using the IRF-PAI submitted through the QIES and a second

threshold set at 100 percent for quality measures data collected and submitted using the CDC NHSN.

Additionally, we stated that we will apply the same thresholds to all measures adopted as the IRF QRP expands and IRFs begin reporting data on previously finalized measure sets. That is, as we finalize new measures through the regulatory process, IRFs will be held accountable for meeting the previously finalized data completion threshold requirements for each measure until such time that updated threshold requirements are proposed and finalized through a subsequent regulatory cycle.

Further, we finalized the requirement that an IRF must meet or exceed both thresholds to avoid receiving a 2 percentage point reduction to their annual payment update for a given fiscal year, beginning with FY 2016 and for all subsequent payment updates. 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). We proposed to codify the IRF QRP Data Completion Thresholds at §412.634. We invited public comments on this proposal.

We received several comments with concerns about the proposal to codify the IRF QRP Data Completion Thresholds at §412.634, which are summarized below.

Comment: One commenter supported the 100 percent standard, but had concerns regarding technical errors with the NHSN that IRFs have experienced in the past year. Several commenters expressed concern about the threshold set at 100 percent for quality measures data collected and submitted using the CDC NHSN, citing significant burden on infection preventionists to review and complete reports in NHSN. One commenter expressed concern that the data completion threshold would be applied to data collected in FY 2014, having a retroactive impact on payment. One commenter recommended changes to the NHSN that could

alleviate the reporting requirement, including minimize the reporting of elements outside of CMS regulatory requirements, as well as altering the system to remove monthly reporting plans or allowing them to be submitted electronically.

Response: We wish to clarify that the IRF QRP thresholds for completeness of IRF data submissions were finalized in the FY 2015 IRF PPS final rule (79 FR 45921 through 45923), beginning with FY 2016, which considered quality data submitted during CY 2014. We have continually maintained that providers should be submitting complete and accurate data, and the adoption of the data completion thresholds in the FY 2015 IRF PPS final rule did not change this policy. We believe that both data completion thresholds are achievable, as evidenced by the 91 percent of IRFs that were able to achieve these thresholds for purposes of the FY 2016 payment determination. We have also taken strides to assist providers achieve compliance, including regular notification of upcoming deadlines, updated guidance documents, increased outreach to providers with incomplete data submissions, and the development of several reports which will help providers better determine where they stand with respect to compliance throughout the year. We appreciate the commenters' concerns related to burden and have taken this into consideration when issuing data completion thresholds.

Final Decision: We are finalizing our proposal to codify the IRF QRP data completion thresholds at §412.634.

K. IRF QRP Data Validation Process for the FY 2016 Payment Determination and Subsequent Years

Validation is intended to provide added assurance of the accuracy of the data that will be reported to the public as required by sections 1886(j)(7)(E) and 1899B(g) of the Act. In the FY 2015 IRF PPS rule (79 FR 45923), we finalized, for the FY 2016 adjustments to the IRF PPS

annual increase factor and subsequent years, a process to validate the data submitted for quality purposes. However, in the FY 2016 IRF PPS final rule (80 FR 47124), we finalized our decision to temporarily suspend the implementation of this policy. We did not propose a data validation policy in the FY 2017 IRF PPS proposed rule, as we are developing a policy that could be applied to several PAC QRPs. We intend to propose a data validation policy through future rulemaking.

L. Previously Adopted and Codified IRF QRP Submission Exception and Extension Policies

Refer to §412.634 for requirements pertaining to submission exception and extension for the FY 2017 payment determination and subsequent years. We proposed to revise §412.634 to change the timing for submission of these exception and extension requests from 30 days to 90 days from the date of the qualifying event which is preventing an IRF from submitting their quality data for the IRF QRP. We proposed the increased time allotted for the submission of the requests from 30 to 90 days to be consistent with other quality reporting programs; for example, the Hospital Inpatient Quality Reporting (IQR) Program also proposed to extend the deadline to 90 days in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR25205). We believe that this increased time will assist providers experiencing an event in having the time needed to submit such a request. We believe that allowing only 30 days was insufficient. With the exception of this one change, we did not propose any additional changes to the exception and extension policies for the IRF QRP at this time.

We invited public comments on the proposal to revise §412.634 to change the timing for submission of these exception and extension requests from 30 days to 90 days from the date of the qualifying event which is preventing an IRF from submitting their quality data for the IRF QRP. We received one comment on this proposal, which is summarized and addressed below in this section.

Comment: One commenter supported changing the timing for submission of exception and extension requests from 30 days to 90 days from the date of the qualifying event preventing an IRF from submitting their IRF QRP data.

Response: We thank the commenter for their support.

Final Decision: After careful consideration of the public comments, we are finalizing our proposal to revise §412.634 to change the timing for submission of these exception and extension requests from 30 days to 90 days from the date of the qualifying event which is preventing an IRF from submitting their quality data for the IRF QRP.

M. Previously Adopted and Finalized IRF QRP Reconsideration and Appeals Procedures

Refer to §412.634 for a summary of our finalized reconsideration and appeals procedures for the IRF QRP for FY 2017 payment determination and subsequent years. We did not propose any changes to this policy. However, we wish to clarify that in order to notify IRFs found to be non-compliant with the reporting requirements set forth for a given payment determination, we may include the QIES mechanism in addition to U.S. Mail, and we may elect to utilize the MACs to administer such notifications.

We received several comments about the previously adopted and finalized IRF QRP reconsideration and appeals procedures, which are summarized below.

Comment: One commenter requested that the notification also include the reason for non-compliance. Multiple commenters appreciated that CMS is using both U.S. Mail and the QIES system to notify IRFs found to be non-compliant. Another commenter recommended that CMS continue using the U.S. Mail method, noting that QIES may not be a reliable way to distribute time-sensitive information. Several commenters were concerned about the possibility of using MACs to administer notifications, citing their lack of expertise in quality reporting, and

requested that CMS clarify the authority that MACs would have to consider IRF QRP compliance and levy corrective action.

Response: We intend to retain this method of notification in addition to the use of QIES. We wish to clarify that the role of the MACs is for notification purposes only. They do not have a role in determining provider compliance in meeting the IRF QRP reporting requirements. We intend to include the reason for non-compliance in the notifications distributed via the CASPER folders; however, we wish to remind facilities that there are reports available in QIES (more information at: <https://www.qtso.com/irfpai.html>) and NHSN (more information at: <http://www.cdc.gov/nhsn/cms/>) that can be utilized to confirm quality measure data submissions. Additional information regarding non-compliance is also available on the IRF QRP Reconsiderations Web site at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Reconsideration-and-Exception-and-Extension.html>.

N. Public Display of Measure Data for the IRF QRP & Procedures for the Opportunity to Review and Correct Data and Information:

1. Public Display of Measures

Section 1886(j)(7)(E) of the Act requires the Secretary to establish procedures for making the IRF QRP data available to the public. In the FY 2016 IRF PPS final rule (80 FR 47126 through 47127), we finalized our proposals to display performance data for the IRF QRP quality measures by Fall 2016 on a CMS Web site, such as the Hospital Compare, after a 30-day preview period, and to give providers an opportunity to review and correct data submitted to the QIES-ASAP system or to the CDC NHSN. The procedures for the opportunity to review and correct data are provided in section VIII.N.2 of this final rule. In addition, we finalized the proposal to

publish a list of IRFs that successfully meet the reporting requirements for the applicable payment determination on the IRF QRP Web site at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/Spotlights-Announcements.html>. In the FY 2016 IRF PPS final rule, we finalized that we will update the list after the reconsideration requests are processed on an annual basis.

Also, in the FY 2016 IRF PPS final rule (80 FR 47126 through 47127), we also finalized that the display of information for fall 2016 contains performance data on three quality measures:

- Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678);
- NHSN CAUTI Outcome Measure (NQF #0138); and
- All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from IRFs (NQF #2502).

The measures Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) and NHSN CAUTI Outcome Measure (NQF #0138) are based on data collected beginning with the first quarter of 2015 or discharges beginning on January 1, 2015. With the exception of the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from IRFs (NQF #2502), rates are displayed based on 4 rolling quarters of data and will initially use discharges from January 1, 2015, through December 31, 2015 (CY 2015) for Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) and data collected from January 1, 2015, through December 31, 2015 (CY 2015) for NHSN CAUTI Outcome Measure (NQF #0138). For the readmissions measure, data will be publicly report beginning with data collected for discharges beginning January 1, 2013, and rates will be displayed based on 2 consecutive years of data. For IRFs with fewer than 25

eligible cases, we proposed to assign the IRF to a separate category: “The number of cases is too small (fewer than 25) to reliably tell how well the IRF is performing.” If an IRF has fewer than 25 eligible cases, the IRF’s readmission rates and interval estimates will not be publicly reported for the measure.

Calculations for all three measures are discussed in detail in the FY 2016 IRF PPS final rule (80 FR 47126 through 47127).

Pending the availability of data, we proposed to publicly report data in CY 2017 on 4 additional measures beginning with data collected on these measures for the first quarter of 2015, or discharges beginning on January 1, 2015: (1) Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure (NQF #1716) ; (2) Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure (NQF #1717) and, beginning with the 2015-16 influenza vaccination season, these two measures; (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).

Standardized infection ratios (SIRs) for the Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure (NQF #1716) and Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure (NQF #1717) will be displayed based on 4 rolling quarters of data and will initially use MRSA bacteremia and CDI events that occurred from January 1, 2015 through December 31, 2015 (CY 2015), for calculations. We proposed that the display of these ratios will be updated quarterly.

Rates for the Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) will initially be displayed for personnel working in the reporting facility October 1, 2015 through March 31, 2016. Rates for the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (NQF #0680) will also initially be displayed for patients in the IRF during the influenza vaccination season, from October 1, 2015, through March 31, 2016. We proposed that the display of these rates will be updated annually for subsequent influenza vaccination seasons.

Calculations for the MRSA and CDI Healthcare Associated Infection (HAI) measures adjust for differences in the characteristics of hospitals and patients using a SIR. The SIR is a summary measure that takes into account differences in the types of patients that a hospital treats. For a more detailed discussion of the SIR, please refer to the FY 2016 IRF PPS final rule (80 FR 47126 through 47127). The MRSA and CDI SIRs may take into account the laboratory methods, bed size of the hospital, and other facility-level factors. It compares the actual number of HAIs in a facility or state to a national benchmark based on previous years of reported data and adjusts the data based on several factors. A confidence interval with a lower and upper limit is displayed around each SIR to indicate that there is a high degree of confidence that the true value of the SIR lies within that interval. A SIR with a lower limit that is greater than 1.0 means that there were more HAIs in a facility or state than were predicted, and the facility is classified as “Worse than the U.S. National Benchmark.” If the SIR has an upper limit that is less than 1, the facility had fewer HAIs than were predicted and is classified as “Better than the U.S. National Benchmark.” If the confidence interval includes the value of 1, there is no statistical difference between the actual number of HAIs and the number predicted, and the facility is

classified as “No Different than U.S. National Benchmark.” If the number of predicted infections is less than 1.0, the SIR and confidence interval are not calculated by CDC.

Calculations for the Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) are based on reported numbers of personnel who received an influenza vaccine at the reporting facility or who provided written documentation of influenza vaccination outside the reporting facility. The sum of these two numbers is divided by the total number of personnel working at the facility for at least 1 day from October 1 through March 31 of the following year, and the result is multiplied by 100 to produce a compliance percentage (vaccination coverage). No risk adjustment is applicable to these calculations. More information on these calculations and measure specifications is available at <http://www.cdc.gov/nhsn/pdfs/hps-manual/vaccination/4-hep-vaccination-module.pdf>. We proposed that this data will be displayed on an annual basis and will include data submitted by IRFs for a specific, annual influenza vaccination season. A single compliance (vaccination coverage) percentage for all eligible healthcare personnel will be displayed for each facility.

We invited public comment on our proposal to begin publicly reporting in CY 2017, pending the availability of data, on Facility-wide Inpatient Hospital-onset MRSA Bacteremia Outcome Measure (NQF #1716); Facility-wide Inpatient Hospital-onset CDI Outcome Measure (NQF #1717); and Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431). These comments are summarized and addressed below.

Comment: Several commenters, including MedPAC, supported public reporting of quality measures. MedPAC encouraged ongoing development and public reporting of cross-cutting measures for all provider settings.

Response: We will continue to move forward with cross-setting measure development and public reporting of these measures to meet the mandate of the IMPACT Act.

Comment: Several commenters stated CMS should risk-adjust IRFs' publicly displayed data for Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) for the number of patients that have pressure ulcers.

Response: We refer commenters to the FY 2016 IRF PPS final rule (80 FR 47126 through 47127) that finalized public display of the risk-adjusted quality measure, the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678)

Comment: One commenter expressed concerns that CMS will utilize data from the CARE Tool or IRF-PAI for public reporting of the quality measures and that such data is subjective and non-evidence based and there is a lack of ability to access the competency of staff completing the tool either within or across PAC settings. Therefore, the commenter is concerned that the publicly reported data will not represent the quality of care provided in IRFs and comparing across IRFs.

Response: We appreciate the comment expressing concern regarding the CARE Tool and IRF-PAI data for public reporting. We would like to clarify that quality measures set for public display have already been finalized, and the Secretary has a statutory obligation under sections 1886(j)(7)(E) and 1899B(g) of the Act to establish procedures to make the data publicly available.

Comment: Several commenters expressed concern that the public display of quality measure information is based on measures that do not exemplify the IRF experience, target very small populations of cases, and are not a good indicator of the overall quality of IRFs. Many

commenters conveyed that the goals of IRFs are to provide medically necessary rehabilitation therapies to bring about recovery and improved function and the measures fail to assess IRFs success at achieving these goals.

Response: Section 3004 of the Affordable Care Act and the IMPACT Act require the Secretary of Health and Human Services to publish the data on the quality measures implemented in the IRF QRP through rulemaking. The public reporting of the three measures finalized for public reporting in the FY 2016 IRF PPS final rule and the four measures proposed for public reporting in the FY 2017 IRF PPS proposed rule supports the goals of the National Quality Strategy, the CMS Quality Strategy, the HHS HAI Action Plan, and the Hospital Acquired Condition Reduction Program. It is both a CMS and an HHS priority to ensure the delivery of high quality, patient-centered, and safe care across all care settings. While the main focus of care in an IRF may be centered on restoration of a patient's functional status, we believe that this cannot be achieved without attention to the basic tenants of patient care, which speak to prevention and patient safety, and believe that our quality measures reflect these aspects of quality. The IMPACT Act requires us to address the domain of functional status and requires the public reporting of this data within 2 years of a finalized quality, resource use, and other measure's specified application date. We believe that the addition of these measures to the public display of IRF quality data will help to address any concerns relayed by the commenter.

Comment: One commenter expressed concerns that the NHSN Facility-Wide Inpatient Hospital-Onset MRSA Bacteremia Outcome Measure (NQF #1716) does not reflect care provided in an IRF, specifically, rehabilitation provided to promote functional recovery and achievement of goals. The commenter also noted that the incidence of MRSA is rare, and generally, if a patient in rehabilitation has MRSA, the infection is present upon admission to the

rehabilitation facility following transfer from the acute care facility. Finally, the commenter noted that the inclusion of the NHSN Facility-Wide Inpatient Hospital-Onset MRSA Bacteremia Outcome Measure (NQF #1716) within the IRF QRP may cause rehabilitation facilities to inappropriately screen for this condition, resulting in unnecessary costs to the Medicare program.

Response: Section 3004 of the Affordable Care Act and the IMPACT Act requires the Secretary of Health and Human Services to publish the data on the quality measures implemented in the IRF QRP through rulemaking. The public reporting of the NHSN Facility-Wide Inpatient Hospital-Onset MRSA Bacteremia Outcome Measure (NQF #1716) support the goals of the National Quality Strategy, the CMS Quality Strategy, the HHS HAI Action Plan, and the Hospital Acquired Condition Reduction Program. It is both a CMS and an HHS priority to ensure the delivery of high quality, patient-centered, and safe care across all care settings.

According to the CDC, the steward of this quality measure, cases defined by NHSN as Community-onset MRSA Bacteremia are excluded from the data that is provided by NHSN to CMS. Only those cases that meet the NHSN definition of Incident and Healthcare Facility-onset are reported as a part of the CMS IRF QRP. For IRF units within a hospital that participate in the CMS IRF QRP will be given a single MRSA bacteremia LabID SIR for each type of CMS-certified IRF unit (adult and pediatric) mapped within the hospital according to CMS Certification Number (CCN). The MRSA Bacteremia LabID SIR is calculated as: number of all incident blood source MRSA LabID events identified > 3 days after admission to an IRF unit and where the patient had no positive MRSA bacteremia LabID events in the prior 14 days in any CMS-certified IRF unit of that type divided by the total number of predicted incident healthcare facility-onset blood source MRSA LabID events. Clinicians should base decisions about diagnostic testing on the needs and clinical picture of the patient. Patients with MRSA

bacteremia would be expected to be symptomatic. Routine collection of blood cultures on patients not suspected of being bacteremic would be outside of the standards of medical care. For additional information on the specifications for this measure, please refer to the CDC reference:

http://www.cdc.gov/nhsn/pdfs/cms/irfs/linelists_irfunits_indicators.pdf.

Comment: Several commenters recommended that CMS revise the Facility-wide Inpatient Hospital-onset CDI Outcome Measure (NQF #1717) because there are multiple C. difficile quality measures for Medicare providers across the continuum of care (acute care hospitals, IRFs, etc.) and one incident of C. difficile onset may be reported by three providers and effectively, and unreasonably, be a “triple hit” for multiple providers so that it is only reported at the first site of discovery.

Response: The Facility-wide Inpatient Hospital-onset CDI Outcome Measure (NQF #1717) was adopted in the IRF QRP and finalized in the FY 2015 IRF PPS final rule (79 FR 45913 through 45914). The CDC, the steward of this measure, noted that the measure specifications for NQF #1717, by design, align with the NHSN LabID Event protocol, which was developed to require minimal investigation on the part of healthcare facilities and to provide a proxy measure of infection. Dates of admission and specimen collection are required and can easily be collected via electronic methods. These dates enable differentiation of healthcare-associated and community-onset events. To require a facility to determine if a CDI LabID Event had been identified in another facility would call for manual review of medical records and potential communication with transferring facilities. The design of LabID event reporting via NHSN is by single facility, which means that events are reported for the facility where they occur. Analysis is by single facility identifier (NHSN organizational ID) and does not cross admissions to a different NHSN facility (or a different type reporting facility such as nursing

home to acute care facility) or transfer from facility A to facility B. Cases defined by NHSN as community-onset Clostridium difficile are excluded from the data that is provided by NHSN to CMS. Only those cases that meet the NHSN definitions of an Incident (non-duplicate) Healthcare Facility-onset are reported as a part of the CMS IRF QRP. Therefore, cases that are identified during the first 3 days of admission to a facility, and which may be related to a discharge from another hospital, will not be included in the Clostridium difficile LabID Event data reported for the admitting facility.

Comment: The commenter was concerned that the public display of these measures will provide misleading interpretations of quality, as almost all the measures will be based on different time frames and will use different minimum patient thresholds and potentially varying patient populations. The commenter recommends that CMS suspend public display of IRF QRP data until (1) all IMPACT Act domains are implemented and (2) the patient populations for each measure are standardized.

Response: The Secretary has a statutory obligation under section 1899B(g) and 1886(j)(7)(E) of the Act to make the data available to the public. We are transitioning towards aligning the data collection periods to follow the calendar year. Once this is achieved, the only measure that will not be in alignment is the influenza measure since these measures require taking into account the influenza season and vaccination season for the data collection period.

Minimum patient thresholds and populations are dependent on the specific measure. Each measure is specifically applied in public reporting so that there is enough volume of cases reported to protect anonymity and provide meaningful results with representative sample size. Public reporting must comply with applicable privacy laws and provide minimum sample sizes

in order for facilities to compare their performance with other IRFs. If the sample size is too small, the results will not reflect their facility performance for comparison purposes.

Final Decision: After careful consideration of the public comments, we are finalizing our proposal to begin publicly reporting in CY 2017, pending the availability of data, on Facility-wide Inpatient Hospital-onset MRSA Bacteremia Outcome Measure (NQF #1716); Facility-wide Inpatient Hospital-onset CDI Outcome Measure (NQF #1717); and Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431).

For the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680), we proposed to display rates annually based on the influenza season to avoid reporting for more than one influenza vaccination within a CY. For example, in 2017 we will display rates for the patient vaccination measure based on discharges starting on July 1, 2015, to June 30, 2016. This is proposed because it includes the entire influenza vaccination season (October 1, 2015, to March 31, 2016).

Calculations for Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) will be based on patients meeting any one of the following criteria: patients who received the influenza vaccine during the influenza season, patients who were offered and declined the influenza vaccine, and patients who were ineligible for the influenza vaccine due to contraindication(s). The facility's summary observed score will be calculated by combining the observed counts of all the criteria. This is consistent with the publicly reported patient influenza vaccination measure for Nursing Home Compare. Additionally, for the patient influenza measure, we will exclude IRFs with fewer than 20 stays in the measure denominator. For additional information on the specifications for this measure, please refer to the IRF Quality Reporting Measures Information webpage at

<https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html>.

We invited public comments on our proposal to begin publicly reporting the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) measure on discharges from July 1st of the previous calendar year to June 30th of the current calendar year. We invited comments on the public display of the measure Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (NQF #0680) in 2017 pending the availability of data.

We received several comments, which are summarized below.

Comment: Several commenters expressed concern that the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680) is not a true indicator of the quality of care provided in IRFs, which focuses on functional recovery so that patients are able to function to their maximum potential in the least restrictive environment. Commenters expressed concern that the influenza vaccination rates do not adequately assess whether quality care was provided and that CMS has not provided any evidence in the IRF QRP that differences in influenza vaccination rates between facilities affect the quality of outcomes or the patient experience.

Response: We appreciate the concerns by several commenters in regards to the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680). However, this quality measure was adopted in the IRF QRP and finalized in the FY 2014 IRF PPS final rule (78 FR 47906 through 47911).

Final Decision: After careful consideration of the public comments, we are finalizing our proposal to begin publicly reporting the Percent of Residents or Patients Who Were Assessed and

Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) measure, pending the availability of data, on discharges from July 1st of the previous calendar year to June 30th of the current calendar year.

Additionally, we requested public comments on whether to include, in the future, public display comparison rates based on CMS regions or US census regions for Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678); All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from IRFs (NQF #2502); and Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) for CY 2017 public display.

We did not receive any comments about whether to include, in the future, public display comparison rates based on CMS regions or US census regions for CY 2017 public display.

2. Procedures for the Opportunity to Review and Correct Data and Information

Section 1899B(g) of the Act requires the Secretary to establish procedures for public reporting of IRFs' performance, including the performance of individual IRFs, on quality measures specified under section 1899B(c)(1) of the Act and resource use and other measures specified under section 1899B(d)(1) of the Act (collectively, IMPACT Act measures) beginning not later than 2 years after the applicable specified application date under section 1899B(a)(2)(E) of the Act. Under section 1899B(g)(2) of the Act, the procedures must ensure, including through a process consistent with the process applied under section 1886(b)(3)(B)(viii)(VII) of the Act, which refers to public display and review requirements in the Hospital IQR Program, that each IRF has the opportunity to review and submit corrections to its data and information that are to be made public prior to the information being made public.

In the FY 2016 IRF PPS final rule (80 FR 47126 through 47128), and as illustrated in Table 10 in section VIII.I.a of this final rule, we finalized that once the provider has an opportunity to review and correct quarterly data related to measures submitted via the QIES-ASAP system or CDC NHSN, we will consider the provider to have been given the opportunity to review and correct this data. We wish to clarify that although the correction of data (including claims) can occur after the submission deadline, if such corrections are made after a particular quarter's submission and correction deadline, such corrections will not be captured in the file that contains data for calculation of measures for public reporting purposes. To have publicly displayed performance data that is based on accurate underlying data, it will be necessary for IRFs to review and correct this data before the quarterly submission and correction deadline.

We restated and proposed additional details surrounding procedures that will allow individual IRFs to review and correct their data and information on measures that are to be made public before those measure data are made public.

For assessment-based measures, we proposed a process by which we will provide each IRF with a confidential feedback report that will allow the IRF to review its performance on such measures and, during a review and correction period, to review and correct the data the IRF submitted to CMS via the CMS QIES-ASAP system for each such measure. In addition, during the review and correction period, the IRF will be able to request correction of any errors in the assessment-based measure rate calculations.

We proposed that these confidential feedback reports will be available to each IRF using the CASPER system. We refer to these reports as the IRF Quality Measure (QM) Reports. We proposed to provide monthly updates to the data contained in these reports as data become available. We proposed to provide the reports so that providers will be able to view their data

and information at both the facility and patient level for its quality measures. The CASPER facility level QM Reports may contain information such as the numerator, denominator, facility rate, and national rate. The CASPER patient-level QM Reports may contain individual patient information which will provide information related to which patients were included in the quality measures to identify any potential errors for those measures in which we receive patient-level data. Currently, we do not receive patient-level data on the CDC measure data received via the NHSN system. In addition, we will make other reports available in the CASPER system, such as IRF-PAI assessment data submission reports and provider validation reports, which will disclose the IRFs data submission status providing details on all items submitted for a selected assessment and the status of records submitted. We refer providers to the CDC/NHSN system Web site for information on obtaining reports specific to NHSN submitted data at <http://www.cdc.gov/nhsn/inpatient-rehab/index.html>. Additional information regarding the content and availability of these confidential feedback reports will be provided on an ongoing basis on our Web site(s) at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/index.html>.

As previously finalized in the FY 2016 IRF PPS final rule and illustrated in Table 18 in section VIII.I.c of this final rule, IRFs will have approximately 4.5 months after the reporting quarter to correct any errors of their assessment-based data (that appear on the CASPER generated QM reports) and NHSN data used to calculate the measures. During the time of data submission for a given quarterly reporting period and up until the quarterly submission deadline, IRFs could review and perform corrections to errors in the assessment data used to calculate the measures and could request correction of measure calculations. However, as already established, once the quarterly submission deadline occurs, the data is “frozen” and calculated for public

reporting and providers can no longer submit any corrections. We will encourage IRFs to submit timely assessment data during a given quarterly reporting period and review their data and information early during the review and correction period so that they can identify errors and resubmit data before the data submission deadline.

As noted above, the assessment data will be populated into the confidential feedback reports, and we intend to update the reports monthly with all data that have been submitted and are available. We believe that the data collection/submission quarterly reporting periods plus 4.5 months to review correct and review the data is sufficient time for IRFs to submit, review and, where necessary, correct their data and information. These time frames and deadlines for review and correction of such measures and data satisfy the statutory requirement that IRFs be provided the opportunity to review and correct their data and information and are consistent with the informal process hospitals follow in the Hospital IQR Program.

In FY 2016 IRF PPS final rule (80 FR 47126 through 47128), we finalized the data submission/correction and review period. Also, we afford IRFs a 30-day preview period prior to public display during which IRFs may preview the performance information on their measures that will be made public. We want to clarify that we will provide the preview report using the CASPER system, with which IRFs are familiar. The CASPER preview reports inform providers of their performance on each measure which will be publicly reported. Please note that the CASPER preview reports for the reporting quarter will be available after the 4.5 month correction period and the applicable data submission/correction deadline have passed and are refreshed on a quarterly basis for those measures publicly reported quarterly, and annually for those measure publicly reported annually. We proposed to give IRFs 30 days to review the preview report beginning from the date on which they can access the report. As already finalized,

corrections to the underlying data will not be permitted during this time; however, IRFs may ask for a correction to their measure calculations during the 30-day preview period, should they believe the calculation is inaccurate. We proposed that if we agree that the measure, as it is displayed in the preview report, contains a calculation error, we could suppress the data on the public reporting Web site, recalculate the measure and publish it at the time of the next scheduled public display date. This process will be consistent with informal processes used in the Hospital IQR Program. If finalized, we intend to utilize a subregulatory mechanism, such as our IRF QRP Web site, to provide more information about the preview reports, such as when they will be made available and explain the process for how and when providers may ask for a correction to their measure calculations. We invited public comment on these proposals to provide preview reports using the CASPER system, giving IRFs 30 days review the preview report and ask for a correction, and to use a subregulatory mechanism to explain the process for how and when providers may ask for a correction.

In addition to assessment-based measures and CDC measure data received via the NHSN system, we have also proposed claims-based measures for the IRF QRP. The claims-based measures include those proposed to meet the requirements of the IMPACT Act as well as the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from IRFs (NQF #2502) which was finalized for public display in the FY 2016 IRF PPS final rule (80 FR 47126 through 47127). As noted in section VII.N.2. of this final rule, section 1899B(g)(2) of the Act requires prepublication provider review and correction procedures that are consistent with those followed in the Hospital IQR Program. Under the Hospital IQR Program's informal procedures, for claims-based measures, we provide hospitals 30 days to preview their claims-based measures

and data in a preview report containing aggregate hospital-level data. We proposed to adopt a similar process for the IRF QRP.

Prior to the public display of our claims-based measures, in alignment with the Hospital IQR, HAC and Hospital VBP Programs, we proposed to make available through the CASPER system, a confidential preview report that will contain information pertaining to claims-based measure rate calculations, for example, facility and national rates. The data and information will be for feedback purposes only and could not be corrected. This information will be accompanied by additional confidential information based on the most recent administrative data available at the time we extract the claims data for purposes of calculating the measures. Because the claims-based measures are recalculated on an annual basis, these confidential CASPER QM reports for claims-based measures will be refreshed annually. As previously finalized in the FY 2016 IRF PPS final rule (80 FR 47126 through 47128), IRFs will have 30 days from the date the preview report is made available in which to review this information. The 30-day preview period is the only time when IRFs will be able to see claims-based measures before they are publicly displayed. IRFs will not be able to make corrections to underlying claims data during this preview period, nor will they be able to add new claims to the data extract. However, IRFs may request that we correct our measure calculation if the IRF believes it is incorrect during the 30 day preview period. We proposed that if we agree that the measure, as it is displayed in the preview report, contains a calculation error, we could suppress the data on the public reporting Web site, recalculate the measure, and publish it at the time of the next scheduled public display date. This process will be consistent with informal policies followed in the Hospital IQR Program. If finalized, we intend to utilize a subregulatory mechanism, such as our IRF QRP

Web site, to explain the process for how and when providers may contest their measure calculations

The proposed claims-based measures— The MSPB–PAC IRF QRP measure; Discharge to Community – PAC, Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP, and Potentially Preventable Within Stay Readmission Measure for IRFs—use Medicare administrative data from hospitalizations for Medicare FFS beneficiaries. Public reporting of data will be based on 2 consecutive calendar years of data, which is consistent with the specifications of the proposed measures. We proposed to create data extracts using claims data for the proposed claims-based measures—The MSPB – PAC IRF QRP measure; Discharge to Community – PAC, Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP, and Potentially Preventable Within Stay Readmission Measure for IRFs—at least 90 days after the last discharge date in the applicable period, which we will use for the calculations. For example, if the last discharge date in the applicable period for a measure is December 31, 2017, for data collection January 1, 2016, through December 31, 2017, we will create the data extract on approximately March 31, 2018, at the earliest, and use that data to calculate the claims-based measures for that applicable period. Since IRFs will not be able to submit corrections to the underlying claims snapshot nor add claims (for measures that use IRF claims) to this data set at the conclusion of the at least the 90-day period following the last date of discharge used in the applicable period, at that time we will consider IRF claims data to be complete for purposes of calculating the claims-based measures.

We proposed that beginning with data that will be publicly displayed in 2018, claims-based measures will be calculated using claims data at least 90 days after the last discharge date in the applicable period, at which time we will create a data extract or snapshot of the available

claims data to use for the measures calculation. This timeframe allows us to balance the need to provide timely program information to IRFs with the need to calculate the claims-based measures using as complete a data set as possible. As noted, under this procedure, during the 30-day preview period, IRFs will not be able to submit corrections to the underlying claims data or to add new claims to the data extract. This is for two reasons: first, for certain measures, the claims data used to calculate the measure is derived not from the IRF's claims, but from the claims of another provider. For example, the proposed measure Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP uses claims data submitted by the hospital to which the patient was readmitted. The claims are not those of the IRF and, therefore, the IRF could not make corrections to them. Second, even where the claims used to calculate the measures are those of the IRF, it will not be possible to correct the data after it is extracted for the measures calculation. This is because it is necessary to take a static "snapshot" of the claims in order to perform the necessary measure calculations.

We seek to have as complete a data set as possible. We recognize that the at least 90-day "run-out" period, when we will take the data extract to calculate the claims-based measures, is less than the Medicare program's current timely claims filing policy under which providers have up to 1 year from the date of discharge to submit claims. We considered a number of factors in determining that the proposed at least 90-day run-out period is appropriate to calculate the claims-based measures. After the data extract is created, it takes several months to incorporate other data needed for the calculations (particularly in the case of risk-adjusted or episode-based measures). We then need to generate and check the calculations. Because several months lead time is necessary after acquiring the data to generate the claims-based calculations, if we were to delay our data extraction point to 12 months after the last date of the last discharge in the

applicable period, we will not be able to deliver the calculations to IRFs sooner than 18 to 24 months after the last discharge. We believe this will create an unacceptably long delay both for IRFs and for us to deliver timely calculations to IRFs for quality improvement.

We invited public comment on these proposals. We received a number of comments, which are summarized below.

Comment: Several commenters expressed concern that for claims-based measures, CMS proposes to calculate claims-based measures on an annual basis and the CASPER QM provider reports for these measures would only be available annually. Commenters also expressed concern that CMS does not propose to allow providers to correct their metrics on claims-based measures; reports would be for feedback purposes only. Several commenters requested CMS provide claims-based feedback reports at least twice a year as well as providing patient-level data.

Response: We appreciate the commenters' concerns and suggestions to provide feedback reports at least twice a year as well as providing patient-level data for claims-based measures. As discussed previously, the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from IRFs (NQF #2502) is based on 2 consecutive years of data in order to ensure a sufficient sample size to reliably assess IRFs' performance. The decision to update claims-based measures on an annual basis was to ensure that the amount of data received during the reporting period was sufficient to generate reliable measure rates. However, we will explore the feasibility of providing IRFs with information more frequently. We believe that we are limited in our ability to provide patient level information that stems from claims submitted by providers other than IRF, but we will explore the feasibility of providing patient-level data. With regard to the concern for the correction of claims-based measures and the IRF's ability to correct their metrics, and that the reports we provide will be for feedback purposes only, we interpret the commenter

to be referring to both the preview reports and the QM reports we discussed. The limitation on claims-based data and corrections is that the measures are calculated after the claims file has been obtained. If the IRF determines there are errors in the claims data they submitted, then they can correct such data. The corrections to the claims data will be reflected in the subsequent measure calculation. We urge IRFs to submit timely and accurate claims-based data.

Comment: One commenter expressed concern that 30 days is inadequate to preview and assess the QM reports and recommends 60 days and that CMS should establish a process to discuss and reconcile issues or incongruities between CMS's and the provider's data.

Response: We interpret the commenter to be referring to the preview reports we will provide prior to public reporting and appreciate their concern for the 30-day timeframe for which IRFs have to review and assess the preview reports. The 30-day preview period, previously finalized, is consistent with other public reporting programmatic procedures. As described, this timeframe is for providers to evaluate their data that will be published and alert us to any discrepancies they may find. In addition, as described, IRFs will have an opportunity to review their information and data using various reports, which are provided through the CASPER system and can be used to inform data correction needs on behalf of the IRF. For example, as discussed, we intend to provide IRF QM Reports that will provide monthly reporting on both facility-level and patient-level CMS assessment-based data. Further, we refer the commenter to the discussion we provide in which IRFs will have 4.5 months to review and correct data prior to the quarterly freeze dates and posting of the final preview reports in QIES.

Final Decision: After careful consideration of the public comments, we are finalizing our proposals related to procedures for the opportunity to review and correct data and information. We are finalizing as proposed, our policies and procedures pertaining to public reporting and the

opportunity to review and correct data and information. We are also finalizing as proposed, our policies and procedures for claims-based measures for public reporting.

O. Mechanism for Providing Feedback Reports to IRFs

Section 1899B(f) of the Act requires the Secretary to provide confidential feedback reports to post-acute care providers on their performance to the measures specified under section 1899B(c)(1) and (d)(1) of the Act, beginning 1 year after the specified application date that applies to such measures and PAC providers. As discussed earlier, the reports we proposed to provide for use by IRFs to review their data and information will be confidential feedback reports that will enable IRFs to review their performance on the measures required under the IRF QRP. We proposed that these confidential feedback reports will be available to each IRF using the CASPER system. Data contained within these CASPER reports will be updated as previously described, on a monthly basis as the data become available except for our claims-based measures, which are only updated on an annual basis.

We intend to provide detailed procedures to IRFs on how to obtain their confidential feedback CASPER reports on the IRF QRP Web site at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/index.html>. We proposed to use the CMS QIES-ASAP system to provide quality measure reports in a manner consistent with how providers obtain various reports to date. The QIES-ASAP system is a confidential and secure system with access granted to providers, or their designees.

We sought public comment on this proposal to satisfy the requirement to provide confidential feedback reports to IRFs. We received several comments, which are summarized are below.

Comment: Several commenters recommended CMS provide more frequent feedback, such as quarterly, for assessment-based measures and every six months reporting for claims-based measures.

Response: We appreciate commenters' suggestion for CMS to provide more frequent feedback, such as quarterly, for assessment-based measures and every 6 months for claims-based measures.

As previously discussed, IRFs will have an opportunity to review and utilize their data using confidential reports provided through the CASPER system. The decision to update claims-based measures on an annual basis was explained previously in response to the comment concerning providing feedback reports at least twice a year.

Comment: One commenter recommended CMS conduct a "dry run" in which providers receive confidential preview reports prior to publicly reporting measures so that providers can become familiar with the methodology, understand the measure results, know how well they are performing, and have an opportunity to give CMS feedback on potential technical issues with the measures.

Response: We intend to offer providers information related to their measures so that they become familiar with the measure's methodology and can utilize their confidential preview reports which they will receive prior to the public reporting of new IRF QRP measures. IRFs will also receive other confidential reports such as the IRF facility and patient level QM Reports as well as an additional confidential facility-level report to incorporate the quarterly freeze dates, for example, the Review and Correct Report. We believe that these various reports will provide an indication on how well the IRF is performing as well as opportunities to provide CMS

feedback on technical issues with the measures. Therefore, no additional dry run period is warranted.

Final Decision: After careful consideration of the public comments, we are finalizing our proposal to provide confidential feedback reports to IRFs, as proposed.

P. Method for Applying the Reduction to the FY 2017 IRF Increase Factor for IRFs That Fail to Meet the Quality Reporting Requirements

As previously noted, section 1886(j)(7)(A)(i) of the Act requires the application of a 2-percentage point reduction of the applicable market basket increase factor for IRFs that fail to comply with the quality data submission requirements. In compliance with section 1886(j)(7)(A)(i) of the Act, we proposed to apply a 2-percentage point reduction to the applicable FY 2017 market basket increase factor in calculating a proposed adjusted FY 2017 standard payment conversion factor to apply to payments for only those IRFs that failed to comply with the data submission requirements. As previously noted, application of the 2-percentage point reduction may result in an update that is less than 0.0 for a fiscal year and in payment rates for a fiscal year being less than such payment rates for the preceding fiscal year. Also, reporting-based reductions to the market basket increase factor will not be cumulative; they will only apply for the FY involved.

We invited public comment on the proposed method for applying the reduction to the FY 2017 IRF increase factor for IRFs that fail to meet the quality reporting requirements. We did not receive any comments on this proposal.

Final Decision: We are finalizing our proposed method for applying the reduction to the FY 2017 IRF increase factor for IRFs that fail to meet the quality reporting requirements.

Table 21 shows the calculation of the adjusted FY 2017 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 21: Calculations to Determine the Adjusted FY 2017 Standard Payment Conversion Factor for IRFs That Failed to Meet the Quality Reporting Requirement

Explanation for Adjustment	Calculations
Standard Payment Conversion Factor for FY 2016	\$ 15,478
Market Basket Increase Factor for FY 2017 (2.7 percent), reduced by 0.3 percentage point for the productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act, reduced by 0.75 percentage point in accordance with sections 1886(j)(3)(C) and (D) of the Act and further reduced by 2 percentage points for IRFs that failed to meet the quality reporting requirement	x 0.9965
Budget Neutrality Factor for the Wage Index and Labor-Related Share	x 0.9992
Budget Neutrality Factor for the Revisions to the CMG Relative Weights	x 0.9992
Adjusted FY 2017 Standard Payment Conversion Factor	= \$ 15,399

IX. Miscellaneous Comments

Comment: Several commenters were supportive of our continued use of the FY 2014 facility-level adjustments and recommended that CMS continue monitoring the adjustments. Other commenters suggested that CMS be more transparent about the methodology and the factors it utilizes for calculating facility adjustment payments to IRFs. Several commenters suggested that CMS should establish a three-year minimum interval for any change in the IRF provider-level adjustment factors and recommended that if any factor varies by a minimum amount, the factor should be adjusted. Some commenters also recommended that CMS monitor the facility-level adjustment factors annually and adjust them if there is a change in excess of 5 to 10 percent.

Response: As we did not propose any changes to the facility-level adjustments, these comments are outside the scope of the proposed rule. In the FY 2017 IRF PPS proposed rule

(81 FR 24177), we noted that, in the FY 2015 IRF PPS final rule (79 FR 45872 at 45882), we froze the facility-level adjustments at FY 2014 levels for FY 2015 and all subsequent years (unless and until we propose to update them again through future notice-and-comment rulemaking). We will continue to monitor the facility-level adjustments and update them as necessary through rulemaking to ensure the continued accuracy of IRF PPS payments.

Comment: Several commenters expressed concerns about the impact of the changes to the 60 percent rule compliance methodology that we finalized in the FY 2014 and FY 2015 IRF PPS final rules on beneficiary access to IRF services, and suggested that we revisit them. These commenters further stated that the translation of International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) codes to International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) codes using the General Equivalence Mapping (GEMS) tool may have unintentionally caused some diagnoses to now be excluded from counting under the presumptive compliance methodology. In particular, the commenters suggested that we review the codes excluded under the IGCs for traumatic brain injury, hip fracture, and major multiple trauma, and add these cases back in as presumptively compliant cases under the 60 percent rule. Some commenters suggested that we issue clarifications to MACs and CMS Regional Offices that these codes are considered presumptively compliant. Further, one commenter suggested that we revisit our decision on no longer considering presumptively compliant diagnoses codes for rheumatoid myopathy and polyneuropathy, unilateral amputations, and amputation status/aftercare.

Response: As we did not propose any changes to the methodology for determining IRFs' compliance with the 60 percent rule in the FY 2017 IRF PPS proposed rule, these comments are outside the scope of the proposed rule. We appreciate the commenter's suggestions, and will

continue to monitor and assess the implications of the changes to the presumptive methodology that we finalized in the FY 2014 and FY 2015 IRF PPS final rules to determine if any further refinements to the methodology are needed. We intend to take a comprehensive look at the ICD-10-CM codes to identify any diagnosis codes that may need to be added to the presumptive compliance methodology, as well as any codes that may need to be removed.

Comment: Several commenters suggested that, as height and weight are now required information on the IRF-PAI (beginning October 1, 2014), CMS should now use this information to identify patients with unilateral joint replacements and body mass indexes (BMI) greater than 50 for presumptive compliance with the 60 percent rule requirements.

Response: As we did not propose any changes to the methodology for determining IRFs' compliance with the 60 percent rule, these comments are outside the scope of the proposed rule. However, we will take these suggestions into consideration.

Comment: One commenter stated that the translation to ICD-10-CM has created a problem with the grouping of rehabilitation diagnosis-related groups (DRGs) in rehabilitation units due to the loss of the "V code" under ICD-10-CM. The commenter expressed concern that rehabilitation patients may not be reimbursed appropriately and in many instances would be paid under the Hospital IPPS MS-DRGs.

Response: As payment under the IRF PPS is not based on diagnosis-related groups, this comment is outside the scope of the proposed rule. This final rule only applies to rehabilitation units that are paid under the IRF PPS, not to other types of rehabilitation units which may be present in an acute care hospital but that are paid under other Medicare payment systems.

Comment: One commenter stated that CMS should review its policy regarding the use of "D-subsequent encounter" as an eligible 7th character for traumatic injury diagnosis codes as

advised by the AHA Coding Clinic for ICD-10-CM and ICD-10-PCS Editorial Advisory Board (reference material for this can be found at

<http://www.ahacentraloffice.org/codes/Resources.shtml>). The commenter stated that

“subsequent encounter” is an appropriate option for rehabilitation services and that CMS should allow the “D” as an eligible 7th character for traumatic injury diagnosis codes.

Response: IRFs are permitted to use “D” as an eligible 7th character for traumatic injury diagnosis codes on both the IRF claim and the IRF-PAI. However, for the reasons indicated in the FY 2015 IRF PPS final rule (79 FR 45872, 45907), effective with discharges occurring on or after October 1, 2015, ICD-10-CM codes with the seventh character extension of “D” are not included in the ICD-10-CM versions of the “List of Comorbidities,” “ICD-10-CM Codes That Meet Presumptive Compliance Criteria,” or “Impairment Group Codes That Meet Presumptive Compliance Criteria.” Whereas the AHA Coding Clinic for ICD-10-CM and ICD-10 PCS (Vol. 2, No. 1) guidelines instruct providers to use the 7th character “D” for traumatic injury diagnosis codes used in an IRF setting, the guidelines specifically say that the AHA Coding Clinic guidelines only apply to the IRF claim and that providers should refer to the instructions provided in the IRF-PAI training manual, which is available for download from the IRF PPS Web site at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/IRFPAI.html>, for instructions on how to code the IRF-PAI. Thus, ICD-10-CM diagnosis codes with the 7th character “D,” if used for traumatic injury diagnosis codes on the IRF-PAI, will not result in a tier payment or result in a case being presumptively compliant with the IRF 60 percent rule for the reasons stated in the FY 2015 IRF PPS final rule (79 FR 45872, 45907).

Comment: Several commenters stated that the FY 2017 update to the standard payment

conversion factor does not include additional payment to IRFs for the time and resources needed to complete assessments for quality reporting. These commenters further stated that the additional quality reporting elements in the FY 2016 IRF PPS final rule will add time spent collecting information while decreasing the time available for direct patient care. Several commenters stated that the proposed increase does not cover the costs of medical inflation, or of the technical implementation, training, and data collection related to the quality reporting measures even though costs will be significant. Several commenters stated that the “minimal increase” does not adequately take into account the estimated costs of implementing the quality reporting measures and request that CMS add the estimated costs of these measures to the FY 2017 payment update.

Response: We refer readers to the FY 2016 IRF PPS final rule (80 FR 47129 through 47137) for details regarding the Collection of Information Requirements and Regulatory Impact Analysis for the finalized measures. We would also like to clarify that quality program reporting requirements are not included in the standard payment conversion factor. However, in accordance with section 1886(j)(7)(A) of the Act, the applicable annual increase factor for any IRF that does not submit the required data to CMS must be reduced by two percentage points.

Comment: One commenter reiterated MedPAC’s March 2016 recommendation that we should analyze patterns of coding across IRFs and reassess the inter-rater reliability of the IRF-PAI.

Response: This comment involves data monitoring activities that are not discussed in the proposed rule, and are therefore outside the scope of the rule. However, we will share this recommendation with the appropriate components within CMS for their consideration of these issues.

X. Provisions of the Final Regulations

In this final rule, we are adopting the provisions set forth in the FY 2017 IRF PPS proposed rule (81 FR 24178). Specifically:

- We will update the FY 2017 IRF PPS relative weights and average length of stay values using the most current and complete Medicare claims and cost report data in a budget-neutral manner, as discussed in section IV of this final rule.
- As established in the FY 2015 IRF PPS final rule (79 FR 45872 at 45882), the facility-level adjustments will remain frozen at FY 2014 levels for FY 2015 and all subsequent years (unless and until we propose to update them again through future notice-and-comment rulemaking), as discussed in section V of this final rule.
- We will update the FY 2017 IRF PPS payment rates by the market basket increase factor, based upon the most current data available, with 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 and the productivity adjustment required by section 1886(j)(3)(C)(ii)(I) of the Act, as described in section VI of this final rule.
- We will update the FY 2017 IRF PPS payment rates by the FY 2017 wage index and the labor-related share in a budget-neutral manner and continue the phase-out of the rural adjustment as discussed in section VI of this final rule.
- We will calculate the final IRF standard payment conversion factor for FY 2017, as discussed in section VI of this final rule.
- We will update the outlier threshold amount for FY 2017, as discussed in section VII of this final rule.
- We will update the cost-to-charge ratio (CCR) ceiling and urban/rural average CCRs

for FY 2017, as discussed in section VII of this final rule.

- We will adopt revisions and updates to quality measures and reporting requirements under the quality reporting program for IRFs in accordance with section 1886(j)(7) of the Act, as discussed in section VIII of this final rule.

XI. Collection of Information Requirements

A. Statutory Requirement for Solicitation of Comments

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

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

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

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

Failure to submit data required under section 1886(j)(7)(C) and (F) of the Act will result in the reduction of the annual update to the standard federal rate for discharges occurring during such fiscal year by 2 percentage points for any IRF that does not comply with the requirements

established by the Secretary. At the time that this analysis was prepared, 91, or approximately 8 percent, of the 1166 active Medicare-certified IRFs did not receive the full annual percentage increase for the FY 2016 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 2017 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, 2016 there are approximately 1131 IRFs currently reporting quality data to CMS. In this final rule, we are adopting 5 measures. For the FY 2018 payment determinations and subsequent years, we proposed four new measures: (1) MSPB -PAC IRF QRP; (2) Discharge to Community-PAC IRF QRP, and (3) Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP; (4) Potentially Preventable 30-Day Within Stay Readmission Measure for IRF QRP. These four measures are Medicare claims-based measures. Because claims-based measures can be calculated based on data that are already reported to the Medicare program for payment purposes, we believe there will be no additional impact.

For the FY 2020 payment determination and subsequent years, we proposed one measure: Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC IRF QRP. Additionally, we proposed that data for this new measure will be collected and reported using the IRF-PAI (version effective October 1, 2018).

Our burden calculations take into account all “new” items required on the IRF-PAI (version effective October 1, 2018) to support data collection and reporting for this measure. The addition of the new items required to collect the newly proposed measure is for the purpose of achieving standardization of data elements.

We estimate the additional elements for the newly proposed Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC IRF QRP measure will take 6 minutes of nursing/clinical staff time to report data on admission and 4 minutes of nursing/clinical staff time to report data on discharge, for a total of 10 minutes. We estimate that the additional IRF-PAI items we proposed will be completed by Registered Nurses (RN) for approximately 75 percent of the time required, and Pharmacists for approximately 25 percent of the time required. Individual providers determine the staffing resources necessary. In accordance with OMB control number 0938-0842, we estimate 398,254 discharges from all IRFs annually, with an additional burden of 10 minutes. This will equate to 66,375.67 total hours or 58.69 hours per IRF. We believe this work will be completed by RNs (75 percent) and Pharmacists (25 percent). We obtained mean hourly wages for these staff from the U.S. Bureau of Labor Statistics' May 2014 National Occupational Employment and Wage Estimates (http://www.bls.gov/oes/current/oes_nat.htm), and to account for overhead and fringe benefits, we have doubled the mean hourly wage. Per the U.S. Bureau of Labor and Statistics, the mean hourly wage for a RN is \$33.55. However, to account for overhead and fringe benefits, we have doubled the mean hourly wage, making it \$67.10 for an RN. Per the U.S. Bureau of Labor and Statistics, the mean hourly wage for a pharmacist is \$56.98. However, to account for overhead and fringe benefits, we have doubled the mean hourly wage, making it \$113.96 for a pharmacist. Given these wages and time estimates, the total cost related to the newly proposed measures is estimated at \$4,625.46 per IRF annually, or \$5,231,398.17 for all IRFs annually.

For the quality reporting during extraordinary circumstances, in section VIII.L of this final rule, we add a previously finalized process that IRFs may request an exception or extension from the FY 2019 payment determination and that of subsequent payment determinations. The

request must be submitted by e-mail within 90 days from the date that the extraordinary circumstances occurred.

While the preparation and submission of the request is an information collection, unlike the aforementioned temporary exemption of the data collection requirements for the new drug regimen review measure, the request is not expected to be submitted to OMB for formal review and approval since we estimate less than two requests (total) per year. Since we estimate fewer than 10 respondents annually, the information collection requirement and associated burden is not subject as stated in 5 CFR 1320.3(c) of the implementing regulations of the Paperwork Reduction Act of 1995.

As discussed in section VIII.M of this final rule, we add a previously finalized process that will enable IRFs to request reconsiderations of our initial non-compliance decision in the event that it believes that it was incorrectly identified as being subject to the 2-percentage point reduction to its annual increase factor due to non-compliance with the IRF QRP reporting requirements. While there is burden associated with filing a reconsideration request, 5 CFR 1320.4 of OMB's implementing regulations for PRA excludes activities during the conduct of administrative actions such as reconsiderations.

We received comments about the collection of information requirements associated with measures being proposed for the IRF QRP, which are summarized and addressed below.

Comment: One commenter appreciated that the claims-based measures being proposed do not place additional burden on the facilities and their staff. Other commenters had concerns about the claims-based measures, noting that while they had no data collection burden, they were associated with time and resources needed to compile and verify data for submission. One

commenter expressed concerns that the burden estimate doubles the resources required to collect data but doesn't take into consideration limited resources smaller organizations have.

Response: We recognize the commenter's concern pertaining to burden due to the requirements being added to the IRF Quality Reporting Program. We are very sensitive to the issue of burden associated with data collection and have proposed only the minimal number of additional items (3) needed to calculate the proposed quality measure. Though we recognize that new IRF-PAI items will require additional activities and efforts by providers, we would like to clarify that burden estimates are intended to reflect only the time needed to complete IRF-PAI items, independent of clinical time spent assessing the patient. Similarly, burden estimates are not intended to reflect costs of training and operational processes; these are considered part of the operating costs for an IRF. Time estimates for coding required items being added for the Drug Regimen Review measure were based on a Drug Regimen Review pilot testing conducted in November and December 2015. It should be noted that with each assessment release, we provide free software to our providers that allows for the completion and submission of any required assessment data. Free downloads of the Inpatient Rehabilitation Validation and Entry (IRVEN) software product are available on the CMS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Software.html>.

We also wish to note that, as pointed out by one commenter, four of the five measures proposed are claims-based and have no additional data collection burden to providers. Since the data source for these measures is claims data, and is not collected by means of an assessment instrument, the measure does not increase data collection burden on the provider as this data is currently collected by providers. We also note that providers will be given a chance to review

their claims-based measure data via feedback provided in the CASPER system. Despite the lack of data collection burden, we appreciate the comments that more education will be required for the public and providers to understand the claims-based measures and the feedback mechanism. We will be providing additional training for the reports that are, and will be, available for providers for reviewing their data.

Although we did not solicit feedback on the burden associated with the measures finalized in the FY 2016 IRF PPS final rule (80 FR 47100 through 47120), including functional status measures, which will be collected via the IRF-PAI Version 1.4 effective October 1, 2016, we received several comments, which are summarized below.

Comment: Several commenters were concerned that the additional 41.5 minutes required to collect new required data elements finalized in the FY 2016 IRF PPS final rule, including training staff and updating medical records, led to increased costs to IRFs that are not covered in the update to the standard payment conversion factor proposed for IRFs. One commenter also noted that delays in training led to additional expenses for preparing staff and electronic health records.

Response: We refer the reader to our discussion of burden due to data set revisions, data collection, or training of staff due to the revisions in the IRF-PAI Version 1.4 in the FY 2016 IRF PPS final rule (80 FR 47086 through 47120). Feedback relating to provider burden will be taken into account as we consider future updates to the IRF QRP.

With regards to comments about the updated SPCF, we refer readers to the IRF PPS FY 2016 final rule (80 FR 47129 through 47137) for details regarding the Collection of Information Requirements and Regulatory Impact Analysis for the measures finalized in FY 2016. We would also like to clarify that QRP requirements are not included in the SPCF, however, per

statutory requirements, the applicable annual increase factor for any IRF that does not submit the required data to CMS is reduced by 2 percentage points. Additional responses to these comments are included in sections VI.E and IX. of this final rule.

XII. Regulatory Impact Analysis

A. Statement of Need

This final rule updates the IRF prospective payment rates for FY 2017 as required under section 1886(j)(3)(C) of the Act. It responds to section 1886(j)(5) of the Act, which requires the Secretary to publish in the **Federal Register** on or before the August 1 that precedes the start of each fiscal year, the classification and weighting factors for the IRF PPS's case-mix groups and a description of the methodology and data used in computing the prospective payment rates for that fiscal year.

This final rule also implements sections 1886(j)(3)(C) and (D) of the Act. Section 1886(j)(3)(C)(ii)(I) of the Act requires the Secretary to apply a multi-factor productivity adjustment to the market basket increase factor, and to apply other adjustments as defined by the Act. The productivity adjustment applies to FYs from 2012 forward. The other adjustments apply to FYs 2010 through 2019.

Furthermore, this final rule also adopts policy changes under the statutory discretion afforded to the Secretary under section 1886(j)(7) of the Act. Specifically, we will revise and update the quality measures and reporting requirements under the IRF quality reporting program.

B. Overall Impacts

We have examined the impacts of this final rule as required by Executive Order 12866 (September 30, 1993, Regulatory Planning and Review), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act

(September 19, 1980, Pub. L. 96-354) (RFA), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for a major final rule with economically significant effects (\$100 million or more in any 1 year). We estimate the total impact of the policy updates described in this final rule by comparing the estimated payments in FY 2017 with those in FY 2016. This analysis results in an estimated \$145 million increase for FY 2017 IRF PPS payments. As a result, this final rule is designated as economically “significant” under section 3(f)(1) of Executive Order 12866, and hence a major rule under the Congressional Review Act. Also, the rule has been reviewed by OMB.

The Regulatory Flexibility Act (RFA) requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most IRFs and most other providers and suppliers are small entities, either by having revenues of \$7.5 million to \$38.5 million or less in any 1 year depending on industry classification, or by being nonprofit organizations that are not dominant in their markets. (For details, see the Small Business Administration's final rule that set forth size standards for health care industries, at 65 FR 69432 at

http://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf, effective March 26, 2012 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. As shown in Table 22, we estimate that the net revenue impact of this final rule on all IRFs is to increase estimated payments by approximately 1.9 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.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. As discussed in detail below in this section, 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 rural hospitals based on the data of the 140 rural units and 11 rural hospitals in our database of 1,133 IRFs for which data were available.

Section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-04, enacted on March 22, 1995) also requires that agencies assess anticipated costs and benefits before issuing

any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2016, that threshold level is approximately \$146 million. This final rule will not mandate spending costs on state, local, or tribal governments, in the aggregate, or by the private sector, of greater than \$146 million.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. As stated, this final rule will not have a substantial effect on state and local governments, preempt state law, or otherwise have a federalism implication.

C. Detailed Economic Analysis

1. Basis and Methodology of Estimates

This final rule updates to the IRF PPS rates contained in the FY 2016 IRF PPS final rule (80 FR 47036). Specifically, this final rule updates the CMG relative weights and average length of stay values, the wage index, and the outlier threshold for high-cost cases. This final rule applies a MFP adjustment to the FY 2017 IRF market basket increase factor in accordance with section 1886(j)(3)(C)(ii)(I) of the Act, and a 0.75 percentage point reduction to the FY 2017 IRF market basket increase factor in accordance with sections 1886(j)(3)(C)(ii)(II) and (D)(v) of the Act. Further, this final rule contains revisions to the IRF quality reporting requirements that are expected to result in some additional financial effects on IRFs. In addition, section VIII of this final rule discusses the implementation of the required 2 percentage point reduction of the market basket increase factor for any IRF that fails to meet the IRF quality reporting requirements, in accordance with section 1886(j)(7) of the Act.

We estimate that the impact of the changes and updates described in this final rule will be a net estimated increase of \$145 million in payments to IRF providers. This estimate does not include the implementation of the required 2 percentage point reduction of the market basket increase factor for any IRF that fails to meet the IRF quality reporting requirements (as discussed in section XII.C.6. of this final rule). The impact analysis in Table 22 of this final rule represents the projected effects of the updates to IRF PPS payments for FY 2017 compared with the estimated IRF PPS payments in FY 2016. We determine the effects by estimating payments while holding all other payment variables constant. We use the best data available, but we do not attempt to predict behavioral responses to these changes, and we do not make adjustments for future changes in such variables as number of discharges or case-mix.

We note that certain events may combine to limit the scope or accuracy of our impact analysis, because such an analysis is future-oriented and, thus, susceptible to forecasting errors because of other changes in the forecasted impact time period. Some examples could be legislative changes made by the Congress to the Medicare program that would impact program funding, or changes specifically related to IRFs. Although some of these changes may not necessarily be specific to the IRF PPS, the nature of the Medicare program is such that the changes may interact, and the complexity of the interaction of these changes could make it difficult to predict accurately the full scope of the impact upon IRFs.

In updating the rates for FY 2017, we are adopting standard annual revisions described in this final rule (for example, the update to the wage and market basket indexes used to adjust the federal rates). We are also implementing a productivity adjustment to the FY 2017 IRF market basket increase factor in accordance with section 1886(j)(3)(C)(ii)(I) of the Act, and a 0.75 percentage point reduction to the FY 2017 IRF market basket increase factor in accordance

with sections 1886(j)(3)(C)(ii)(II) and -(D)(v) of the Act. We estimate the total increase in payments to IRFs in FY 2017, relative to FY 2016, will be approximately \$145 million.

This estimate is derived from the application of the FY 2017 IRF market basket increase factor, as reduced by a productivity adjustment in accordance with section 1886(j)(3)(C)(i)(I) of the Act, and a 0.75 percentage point reduction in accordance with sections 1886(j)(3)(C)(ii)(II) and (D)(v) of the Act, which yields an estimated increase in aggregate payments to IRFs of \$125 million. Furthermore, there is an additional estimated \$20 million increase in aggregate payments to IRFs due to the update of the outlier threshold amount. Outlier payments are estimated to increase from approximately 2.7 percent in FY 2016 to 3.0 percent in FY 2017. Therefore, summed together, we estimate that these updates will result in a net increase in estimated payments of \$145 million from FY 2016 to FY 2017.

The effects of the updates that impact IRF PPS payment rates are shown in Table 22. The following updates that affect the IRF PPS payment rates are discussed separately below:

- The effects of the update to the outlier threshold amount, from approximately 2.7 percent to 3.0 percent of total estimated payments for FY 2017, consistent with section 1886(j)(4) of the Act.
- The effects of the annual market basket update (using the IRF market basket) to IRF PPS payment rates, as required by section 1886(j)(3)(A)(i) and sections 1886(j)(3)(C) and (D) of the Act, including a productivity adjustment in accordance with section 1886(j)(3)(C)(i)(I) of the Act, and a 0.75 percentage point reduction in accordance with sections 1886(j)(3)(C)(ii)(II) and (D)(v) of the Act.
- The effects of applying the budget-neutral labor-related share and wage index adjustment, as required under section 1886(j)(6) of the Act.

- The effects of the budget-neutral changes to the CMG relative weights and average length of stay values, under the authority of section 1886(j)(2)(C)(i) of the Act.
- The total change in estimated payments based on the FY 2017 payment changes relative to the estimated FY 2016 payments.

2. Description of Table 22

Table 22 categorizes IRFs by geographic location, including urban or rural location, and location for CMS's 9 Census divisions (as defined on the cost report) of the country. In addition, the table divides IRFs into those that are separate rehabilitation hospitals (otherwise called freestanding hospitals in this section), those that are rehabilitation units of a hospital (otherwise called hospital units in this section), rural or urban facilities, ownership (otherwise called for-profit, non-profit, and government), by teaching status, and by disproportionate share patient percentage (DSH PP). The top row of Table 22 shows the overall impact on the 1,133 IRFs included in the analysis.

The next 12 rows of Table 22 contain IRFs categorized according to their geographic location, designation as either a freestanding hospital or a unit of a hospital, and by type of ownership; all urban, which is further divided into urban units of a hospital, urban freestanding hospitals, and by type of ownership; and all rural, which is further divided into rural units of a hospital, rural freestanding hospitals, and by type of ownership. There are 982 IRFs located in urban areas included in our analysis. Among these, there are 730 IRF units of hospitals located in urban areas and 252 freestanding IRF hospitals located in urban areas. There are 151 IRFs located in rural areas included in our analysis. Among these, there are 140 IRF units of hospitals located in rural areas and 11 freestanding IRF hospitals located in rural areas. There are 409 for-profit IRFs. Among these, there are 356 IRFs in urban areas and 53 IRFs in rural areas. There

are 653 non-profit IRFs. Among these, there are 564 urban IRFs and 89 rural IRFs. There are 71 government-owned IRFs. Among these, there are 62 urban IRFs and 9 rural IRFs.

The remaining four parts of Table 22 show IRFs grouped by their geographic location within a region, by teaching status, and by DSH PP. First, IRFs located in urban areas are categorized for their location within a particular one of the nine Census geographic regions. Second, IRFs located in rural areas are categorized for their location within a particular one of the nine Census geographic regions. In some cases, especially for rural IRFs located in the New England, Mountain, and Pacific regions, the number of IRFs represented is small. IRFs are then grouped by teaching status, including non-teaching IRFs, IRFs with an intern and resident to average daily census (ADC) ratio less than 10 percent, IRFs with an intern and resident to ADC ratio greater than or equal to 10 percent and less than or equal to 19 percent, and IRFs with an intern and resident to ADC ratio greater than 19 percent. Finally, IRFs are grouped by DSH PP, including IRFs with zero DSH PP, IRFs with a DSH PP less than 5 percent, IRFs with a DSH PP between 5 and less than 10 percent, IRFs with a DSH PP between 10 and 20 percent, and IRFs with a DSH PP greater than 20 percent.

The estimated impacts of each policy described in this final rule to the facility categories listed are shown in the columns of Table 22. The description of each column is as follows:

- Column (1) shows the facility classification categories.
- Column (2) shows the number of IRFs in each category in our FY 2016 analysis file.
- Column (3) shows the number of cases in each category in our FY 2016 analysis file.
- Column (4) shows the estimated effect of the adjustment to the outlier threshold amount.

- Column (5) shows the estimated effect of the update to the IRF labor-related share and wage index, in a budget-neutral manner.
- Column (6) shows the estimated effect of the update to the CMG relative weights and average length of stay values, in a budget-neutral manner.
- Column (7) compares our estimates of the payments per discharge, incorporating all of the policies reflected in this final rule for FY 2017 to our estimates of payments per discharge in FY 2016.

The average estimated increase for all IRFs is approximately 1.9 percent. This estimated net increase includes the effects of the IRF market basket increase factor for FY 2017 of 2.7 percent, reduced by a productivity adjustment of 0.3 percentage point in accordance with section 1886(j)(3)(C)(ii)(I) of the Act, and further reduced by 0.75 percentage point in accordance with sections 1886(j)(3)(C)(ii)(II) and (D)(v) of the Act. It also includes the approximate 0.3 percent overall increase in estimated IRF outlier payments from the update to the outlier threshold amount. Since we are making the updates to the IRF wage index and the CMG relative weights in a budget-neutral manner, they will not be expected to affect total estimated IRF payments in the aggregate. However, as described in more detail in each section, they will be expected to affect the estimated distribution of payments among providers.

TABLE 22: IRF Impact Table for FY 2017 (Columns 4 through 7 in percentage)

Facility Classification	Number of IRFs	Number of Cases	Outlier	FY 2017 CBSA wage index and labor-share	CMG Weights	Total Percent Change¹
(1)	(2)	(3)	(4)	(5)	(6)	(7)
Total	1,133	400,781	0.3	0.0	0.0	1.9
Urban unit	730	180,021	0.5	0.0	0.0	2.2
Rural unit	140	23,192	0.4	-0.6	0.0	1.5
Urban hospital	252	193,104	0.1	0.1	0.0	1.8
Rural hospital	11	4,464	0.0	-1.6	0.0	0.0
Urban For-Profit	356	181,789	0.2	-0.1	0.0	1.7
Rural For-Profit	53	10,255	0.3	-0.9	0.0	1.1
Urban Non-Profit	564	172,204	0.4	0.2	0.0	2.3
Rural Non-Profit	89	15,724	0.4	-0.7	0.0	1.4
Urban Government	62	19,132	0.4	-0.4	0.0	1.8
Rural Government	9	1,677	0.3	-1.3	0.1	0.7
Urban	982	373,125	0.3	0.1	0.0	2.0
Rural	151	27,656	0.3	-0.8	0.0	1.2
Urban by region						
Urban New England	31	16,762	0.2	0.2	0.1	2.1
Urban Middle Atlantic	144	57,765	0.2	0.8	0.0	2.7
Urban South Atlantic	146	73,307	0.2	-0.1	0.0	1.8
Urban East North Central	170	50,459	0.3	-0.1	0.1	2.0
Urban East South Central	57	26,179	0.2	-0.5	-0.1	1.4
Urban West North Central	74	20,139	0.3	-0.7	0.0	1.3
Urban West South Central	183	77,887	0.2	-0.1	0.0	1.7
Urban Mountain	77	26,367	0.2	0.0	0.0	1.9
Urban Pacific	100	24,260	0.6	0.3	0.0	2.6
Rural by region						
Rural New England	5	1,321	0.4	-1.6	0.0	0.4
Rural Middle Atlantic	12	1,717	0.3	-2.0	0.1	0.0
Rural South Atlantic	17	4,536	0.2	-0.4	0.0	1.4
Rural East North Central	28	4,906	0.3	0.1	0.0	2.0
Rural East South Central	18	3,515	0.3	-0.5	0.0	1.4
Rural West North Central	21	3,106	0.5	-0.5	0.0	1.7
Rural West South Central	40	7,742	0.3	-1.4	0.0	0.6
Rural Mountain	7	601	1.0	-0.6	0.0	2.1
Rural Pacific	3	212	1.4	0.1	-0.1	3.1
Teaching status						
Non-teaching	1,025	357,005	0.3	0.0	0.0	1.9
Resident to ADC less than 10%	64	31,283	0.3	0.1	0.1	2.1
Resident to ADC 10%-19%	31	10,703	0.4	0.2	0.0	2.3
Resident to ADC greater than 19%	13	1,790	0.2	-0.4	-0.1	1.4
Disproportionate share patient percentage (DSH PP)						
DSH PP = 0%	34	7,345	0.4	-0.1	0.0	2.0
DSH PP <5%	157	60,158	0.2	0.4	0.0	2.3
DSH PP 5% -10%	316	129,305	0.2	-0.1	0.0	1.8
DSH PP 10% -20%	371	137,759	0.3	-0.1	0.0	1.8
DSH PP greater than 20%	255	66,214	0.4	0.0	0.0	2.1

¹This column includes the impact of the updates in columns (4), (5), and (6) above, and of the IRF market basket increase factor for FY 2017 (2.7 percent), reduced by 0.3 percentage point for the productivity adjustment as

required by section 1886(j)(3)(C)(ii)(I) of the Act, and reduced by 0.75 percentage point in accordance with sections 1886(j)(3)(C)(ii)(II) and -(D)(v) of the Act.

3. Impact of the Update to the Outlier Threshold Amount

The estimated effects of the update to the outlier threshold adjustment are presented in column 4 of Table 22.

For the FY 2017 IRF PPS proposed rule, we used preliminary FY 2015 IRF claims data, and, based on that preliminary analysis, we estimated that IRF outlier payments as a percentage of total estimated IRF payments would be 2.8 percent in FY 2016 (81 FR 24178, 24193). As we typically do between the proposed and final rules each year, we updated our FY 2015 IRF claims data to ensure that we are using the most recent available data in setting IRF payments.

Therefore, based on updated analysis of the most recent IRF claims data for this final rule, we now estimate that IRF outlier payments as a percentage of total estimated IRF payments are 2.7 percent in FY 2016. Thus, we are adjusting the outlier threshold amount in this final rule to set total estimated outlier payments equal to 3 percent of total estimated payments in FY 2017. The estimated change in total IRF payments for FY 2017, therefore, includes an approximate 0.3 percent increase in payments because the estimated outlier portion of total payments is estimated to increase from approximately 2.7 percent to 3 percent.

The impact of this outlier adjustment update (as shown in column 4 of Table 22) is to increase estimated overall payments to IRFs by about 0.3 percent. We estimate the largest increase in payments from the update to the outlier threshold amount to be 1.4 percent for rural IRFs in the Pacific region.

4. Impact of the CBSA Wage Index and Labor-Related Share

In column 5 of Table 22, we present the effects of the budget-neutral update of the wage index and labor-related share. The changes to the wage index and the labor-related share are

discussed together because the wage index is applied to the labor-related share portion of payments, so the changes in the two have a combined effect on payments to providers. As discussed in section VI.C. of this final rule, we will decrease the labor-related share from 71.0 percent in FY 2016 to 70.9 percent in FY 2017.

5. Impact of the Update to the CMG Relative Weights and Average Length of Stay Values.

In column 6 of Table 22, we present the effects of the budget-neutral update of the CMG relative weights and average length of stay values. In the aggregate, we do not estimate that these updates will affect overall estimated payments of IRFs. However, we do expect these updates to have small distributional effects. The largest estimated increase in payments is a 0.1 percent increase for rural IRFs in the Middle Atlantic region, and urban IRFs in the New England and East North Central regions. Rural IRFs in the Pacific region and urban IRFs in the East south Central regions are estimated to experience a 0.1 percent decrease in payments due to the CMG relative weights change.

6. Effects of Requirements for the IRF QRP for FY 2018

In accordance with section 1886(j)(7) of the Act, we will implement a 2 percentage point reduction in the FY 2018 increase factor for IRFs that have failed to report the required quality reporting data to us during the most recent IRF quality reporting period. In section VIII.P of this final rule, we discuss the proposed method for applying the 2 percentage point reduction to IRFs that fail to meet the IRF QRP requirements. At the time that this analysis was prepared, 91, or approximately 8 percent, of the 1166 active Medicare-certified IRFs did not receive the full annual percentage increase for the FY 2016 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 2017 payment determination.

In section VIII.L of this final rule, we discuss our proposal to suspend the previously finalized data accuracy validation policy for IRFs. While we cannot estimate the change in the number of IRFs that will meet IRF QRP compliance standards at this time, we believe that this number will increase due to the temporary suspension of this policy. Thus, we estimate that the suspension of this policy will decrease impact on overall IRF payments, by increasing the rate of compliance, in addition to decreasing the cost of the IRF QRP to each IRF provider by approximately \$47,320 per IRF, which was the estimated cost to each IRF provider to the implement the previously finalized policy.

In section VIII.F of this final rule, we are finalizing four measures for the FY 2018 payment determinations and subsequent years: (1) MSPB -PAC IRF QRP; (2) Discharge to Community-PAC IRF QRP, and (3) Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP; (4) Potentially Preventable Within Stay Readmission Measure IRFs. These four measures are Medicare claims-based measures; because claims-based measures can be calculated based on data that are already reported to the Medicare program for payment purposes, we believe there will be no additional impact.

In section VIII.G of this final rule, we are also finalizing one measure for the FY 2020 payment determination and subsequent years: Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC IRF QRP. Additionally, data for this measure will be collected and reported using the IRF-PAI (version effective October 1, 2018). While the reporting of data on quality measures is an information collection, we believe that the burden associated with modifications to the IRF-PAI discussed in this final rule fall under the PRA exceptions provided in 1899B(m) of the Act because they are required to achieve the standardization of patient assessment data. Section 1899B(m) of the Act provides that the PRA does not apply to section

1899B and the sections referenced in section 1899B(a)(2)(B) of the Act that require modification to achieve the standardization of patient assessment data. The requirement and burden will, however, be submitted to OMB for review and approval when the modifications to the IRF-PAI or other applicable PAC assessment instrument are not used to achieve the standardization of patient assessment data.

The total cost related to the proposed measures is estimated at \$4,625.46 per IRF annually, or \$5,231,398.17 for all IRFs annually.

We intend to continue to closely monitor the effects of this new quality reporting program on IRF providers and help perpetuate successful reporting outcomes through ongoing stakeholder education, national trainings, IRF provider announcements, Web site postings, CMS Open Door Forums, and general and technical help desks.

We did not receive any comments related to the Effects of Proposed Requirements for the IRF QRP for FY 2018.

D. Alternatives Considered

The following is a discussion of the alternatives considered for the IRF PPS updates contained in this final rule.

Section 1886(j)(3)(C) of the Act requires the Secretary to update the IRF PPS payment rates by an increase factor that reflects changes over time in the prices of an appropriate mix of goods and services included in the covered IRF services. Thus, we did not consider alternatives to updating payments using the estimated IRF market basket increase factor for FY 2017.

However, as noted previously in this final rule, section 1886(j)(3)(C)(ii)(I) of the Act requires the Secretary to apply a productivity adjustment to the market basket increase factor for FY 2017, and sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(v) of the Act require the Secretary to apply a

0.75 percentage point reduction to the market basket increase factor for FY 2017. Thus, in accordance with section 1886(j)(3)(C) of the Act, we update the IRF federal prospective payments in this final rule by 1.65 percent (which equals the 2.7 percent estimated IRF market basket increase factor for FY 2017 reduced by a 0.3 percentage point productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act and further reduced by 0.75 percentage point).

We considered maintaining the existing CMG relative weights and average length of stay values for FY 2017. However, in light of recently available data and our desire to ensure that the CMG relative weights and average length of stay values are as reflective as possible of recent changes in IRF utilization and case mix, we believe that it is appropriate to update the CMG relative weights and average length of stay values at this time to ensure that IRF PPS payments continue to reflect as accurately as possible the current costs of care in IRFs.

We considered updating facility-level adjustment factors for FY 2017. However, as discussed in more detail in the FY 2015 final rule (79 FR 45872), we believe that freezing the facility-level adjustments at FY 2014 levels for FY 2015 and all subsequent years (unless and until the data indicate that they need to be further updated) will allow us an opportunity to monitor the effects of the substantial changes to the adjustment factors for FY 2014, and will allow IRFs time to adjust to the previous changes.

We considered maintaining the existing outlier threshold amount for FY 2017. However, analysis of updated FY 2015 data indicates that estimated outlier payments would be lower than 3 percent of total estimated payments for FY 2017, by approximately 0.3 percent, unless we updated the outlier threshold amount. Consequently, we are adjusting the outlier threshold amount in this final rule to reflect a 0.3 percent increase thereby setting the total outlier payments equal to 3 percent, instead of 2.7 percent, of aggregate estimated payments in FY 2017.

E. Accounting Statement

As required by OMB Circular A-4 (available at <http://www.whitehouse.gov/sites/default/files/omb/assets/omb/circulars/a004/a-4.pdf>), in Table 23, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final rule. Table 23 provides our best estimate of the increase in Medicare payments under the IRF PPS as a result of the updates presented in this final rule based on the data for 1,133 IRFs in our database. In addition, Table 23 presents the costs associated with the new IRF quality reporting program for FY 2017.

TABLE 23: Accounting Statement: Classification of Estimated Expenditures

<u>Change in Estimated Transfers from FY 2016 IRF PPS to FY 2017 IRF PPS:</u>	
Category	Transfers
Annualized Monetized Transfers	\$145 million
From Whom to Whom?	Federal Government to IRF Medicare Providers
<u>FY 2017 Cost to Updating the Quality Reporting Program:</u>	
Category	Costs
Cost for IRFs to Submit Data for the Quality Reporting Program	\$5,231,398.17

F. Conclusion

Overall, the estimated payments per discharge for IRFs in FY 2017 are projected to increase by 1.9 percent, compared with the estimated payments in FY 2016, as reflected in column 7 of Table 22.

IRF payments per discharge are estimated to increase by 2.0 percent in urban areas and 1.2 percent in rural areas, compared with estimated FY 2016 payments. Payments per discharge to rehabilitation units are estimated to increase 2.2 percent in urban areas and 1.5 percent in rural

areas. Payments per discharge to freestanding rehabilitation hospitals are estimated to increase 1.8 percent in urban areas and 0.0 percent in rural areas.

Overall, IRFs are estimated to experience a net increase in payments as a result of the proposed policies in this final rule. The largest payment increase is estimated to be a 3.1 percent increase for rural IRFs located in the Pacific region.

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

List of Subjects in 42 CFR Part 412

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

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

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

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

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

2. Section 412.634 is amended by revising paragraph (c)(2) and adding paragraph (f) to read as follows:

§412.634 Requirements under the Inpatient Rehabilitation Facility (IRF) Quality Reporting Program (QRP).

* * * * *

(c) * * *

(2) An IRF must request an exception or extension within 90 days of the date that the extraordinary circumstances occurred.

* * * * *

(f) Data Completion Thresholds. (1) IRFs must meet or exceed two separate data completeness thresholds: one threshold set at 95 percent for completion of quality measures data collected using the IRF-PAI submitted through the QIES and a second threshold set at 100 percent for quality measures data collected and submitted using the CDC NHSN.

(2) These thresholds will apply to all measures adopted into IRF QRP.

(3) An IRF must meet or exceed both thresholds to avoid receiving a 2 percentage point reduction to their annual payment update for a given fiscal year, beginning with FY 2016 and for all subsequent payment updates.

CMS-1647-F

Dated: July 18, 2016.

Andrew M. Slavitt,

Acting Administrator,

Centers for Medicare & Medicaid Services.

Dated: July 25, 2016.

Sylvia M. Burwell,

Secretary,

Department of Health and Human Services.

BILLING CODE 4120-01-P

[FR Doc. 2016-18196 Filed: 7/29/2016 4:15 pm; Publication Date: 8/5/2016]