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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 412

[CMS-1448-F]

RIN 0938-AR66

Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2014

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

ACTION: Final rule.

SUMMARY: This final rule updates the prospective payment rates for inpatient rehabilitation facilities (IRFs) for federal fiscal year (FY) 2014 (for discharges occurring on or after October 1, 2013 and on or before September 30, 2014) as required by the statute. This final rule also revised the list of diagnosis codes that may be counted toward an IRF's "60 percent rule" compliance calculation to determine "presumptive compliance," update the IRF facility-level adjustment factors using an enhanced estimation methodology, revise sections of the Inpatient Rehabilitation Facility-Patient Assessment Instrument, revise requirements for acute care hospitals that have IRF units, clarify the IRF regulation text regarding limitation of review, update references to previously changed sections in the regulations text, and revise and update quality measures and reporting requirements under the IRF quality reporting program.

DATES: *Effective Dates:* The regulatory amendments in this rule are effective

October 1, 2013, except for the amendment to § 412.25 which is effective October 1, 2014.

Applicability Dates: The revisions to the list of diagnosis codes that are used to determine presumptive compliance under the "60 percent rule" are applicable for compliance review periods beginning on or after October 1, 2014. The updated IRF prospective payment rates are applicable for IRF discharges occurring on or after October 1, 2013 and on or before September 30, 2014 (FY 2014). The changes to the Inpatient Rehabilitation Facility-Patient Assessment Instrument, the amendments to § 412.25, and the revised and updated quality measures and reporting requirements under the IRF quality reporting program are applicable for IRF discharges occurring on or after October 1, 2014.

FOR FURTHER INFORMATION CONTACT:

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

Caroline Gallaher, (410) 786-8705, for information about the quality reporting program.

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

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

Executive Summary

A. Purpose

This final rule updates the payment rates for inpatient rehabilitation

facilities (IRFs) for federal fiscal year (FY) 2014 (that is, for discharges occurring on or after October 1, 2013 and on or before September 30, 2014) as required under section 1886(j)(3)(C) of the Social Security Act (the Act). Section 1886(j)(5) of the Act requires the Secretary to publish in the **Federal Register** on or before the August 1 that precedes the start of each fiscal year, the classification and weighting factors for the IRF prospective payment system's (PPS) case-mix groups and a description of the methodology and data used in computing the prospective payment rates for that fiscal year.

B. Summary of Major Provisions

In this final rule, we use the methods described in the July 30, 2012 FY 2013 IRF PPS notice (77 FR 44618) to update the federal prospective payment rates for FY 2014 using updated FY 2012 IRF claims and the most recent available IRF cost report data. We are also revising the list of diagnosis codes that are used to determine presumptive compliance under the "60 percent rule," updating the IRF facility-level adjustment factors using an enhanced estimation methodology, revising sections of the Inpatient Rehabilitation Facility-Patient Assessment Instrument, revising requirements for acute care hospitals that have IRF units, clarifying the IRF regulation text regarding limitation of review, updating references to previously changed sections in the regulations text, and revising and updating quality measures and reporting requirements under the IRF quality reporting program.

C. Summary of Costs, Benefits and Transfers

| Provision description | Transfers |
|---|---|
| FY 2014 IRF PPS payment rate update | The overall economic impact of this final rule is an estimated \$170 million in increased payments from the Federal government to IRFs during FY 2014. |
| Refinements to the presumptive compliance method under the '60 percent rule'. | The estimated FY 2015 impact of the refinements to the presumptive compliance method reflects a decrease of payments between \$0 to \$520 million, depending on the IRFs' behavioral responses to the changes, with \$520 million representing the upper bound. |
| Provision description | Costs |
| New quality reporting program requirements | The total costs in FY 2015 for IRFs as a result of the new quality reporting requirements are estimated to be \$9.2 million. |

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I. Background

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

Section 1886(j) of the Act provides for the implementation of a per-discharge prospective payment system (PPS) for inpatient rehabilitation hospitals and inpatient rehabilitation units of a hospital (hereinafter referred to as IRFs).

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

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

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

certain comorbidities would have on resource use.

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

We applied the relative weighting factors to the standard payment conversion factor to compute the unadjusted federal prospective payment rates under the IRF PPS from FYs 2002 through 2005. Within the structure of the payment system, we then made adjustments to account for interrupted stays, transfers, short stays, and deaths. Finally, we applied the applicable adjustments to account for geographic variations in wages (wage index), the percentage of low-income patients, location in a rural area (if applicable), and outlier payments (if applicable) to the IRF's 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 IRF 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. The Web site is: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/index.html>. The Web site may be accessed to download or view publications, software, data specifications, educational materials, and other information pertinent to the IRF PPS.

Section 1886(j) of the Act confers broad statutory authority upon the Secretary to propose refinements to the IRF PPS. In the FY 2006 IRF PPS final rule (70 FR 47880) and in correcting amendments to the FY 2006 IRF PPS

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

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

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

After publication of the FY 2008 IRF PPS final rule (72 FR 44284), section 115 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (Pub. L. 110-173, enacted on December 29, 2007) (MMSEA), amended section 1886(j)(3)(C) of the Act to apply a zero percent increase factor for FYs 2008 and

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

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

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

rule in this final rule also includes the provisions effective in the correcting amendments. For more information on the policy changes implemented for FY 2010, please refer to the FY 2010 IRF PPS final rule (74 FR 39762 and 74 FR 50712), in which we published the final FY 2010 IRF federal prospective payment rates.

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

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

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

Sections 1886(j)(3)(c)(ii)(I) 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, November 16, 2010) 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 July 30, 2012 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 July 30, 2012 FY 2013 IRF PPS notice (77 FR 44618).

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

The Affordable Care Act included several provisions that affect the IRF PPS in FYs 2012 and beyond. In addition to what was discussed above, section 3401(d) of the Affordable Care Act also added section 1886(j)(3)(C)(ii)(I) (providing for a “productivity adjustment” for fiscal year 2012 and each subsequent fiscal year). The productivity adjustment for FY 2014 is discussed in section VI.A. of this final rule. Section 3401(d) of the Affordable Care Act requires an additional 0.3 percentage point adjustment to the IRF increase factor for FY 2014, as discussed in section VI.A. of this final rule. Section 1886(j)(3)(C)(ii)(II) of the Act notes that the application of these adjustments to the market basket update may result in an update that is less than 0.0 for a fiscal year and in payment rates for a fiscal year being less than such payment rates for the preceding fiscal year.

Section 3004(b) of the Affordable Care Act also addressed the IRF PPS program. It reassigned the previously designated section 1886(j)(7) of the Act to section 1886(j)(8) and inserted a new section 1886(j)(7), which contains new 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 will require 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). Under section 1886(j)(7)(D)(iii) of the Act, the Secretary is required to publish the measures that will be used in FY 2014 no later than October 1, 2012.

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

C. Operational Overview of the Current IRF PPS

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

The GROUPER software produces a 5-digit CMG number. The first digit is an alpha-character that indicates the comorbidity tier. The last 4 digits

represent the distinct CMG number. Free downloads of the Inpatient Rehabilitation Validation and Entry (IRVEN) software product, including the GROUPER software, are available on the CMS Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Software.html>.

Once a Medicare Fee-for-Service Part A patient is discharged, the IRF submits a Medicare claim as a Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191, enacted on August 21, 1996) (HIPAA) compliant electronic claim or, if the Administrative Simplification Compliance Act of 2002 (Pub. L. 107–105, enacted on December 27, 2002) (ASCA) permits, a paper claim (a UB–04 or a CMS–1450 as appropriate) using the five-digit CMG number and sends it to the appropriate Medicare Administrative Contractor (MAC). In addition, once a Medicare Advantage patient is discharged, in accordance with the Medicare Claims Processing Manual chapter 3 section 20.3 (Pub. 100–04), hospitals (including IRFs) must submit an informational-only bill (TOB 111) which includes Condition Code 04 to their Medicare contractor. 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, November 25, 2005). 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 healthcare providers, to conduct covered electronic transactions according to the applicable transaction standards. (See the CMS program claim memoranda at <http://www.cms.gov/ElectronicBillingEDITrans/> and listed in the addenda to the Medicare Intermediary Manual, Part 3, section 3600).

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

II. Summary of Provisions of the Proposed Rule

In the FY 2014 IRF PPS proposed rule (78 FR 26880), we proposed to update the IRF Federal prospective payment rates, to revise the list of eligible International Classification of Diseases, Ninth Revision, Clinical Modification (ICD–9–CM) diagnosis codes that are used to determine presumptive compliance under the “60 percent rule,” to update the IRF facility-level adjustment factors, to revise the Inpatient Rehabilitation Facility–Patient Assessment Instrument (IRF–PAI), to revise requirements for acute care hospitals that have IRF units, clarify the IRF regulation text regarding limitation of review, and to revise and update quality measures and reporting requirements under the quality reporting program for IRFs. We also proposed to revise existing regulations text for the purpose of updating and providing greater clarity. These proposals were as follows:

A. Proposed Updates to the IRF Federal Prospective Payment Rates for Federal Fiscal Year (FY) 2014

The proposed updates to the IRF federal prospective payment rates for FY 2014 were as follows:

- Update the FY 2014 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 2014 IRF PPS proposed rule (78 FR 26880, 26885 through 26888).
- Update the FY 2014 IRF PPS facility-level adjustment factors, using the most current and complete Medicare claims and cost report data with an enhanced estimation methodology, in a budget-neutral manner, as discussed in section IV of the FY 2014 IRF PPS proposed rule (78 FR 26880, 26888 through 26890).
- Update the FY 2014 IRF PPS payment rates by the proposed market basket increase factor, based upon the most current data available, with a 0.3 percentage point reduction as required by sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(iii) 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 2014 IRF PPS proposed rule (78 FR 26880, 26890 through 26891).
- Discuss the Secretary's Proposed Recommendation for updating IRF PPS payments for FY 2014, in accordance with the statutory requirements, as described in section V of the FY 2014 IRF PPS proposed rule (78 FR 26880 at 26891).
- Update the FY 2014 IRF PPS payment rates by the FY 2014 wage index and the labor-related share in a budget-neutral manner, as discussed in section V of the FY 2014 IRF PPS proposed rule (78 FR 26880, 26891 through 26892).
- Describe the calculation of the IRF Standard Payment Conversion Factor for FY 2014, as discussed in section V of the FY 2014 IRF PPS proposed rule (78 FR 26880 at 26892).
- Update the outlier threshold amount for FY 2014, as discussed in section VI of the FY 2014 IRF PPS proposed rule (78 FR 26880 at 26895).
- Update the cost-to-charge ratio (CCR) ceiling and urban/rural average CCRs for FY 2014, as discussed in section VI of the FY 2014 IRF PPS proposed rule (78 FR 26880 at 26895).
- Describe proposed revisions to the list of eligible ICD–9–CM diagnosis codes that are used to determine presumptive compliance under the 60 percent rule in section VII of the FY

2014 IRF PPS proposed rule (78 FR 26880, 26895 through 26906).

- Describe proposed non-quality-related revisions to IRF-PAI sections in section VIII of the FY 2014 IRF PPS proposed rule (78 FR 26880, 26906 through 26907).

- 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 XIII of the FY 2014 IRF PPS proposed rule (78 FR 26880, 26909 through 26922).

B. Proposed Revisions to Existing Regulation Text

In the FY 2014 IRF PPS proposed rule (78 FR 26880), we also proposed the following revisions to the existing regulations:

- Revisions to § 412.25(a)(1)(iii) to specify a minimum required number of beds that are not excluded from the inpatient prospective payment system (IPPS) for a hospital that has an IRF unit, as described in section X of the FY 2014 IRF PPS proposed rule (78 FR 26880 at 26908).

- Technical corrections to § 412.130, to reflect prior changes to the regulations at § 412.29 and § 412.30 that we made in the FY 2012 IRF PPS final rule (76 FR 47836), as described in section IX of the FY 2014 IRF PPS proposed rule (78 FR 26880, 26907 through 26908).

- Clarifications to § 412.630, to reflect the scope of section 1886(j)(8) of the Act, as described in section XI of the FY 2014 IRF PPS proposed rule (78 FR 26880 at 26908).

- Revision to § 412.29(d), to clarify that Medicare requires the rehabilitation physician's review and concurrence on the preadmission screening for Medicare Part A Fee-for-Service patients only, as described in section XII of the FY 2014 IRF PPS proposed rule (78 FR 26880, 26908 through 26909).

III. Analysis and Responses to Public Comments

We received 47 timely responses from the public, many of which contained multiple comments on the FY 2014 IRF PPS proposed rule (78 FR 26880). We received comments from various trade associations, inpatient rehabilitation facilities, individual physicians, therapists, clinicians, health care industry organizations, law firms and

health care consulting firms. The following sections, arranged by subject area, include a summary of the public comments that we received, and our responses.

IV. Update to the Case-Mix Group (CMG) Relative Weights and Average Length of Stay Values for FY 2014

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 2014 IRF PPS proposed rule (78 FR 26880, 26885 through 26888), we proposed to update the CMG relative weights and average length of stay values for FY 2014. 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 2014, we proposed to use the FY 2012 IRF claims and FY 2011 IRF cost report data. These data are the most current and complete data available at this time. Currently, only a small portion of the FY 2012 IRF cost report data are available for analysis, but the majority of the FY 2012 IRF claims data are available for analysis.

In the FY 2014 IRF PPS proposed rule (78 FR 26880, 26885 through 26888), 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 in the FY 2011 notice (75 FR 42836), the FY 2012 final rule (76 FR 47836), and the FY 2013 notice (77 FR 44618). 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 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 2014 CMG relative weights to the same average CMG relative weight from the CMG relative weights implemented in the July 30, 2012 FY 2013 IRF PPS notice (77 FR 44618).

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 2014 in such a way that total estimated aggregate payments to IRFs for FY 2014 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 2014 CMG relative weights, we use the following steps:

Step 1. Calculate the estimated total amount of IRF PPS payments for FY 2014 (with no changes to the CMG relative weights).

Step 2. Calculate the estimated total amount of IRF PPS payments for FY 2014 by applying the changes to the CMG relative weights (as discussed above).

Step 3. Divide the amount calculated in step 1 by the amount calculated in step 2 to determine the budget neutrality factor (1.0000) that would maintain the same total estimated aggregate payments in FY 2014 with and without the changes to the CMG relative weights.

Step 4. Apply the budget neutrality factor (1.0000) to the FY 2013 IRF PPS standard payment amount after the application of the budget-neutral wage adjustment factor.

In section VI.E. of this final rule, we discuss the use of the existing methodology to calculate the standard payment conversion factor for FY 2014.

Table 1, "Relative Weights and Average Length of Stay Values for Case-Mix Groups," presents the CMGs, the comorbidity tiers, the corresponding relative weights, and the average length of stay values for each CMG and tier for FY 2014. 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 | 0.7983 | 0.7151 | 0.6539 | 0.6239 | 9 | 9 | 9 | 8 |
| 0102 | Stroke M > 44.45 and M < 51.05 and C > 18.5. | 0.9911 | 0.8878 | 0.8118 | 0.7745 | 11 | 12 | 10 | 10 |
| 0103 | Stroke M > 44.45 and M < 51.05 and C < 18.5. | 1.1608 | 1.0398 | 0.9508 | 0.9071 | 13 | 13 | 12 | 11 |
| 0104 | Stroke M > 38.85 and M < 44.45 | 1.2212 | 1.0939 | 1.0002 | 0.9543 | 13 | 12 | 12 | 12 |
| 0105 | Stroke M > 34.25 and M < 38.85 | 1.4275 | 1.2787 | 1.1692 | 1.1155 | 15 | 15 | 14 | 14 |
| 0106 | Stroke M > 30.05 and M < 34.25 | 1.6285 | 1.4588 | 1.3339 | 1.2726 | 16 | 17 | 16 | 15 |
| 0107 | Stroke M > 26.15 and M < 30.05 | 1.8385 | 1.6468 | 1.5059 | 1.4367 | 19 | 20 | 17 | 17 |
| 0108 | Stroke M < 26.15 and A > 84.5 | 2.3157 | 2.0743 | 1.8967 | 1.8096 | 22 | 24 | 22 | 21 |
| 0109 | Stroke M > 22.35 and M < 26.15 and A < 84.5. | 2.0990 | 1.8802 | 1.7192 | 1.6403 | 21 | 21 | 19 | 20 |
| 0110 | Stroke M < 22.35 and A < 84.5 | 2.7382 | 2.4527 | 2.2427 | 2.1398 | 29 | 28 | 25 | 25 |
| 0201 | Traumatic brain injury M > 53.35 and C > 23.5. | 0.8252 | 0.6953 | 0.6182 | 0.5757 | 10 | 10 | 8 | 8 |
| 0202 | Traumatic brain injury M > 44.25 and M < 53.35 and C > 23.5. | 1.0549 | 0.8889 | 0.7904 | 0.7360 | 12 | 10 | 10 | 10 |
| 0203 | Traumatic brain injury M > 44.25 and C < 23.5. | 1.2520 | 1.0550 | 0.9380 | 0.8735 | 15 | 13 | 12 | 11 |
| 0204 | Traumatic brain injury M > 40.65 and M < 44.25. | 1.3077 | 1.1020 | 0.9798 | 0.9124 | 12 | 13 | 12 | 12 |
| 0205 | Traumatic brain injury M > 28.75 and M < 40.65. | 1.5791 | 1.3307 | 1.1831 | 1.1017 | 17 | 16 | 14 | 14 |
| 0206 | Traumatic brain injury M > 22.05 and M < 28.75. | 1.9472 | 1.6409 | 1.4589 | 1.3585 | 18 | 19 | 18 | 16 |
| 0207 | Traumatic brain injury M < 22.05 | 2.5767 | 2.1713 | 1.9305 | 1.7977 | 33 | 26 | 21 | 20 |
| 0301 | Non-traumatic brain injury M > 41.05 | 1.0984 | 0.9453 | 0.8469 | 0.7832 | 10 | 11 | 11 | 10 |
| 0302 | Non-traumatic brain injury M > 35.05 and M < 41.05. | 1.3755 | 1.1838 | 1.0606 | 0.9808 | 13 | 14 | 12 | 12 |
| 0303 | Non-traumatic brain injury M > 26.15 and M < 35.05. | 1.6219 | 1.3958 | 1.2506 | 1.1565 | 17 | 16 | 14 | 14 |
| 0304 | Non-traumatic brain injury M < 26.15 | 2.1792 | 1.8755 | 1.6803 | 1.5539 | 24 | 21 | 19 | 18 |
| 0401 | Traumatic spinal cord injury M > 48.45 | 1.1342 | 0.9427 | 0.8778 | 0.7849 | 12 | 12 | 11 | 10 |
| 0402 | Traumatic spinal cord injury M > 30.35 and M < 48.45. | 1.4129 | 1.1744 | 1.0936 | 0.9778 | 18 | 14 | 15 | 12 |
| 0403 | Traumatic spinal cord injury M > 16.05 and M < 30.35. | 2.3155 | 1.9246 | 1.7921 | 1.6024 | 26 | 24 | 20 | 20 |
| 0404 | Traumatic spinal cord injury M < 16.05 and A > 63.5. | 4.2535 | 3.5355 | 3.2921 | 2.9436 | 47 | 41 | 36 | 35 |
| 0405 | Traumatic spinal cord injury M < 16.05 and A < 63.5. | 3.4992 | 2.9086 | 2.7083 | 2.4216 | 37 | 32 | 33 | 27 |
| 0501 | Non-traumatic spinal cord injury M > 51.35 | 0.8384 | 0.6587 | 0.6208 | 0.5653 | 9 | 9 | 8 | 8 |
| 0502 | Non-traumatic spinal cord injury M > 40.15 and M < 51.35. | 1.1090 | 0.8712 | 0.8211 | 0.7477 | 12 | 11 | 10 | 10 |
| 0503 | Non-traumatic spinal cord injury M > 31.25 and M < 40.15. | 1.4334 | 1.1261 | 1.0613 | 0.9664 | 15 | 13 | 13 | 12 |
| 0504 | Non-traumatic spinal cord injury M > 29.25 and M < 31.25. | 1.6565 | 1.3014 | 1.2265 | 1.1168 | 14 | 16 | 14 | 14 |
| 0505 | Non-traumatic spinal cord injury M > 23.75 and M < 29.25. | 1.9708 | 1.5483 | 1.4592 | 1.3287 | 21 | 18 | 17 | 16 |
| 0506 | Non-traumatic spinal cord injury M < 23.75 | 2.7518 | 2.1619 | 2.0375 | 1.8553 | 30 | 25 | 23 | 22 |
| 0601 | Neurological M > 47.75 | 0.9645 | 0.7830 | 0.7227 | 0.6551 | 10 | 10 | 9 | 9 |
| 0602 | Neurological M > 37.35 and M < 47.75 | 1.2974 | 1.0533 | 0.9721 | 0.8811 | 12 | 12 | 11 | 11 |
| 0603 | Neurological M > 25.85 and M < 37.35 | 1.6228 | 1.3174 | 1.2159 | 1.1021 | 15 | 15 | 14 | 13 |
| 0604 | Neurological M < 25.85 | 2.1683 | 1.7603 | 1.6246 | 1.4726 | 22 | 19 | 18 | 17 |
| 0701 | Fracture of lower extremity M > 42.15 | 0.9369 | 0.7995 | 0.7648 | 0.6945 | 10 | 10 | 10 | 9 |
| 0702 | Fracture of lower extremity M > 34.15 and M < 42.15. | 1.2132 | 1.0353 | 0.9904 | 0.8993 | 12 | 12 | 12 | 11 |
| 0703 | Fracture of lower extremity M > 28.15 and M < 34.15. | 1.4741 | 1.2579 | 1.2033 | 1.0927 | 15 | 15 | 14 | 13 |
| 0704 | Fracture of lower extremity M < 28.15 | 1.8716 | 1.5971 | 1.5278 | 1.3874 | 18 | 18 | 18 | 17 |
| 0801 | Replacement of lower extremity joint M > 49.55. | 0.7037 | 0.6193 | 0.5667 | 0.5186 | 7 | 8 | 7 | 7 |
| 0802 | Replacement of lower extremity joint M > 37.05 and M < 49.55. | 0.9255 | 0.8145 | 0.7454 | 0.6821 | 10 | 10 | 9 | 9 |
| 0803 | Replacement of lower extremity joint M > 28.65 and M < 37.05 and A > 83.5. | 1.2589 | 1.1078 | 1.0138 | 0.9277 | 12 | 14 | 13 | 12 |
| 0804 | Replacement of lower extremity joint M > 28.65 and M < 37.05 and A < 83.5. | 1.1139 | 0.9803 | 0.8971 | 0.8209 | 11 | 12 | 11 | 10 |

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

| CMG | CMG Description (M = motor, C = cognitive, A = age) | Relative weight | | | | Average length of stay | | | |
|------|--|-----------------|--------|--------|--------|------------------------|--------|--------|------|
| | | Tier 1 | Tier 2 | Tier 3 | None | Tier 1 | Tier 2 | Tier 3 | None |
| 0805 | Replacement of lower extremity joint M > 22.05 and M < 28.65. | 1.3754 | 1.2104 | 1.1077 | 1.0136 | 15 | 15 | 13 | 12 |
| 0806 | Replacement of lower extremity joint M < 22.05. | 1.6683 | 1.4682 | 1.3435 | 1.2294 | 17 | 17 | 15 | 15 |
| 0901 | Other orthopedic M > 44.75 | 0.9010 | 0.7452 | 0.6891 | 0.6241 | 10 | 9 | 9 | 8 |
| 0902 | Other orthopedic M > 34.35 and M < 44.75 | 1.2081 | 0.9992 | 0.9241 | 0.8369 | 13 | 12 | 11 | 11 |
| 0903 | Other orthopedic M > 24.15 and M < 34.35 | 1.5080 | 1.2472 | 1.1534 | 1.0446 | 15 | 15 | 14 | 13 |
| 0904 | Other orthopedic M < 24.15 | 1.9669 | 1.6268 | 1.5045 | 1.3626 | 20 | 19 | 17 | 16 |
| 1001 | Amputation, lower extremity M > 47.65 | 1.0276 | 0.9345 | 0.8023 | 0.7417 | 12 | 11 | 10 | 10 |
| 1002 | Amputation, lower extremity M > 36.25 and M < 47.65. | 1.3077 | 1.1892 | 1.0210 | 0.9439 | 13 | 13 | 12 | 12 |
| 1003 | Amputation, lower extremity M < 36.25 | 1.9362 | 1.7608 | 1.5117 | 1.3975 | 19 | 20 | 17 | 16 |
| 1101 | Amputation, non-lower extremity M > 36.35 | 1.2199 | 1.1157 | 1.0302 | 1.0056 | 13 | 13 | 12 | 12 |
| 1102 | Amputation, non-lower extremity M < 36.35 | 1.7115 | 1.5652 | 1.4454 | 1.4107 | 16 | 17 | 16 | 17 |
| 1201 | Osteoarthritis M > 37.65 | 0.9454 | 0.9411 | 0.8445 | 0.7724 | 9 | 11 | 10 | 10 |
| 1202 | Osteoarthritis M > 30.75 and M < 37.65 | 1.1749 | 1.1695 | 1.0495 | 0.9599 | 14 | 14 | 13 | 12 |
| 1203 | Osteoarthritis M < 30.75 | 1.4677 | 1.4609 | 1.3110 | 1.1991 | 13 | 18 | 15 | 14 |
| 1301 | Rheumatoid, other arthritis M > 36.35 | 1.1678 | 0.9974 | 0.9062 | 0.8219 | 12 | 10 | 11 | 10 |
| 1302 | Rheumatoid, other arthritis M > 26.15 and M < 36.35. | 1.5025 | 1.2832 | 1.1659 | 1.0575 | 16 | 15 | 14 | 13 |
| 1303 | Rheumatoid, other arthritis M < 26.15 | 1.9254 | 1.6444 | 1.4941 | 1.3551 | 18 | 18 | 17 | 16 |
| 1401 | Cardiac M > 48.85 | 0.8869 | 0.7263 | 0.6555 | 0.5937 | 9 | 9 | 8 | 8 |
| 1402 | Cardiac M > 38.55 and M < 48.85 | 1.1928 | 0.9768 | 0.8816 | 0.7985 | 12 | 11 | 11 | 10 |
| 1403 | Cardiac M > 31.15 and M < 38.55 | 1.4581 | 1.1941 | 1.0777 | 0.9761 | 14 | 14 | 12 | 12 |
| 1404 | Cardiac M < 31.15 | 1.8587 | 1.5222 | 1.3738 | 1.2443 | 19 | 17 | 15 | 14 |
| 1501 | Pulmonary M > 49.25 | 1.0128 | 0.8635 | 0.7803 | 0.7474 | 10 | 9 | 9 | 9 |
| 1502 | Pulmonary M > 39.05 and M < 49.25 | 1.2651 | 1.0787 | 0.9747 | 0.9336 | 12 | 12 | 11 | 11 |
| 1503 | Pulmonary M > 29.15 and M < 39.05 | 1.5357 | 1.3094 | 1.1832 | 1.1333 | 15 | 14 | 13 | 13 |
| 1504 | Pulmonary M < 29.15 | 1.9057 | 1.6248 | 1.4683 | 1.4063 | 21 | 17 | 16 | 15 |
| 1601 | Pain syndrome M > 37.15 | 1.0707 | 0.8883 | 0.8327 | 0.7639 | 9 | 10 | 10 | 9 |
| 1602 | Pain syndrome M > 26.75 and M < 37.15 | 1.3889 | 1.1523 | 1.0802 | 0.9909 | 12 | 14 | 12 | 12 |
| 1603 | Pain syndrome M < 26.75 | 1.7566 | 1.4573 | 1.3662 | 1.2533 | 18 | 17 | 15 | 15 |
| 1701 | Major multiple trauma without brain or spinal cord injury M > 39.25. | 1.1053 | 0.9551 | 0.8619 | 0.7769 | 11 | 12 | 11 | 10 |
| 1702 | Major multiple trauma without brain or spinal cord injury M > 31.05 and M < 39.25. | 1.3905 | 1.2016 | 1.0843 | 0.9774 | 13 | 15 | 13 | 12 |
| 1703 | Major multiple trauma without brain or spinal cord injury M > 25.55 and M < 31.05. | 1.6553 | 1.4304 | 1.2908 | 1.1635 | 17 | 16 | 15 | 14 |
| 1704 | Major multiple trauma without brain or spinal cord injury M < 25.55. | 2.1005 | 1.8152 | 1.6380 | 1.4764 | 24 | 20 | 18 | 18 |
| 1801 | Major multiple trauma with brain or spinal cord injury M > 40.85. | 1.1378 | 1.0183 | 0.9216 | 0.7648 | 13 | 12 | 12 | 10 |
| 1802 | Major multiple trauma with brain or spinal cord injury M > 23.05 and M < 40.85. | 1.7508 | 1.5669 | 1.4182 | 1.1769 | 18 | 19 | 17 | 14 |
| 1803 | Major multiple trauma with brain or spinal cord injury M < 23.05. | 2.7973 | 2.5035 | 2.2659 | 1.8804 | 33 | 28 | 24 | 22 |
| 1901 | Guillain Barre M > 35.95 | 1.0836 | 0.9288 | 0.8847 | 0.8716 | 14 | 10 | 11 | 11 |
| 1902 | Guillain Barre M > 18.05 and M < 35.95 | 2.1258 | 1.8221 | 1.7355 | 1.7097 | 23 | 21 | 19 | 20 |
| 1903 | Guillain Barre M < 18.05 | 3.5333 | 3.0287 | 2.8846 | 2.8418 | 56 | 32 | 31 | 30 |
| 2001 | Miscellaneous M > 49.15 | 0.8877 | 0.7267 | 0.6691 | 0.6107 | 9 | 9 | 8 | 8 |
| 2002 | Miscellaneous M > 38.75 and M < 49.15 | 1.1867 | 0.9714 | 0.8945 | 0.8164 | 12 | 11 | 11 | 10 |
| 2003 | Miscellaneous M > 27.85 and M < 38.75 | 1.4947 | 1.2235 | 1.1266 | 1.0283 | 15 | 14 | 13 | 12 |
| 2004 | Miscellaneous M < 27.85 | 1.9610 | 1.6051 | 1.4780 | 1.3490 | 20 | 18 | 17 | 15 |
| 2101 | Burns M > 0 | 2.1953 | 1.5624 | 1.5111 | 1.4146 | 24 | 21 | 17 | 17 |
| 5001 | Short-stay cases, length of stay is 3 days or fewer. | | | | 0.1538 | | | | 3 |
| 5101 | Expired, orthopedic, length of stay is 13 days or fewer. | | | | 0.6617 | | | | 8 |
| 5102 | Expired, orthopedic, length of stay is 14 days or more. | | | | 1.4346 | | | | 17 |
| 5103 | Expired, not orthopedic, length of stay is 15 days or fewer. | | | | 0.7653 | | | | 8 |
| 5104 | Expired, not orthopedic, length of stay is 16 days or more. | | | | 1.9685 | | | | 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 the application of the revisions for FY 2014 will affect particular CMG relative

weight values, which affect the overall distribution of payments within CMGs and tiers. Note that, because we are implementing the CMG relative weight

revisions in a budget-neutral manner (as described above), total estimated aggregate payments to IRFs for FY 2014 will not be affected as a result of the

CMG relative weight revisions. However, the revisions will affect the distribution of payments within CMGs and tiers.

TABLE 2—DISTRIBUTIONAL EFFECTS OF THE CHANGES TO THE CMG RELATIVE WEIGHTS (FY 2013 VALUES COMPARED WITH FY 2014 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% | 2,492 | 0.7 |
| Changed by less than 5% | 363,629 | 98.7 |
| Decreased by between 5% and 15% | 2,118 | 0.6 |
| Decreased by 15% or more | 97 | 0.0 |

As Table 2 shows, almost 99 percent of all IRF cases are in CMGs and tiers that will experience less than a 5 percent change (either increase or decrease) in the CMG relative weight value as a result of the revisions for FY 2014. The largest increase in the CMG relative weight values that affects a particularly large number of IRF discharges is a 0.8 percent increase in the CMG relative weight value for CMG 0704—Fracture of Lower Extremity, with a motor score less than 28.15—in the “no comorbidity” tier. In the FY 2012 data, 19,981 IRF discharges (5.4 percent of all IRF discharges) were classified into this CMG and tier.

The largest decrease in a CMG relative weight value affecting the most cases is a 2.1 percent decrease in the CMG relative weight for CMG 0903—Other Orthopedic with a motor score between 24.15 and 34.35—in the no comorbidity tier. In the FY 2012 IRF claims data, this change affects 7,047 cases (1.9 percent of all IRF cases).

The changes in the average length of stay values for FY 2014, compared with the FY 2013 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 updates to the CMG relative weights and average length of stay values for FY 2014, which are summarized below.

Comment: Several commenters supported the use of the same methodology that we used in the FY 2011 notice, the FY 2012 final rule, and the FY 2013 notice to update the CMG relative weights and average length of stay values for FY 2014, using the most recent available data. However, one commenter expressed concern about changes to some of the specific CMG relative weights, indicating that some of the changes were not necessary and that others might affect whether or not the CMGs would be adequately

compensating providers for treating certain types of patients requiring unusually high-cost treatments.

Response: We believe that updating the relative weights using the most recent available data ensures that the payments per case continue to accurately reflect the costs of care provided in IRFs. Although we acknowledge the commenter’s concerns with some of the specific CMG relative weight changes, these changes are based on IRFs’ reported costs of care for these types of cases, and we believe that it is essential to recognize these reported costs to ensure that the CMG relative weights reflect as closely as possible the relative costs of treating different types of patients in IRFs. Further, we note that the IRF PPS high-cost outlier policy is designed to compensate IRFs for providing care to patients whose costs greatly exceed the average cost of a case in a particular CMG and tier.

Comment: A few commenters requested that we outline the methodology used to calculate the average length of stay values. These same commenters agreed that the average length of stay values should only be used to determine when an IRF discharge meets the definition of a short-stay transfer, which results in a per diem case level adjustment, and are not intended to be used as clinical guidelines for patients’ lengths of stay in an IRF.

Response: We will post our methodology for calculating the average length of stay values on the IRF PPS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Research.html> in conjunction with the publication of this final rule.

We continue to support the commenters’ position that the average length of stay values in the rule are not intended as “targets” or as clinical guidelines for determining a patient’s length of stay in the IRF. A patient’s

length of stay in the IRF should be determined by the patient’s individual care needs.

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 2014. These updates are effective October 1, 2013.

V. Updates to the Facility-Level Adjustment Factors for FY 2014

A. Background on Facility-Level Adjustments

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

In the FY 2010 IRF PPS final rule (74 FR 39762), we updated the adjustment factors for calculating the rural, LIP, and teaching status adjustments based on the most recent three consecutive years’ worth of IRF claims data (at that time, FY 2006, FY 2007, and FY 2008) and the most recent available corresponding IRF cost report data. As discussed in the FY 2010 IRF PPS proposed rule (74 FR 21060 through 21061), we observed relatively large year-to-year fluctuations in the underlying data used to compute the adjustment factors, especially the teaching status adjustment factor. Therefore, we implemented a 3-year moving average approach to updating the facility-level adjustment factors in the FY 2010 IRF PPS final rule (74 FR 39762) to provide greater stability and predictability of Medicare payments for IRFs.

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

B. Updates to the IRF Facility-Level Adjustment Factors

Since the FY 2012 final rule (76 FR 47836), we have conducted further research into the best methodology to use to estimate the IRF facility-level adjustment factors, to ensure that the adjustment factors reflect as accurately as possible the costs of providing IRF care across the full spectrum of IRF providers. Our recent research efforts have shown that significant differences exist between the cost structures of freestanding IRFs and the cost structures of IRF units of acute care hospitals (and critical access hospitals, otherwise known as "CAHs"). We have found that these cost structure differences substantially influence the estimates of the adjustment factors. Therefore, we

believe that it is important to control for these cost structure differences between hospital-based and freestanding IRFs in our regression analysis, so that these differences do not inappropriately influence the adjustment factor estimates. In Medicare's payment system for the treatment of end-stage renal disease (ESRD), we already control for the cost structure differences between hospital-based and freestanding facilities in the regression analyses that are used to set payment rates. Also, we received comments from an IRF industry association on the FY 2012 IRF PPS proposed rule suggesting that the addition of this particular control variable to the model could improve the methodology for estimating the IRF facility-level adjustment factors.

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

Therefore, in the FY 2014 IRF PPS proposed rule, we proposed to use the same methodology used in the FY 2010 IRF PPS final rule (74 FR 39762), including the 3-year moving average approach, with the addition of this new control variable, which equals "1" if the facility is a freestanding IRF hospital and "0" if it is an IRF unit of an acute care hospital (or a CAH). We proposed to update the adjustment factors using the most recent three years' worth of IRF claims data (FY 2010, FY 2011, and FY 2012) and the most recent available corresponding IRF cost report data. As we did in the FY 2010 IRF PPS final rule (74 FR 39762), we also proposed to use the cost report data that corresponds with each IRF claim, when available. In

the rare instances in which the corresponding year's cost report data are not available, we proposed to use the most recent available cost report data, as we also did in the FY 2010 IRF PPS final rule (74 FR 39762).

To calculate the updates to the rural, LIP, and teaching status adjustment factors for FY 2014, we use the following steps:

[Steps 1 and 2 are performed independently for each of three years of IRF claims data: FY 2010, FY 2011, and FY 2012.]

Step 1. Calculate the average cost per case for each IRF in the IRF claims data.

Step 2. Use logarithmic regression analysis on average cost per case to compute the coefficients for the rural, LIP, and teaching status adjustments. We proposed to incorporate an additional indicator variable to account for whether a facility is a freestanding IRF hospital or a unit of an acute care hospital (or a CAH).

Step 3. Calculate a simple mean for each of the coefficients across the three years of data (using logarithms for the LIP and teaching status adjustment coefficients (because they are continuous variables), but not for the rural adjustment coefficient (because the rural variable is either zero (if not rural) or 1 (if rural)). To compute the LIP and teaching status adjustment factors, we convert these factors back out of the logarithmic form.

Based on this methodology, we proposed to update the rural adjustment factor for FY 2014 from 18.4 percent to 14.9 percent. We proposed to update the LIP adjustment factor for FY 2014 from 0.4613 to 0.3177 and the teaching status adjustment factor for FY 2014 from 0.6876 to 1.0163.

C. Budget Neutrality Methodology for the Updates to the IRF Facility-Level Adjustment Factors

Consistent with the way that we implemented changes to the IRF facility-level adjustment factors (the rural, LIP, and teaching status adjustments factors) in the FY 2006 IRF PPS final rule (70 FR 47880 and 70 FR 57166), which was the only year in which we updated these adjustment factors, we proposed to make changes to the rural, LIP, and teaching status adjustment factors for FY 2014 in such a way that total estimated aggregate payments to IRFs for FY 2014 would be the same with or without the proposed changes (that is, in a budget-neutral manner) by applying budget neutrality factors for each of these three changes to the standard payment amount. To calculate the budget neutrality factors used to update the rural, LIP, and teaching status

adjustment factors, we use the following steps:

Step 1. Using the most recent available data (currently FY 2012), calculate the estimated total amount of IRF PPS payments that would be made in FY 2014 (without applying the changes to the rural, LIP, or teaching status adjustment factors).

Step 2. Calculate the estimated total amount of IRF PPS payments that will be made in FY 2014 if the update to the rural adjustment factor were applied.

Step 3. Divide the amount calculated in step 1 by the amount calculated in step 2 to determine the budget neutrality factor (1.0025) that will maintain the same total estimated aggregate payments in FY 2014 with and without the change to the rural adjustment factor.

Step 4. Calculate the estimated total amount of IRF PPS payments that will be made in FY 2014 if the update to the LIP adjustment factor were applied.

Step 5. Divide the amount calculated in step 1 by the amount calculated in step 4 to determine the budget neutrality factor (1.0171) that will maintain the same total estimated aggregate payments in FY 2014 with and without the change to the LIP adjustment factor.

Step 6. Calculate the estimated total amount of IRF PPS payments that will be made in FY 2014 if the update to the teaching status adjustment factor were applied.

Step 7. Divide the amount calculated in step 1 by the amount calculated in step 6 to determine the budget neutrality factor (0.9962) that will maintain the same total estimated aggregate payments in FY 2014 with and without the change to the teaching status adjustment factor.

Step 8. Apply the budget neutrality factors for the updates to the rural, LIP, and teaching status adjustment factors to the FY 2013 IRF PPS standard payment amount after the application of the budget neutrality factors for the wage adjustment and the CMG relative weights.

In section VI.E. of this final rule, we discuss the methodology for calculating the standard payment conversion factor for FY 2014.

We received 19 comments on the proposed updates to the facility-level adjustment factors, which are summarized below.

Comment: Several commenters expressed concerns about the financial impact that the reductions to the rural and LIP adjustments would have on individual IRFs. These commenters also expressed concerns about the potential effects of this policy change combined

with possible state Medicaid expansions under the Affordable Care Act. These commenters suggested that we delay implementation until FY 2015, phase in the updates over multiple years, or implement a stop-loss policy to mitigate the financial impact of the changes.

Response: Although we are mindful of the significant financial impacts on a small number of individual IRFs of finalizing these proposals, we believe that updating the facility level adjustments as proposed is necessary at this time to ensure that the adjustment factors reflect as accurately as possible the costs of providing IRF care across the full spectrum of IRF providers. In addition, we estimate that the maximum financial impact on any one facility from these proposed policy changes is similar to the financial impact that can result from annual fluctuations in the geographic wage index values, and we do not typically implement a delay or phase-in period to account for annual wage index fluctuations.

Although we understand that providers are subject to multiple financial pressures in today's economic climate, the policies established by this final rule are focused on providing accurate payment for Medicare Part A services provided in an IRF setting. However, we note that, to the extent that Medicaid coverage is expanded under the Affordable Care Act provisions, we believe that this could increase IRFs' LIP percentages, potentially leading to higher LIP adjustment payments under the IRF PPS. We do not believe that such potential increases in spending for the LIP adjustment undercut the need to ensure that LIP adjustment payments are as fair and accurate as possible for FY 2014.

Further, whereas the proposed updates to the facility-level adjustment factors would decrease payments to some IRFs, they would increase payments to other IRFs, by as much as 16.8 percent. By updating the facility-level adjustment factors with the proposed methodology, we ensure that the adjustment factors reflect as accurately as possible the costs of providing IRF care across the full spectrum of IRF providers where individual providers may see an increase or decrease. In addition, because we update the rural and LIP adjustments in a budget-neutral manner, decreases to these adjustments result in increases to the base payment rates for all IRF providers, partially offsetting some of the decreases in the rural and LIP adjustment payments for the affected providers. Thus, we believe it is necessary to update the adjustments at this time, using the proposed new

enhancement to the methodology, to pay providers as accurately and fairly as possible.

Comment: Several commenters did not support our proposal to include an indicator variable for an IRF's freestanding/hospital-based status in the regression model, based on their belief that such variables should only be included if they are used as payment adjusters. These commenters further suggested that CMS pursue further analysis to explain the fluctuations in the teaching status adjustment factor over time. One commenter recommended that CMS cap the IRF teaching status adjustment factor at the same level as the IPPS IME adjustment, the IPF teaching status adjustment, or some combination of these adjustments.

Response: We appreciate the commenters' concerns and recommendations. However, given that our analysis showed large differences in cost structures between freestanding and hospital-based IRFs, and that a significant amount of the differences in costs between different types of IRFs (for example, urban/rural, teaching/non-teaching, and high LIP percentage/low LIP percentage) can be attributed instead to a facility's freestanding/hospital-based status, we believe that we would be remiss in not accounting for this indicator variable in the regression analysis. Thus, we believe that the inclusion of the indicator variable enables us to more precisely and accurately calculate each of the facility-level adjustment factors.

For several reasons, however, we do not believe that a facility's freestanding/hospital-based status can be used as a payment adjuster at this time. First, we do not know how much of the higher costs we observe in hospital-based IRFs can be attributed to the actual costs of treating patients in hospital-based settings (versus freestanding settings) and how much of the higher costs result from a hospital's decisions about allocating costs among its different components. Secondly, the IRF PPS has traditionally treated freestanding IRF hospitals and IRF units of acute care hospitals (or CAHs) the same for Medicare payment purposes. Thus, we do not believe it is appropriate to introduce a freestanding/hospital-based payment adjuster for the IRF PPS without substantial evidence that a change in policy is warranted at this time. However, we do believe that it is necessary to recognize the important differences in cost structures of the two types of facilities in order to pay IRFs as accurately and fairly as possible under the IRF PPS.

As one commenter suggested, we have done extensive analysis to uncover the reasons for the fluctuations in the IRF teaching status adjustment factor over time. Our analysis shows that such fluctuations are related primarily to the fact that there are relatively few IRF teaching facilities (around 110 in each year), and therefore fluctuations in the teaching status of one or two of these IRFs will be evident in overall fluctuations in the teaching adjustment factor over time. Specifically, we found that one IRF did not report training any interns and residents from 2007 through 2009, then reported relatively large intern and resident to average daily census ratios in 2010 and 2011, and then did not report training any interns and residents after 2011. This one provider appears to have contributed to swings in the overall teaching status adjustment factor over time. However, we have no reason to believe that any of the teaching status information for this provider is incorrect, and therefore believe that including this data is appropriate.

Further, our analysis of the IRF teaching adjustment trends shows no significant cause for concern in terms of unusually high or increasing Medicare payments for this adjustment over time. We found that the number of IRFs receiving this adjustment and the Medicare payments per IRF for this adjustment have remained very stable over time. Total Medicare spending for the IRF teaching adjustment peaked at \$78 million (almost 9 percent of total IRF PPS payments) for 124 facilities in FY 2006, and fell to \$56 million (6 percent of total IRF PPS payments) for 111 facilities in FY 2012. The average Medicare payment to an individual IRF for the teaching status adjustment decreased from \$773,000 in FY 2006 to \$508,000 in FY 2012. The average number of interns and residents relative to an IRF's average daily census (the factor on which an IRF's teaching status

adjustment is based) was 0.12 in FY 2006, and declined to 0.11 in FY 2012. Given the small magnitude of the IRF teaching status adjustment relative to total IRF expenditures, the lack of growth in spending for this adjustment, and the need to ensure that IRFs are adequately compensated for training a new generation of physicians in the rehabilitation of Medicare beneficiaries in the IRF setting, we believe that continued funding of this adjustment is beneficial to the Medicare program and Medicare beneficiaries.

As one commenter suggested, we explored the possibility of capping the IRF teaching status adjustment at the level of either the IPPS capital or operating IME adjustments. However, either of these options would decrease the IRF teaching status adjustment factor to such an extremely low level (0.03 or 0.04 compared with the current 0.6876) that the additional payment per facility would not be enough to adequately compensate or encourage the training of a new generation of physicians in the rehabilitation of Medicare beneficiaries in the IRF setting. While capping the adjustment at the amount currently reflected in the inpatient psychiatric facility teaching status adjustment (0.5150) would seem to provide greater compensation than capping at either the IPPS capital or operating IME adjustment levels, at this time there is not enough evidence to believe that teaching costs or compensation should be the same for these settings. In fact, inpatient psychiatric facilities are not similar to IRFs in the types of patients they treat or the types of services they provide, so we cannot find any logical justification for capping the IRF teaching status adjustment factor at the teaching status adjustment factor used in the IPF PPS.

Comment: One commenter requested clarification on the 3-year moving average approach, including how the approach is used and whether or not the

IRF area wage index adjustment is included as one of the adjustments that we estimate using this approach.

Response: The 3-year moving average approach was implemented to decrease year-to-year fluctuations in the facility-level adjustment factors. The IRF area wage index adjustment is not included in the facility-level adjustments that we estimate using a 3-year moving average approach.

Comment: Several commenters requested more information about the methodology used to compute the IRF facility-level adjustments, and the data to enable providers to replicate our analysis. In addition, one commenter requested that we provide the estimates that were averaged over the 3-year period to obtain the facility-level adjustment factors, and that we run our regression analysis on three years' worth of pooled discharge data instead of averaging each year's regression coefficients over three years.

Response: Our regression analysis for computing the IRF facility-level adjustments was posted on the IRF PPS Web site at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Downloads/Facility-Payment-Adjustment_KJS.pdf in 2011. As we discussed in the proposed rule, the only change to this regression analysis would be the addition of an indicator variable for an IRF's freestanding/hospital-based status, which would equal "1" if the IRF was a freestanding facility and "0" if the IRF was a hospital-based facility. The data that we used to analyze the adjustments is available from the IRF rate-setting files on the IRF PPS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Data-Files.html>. The annual IRF facility-level adjustment factor estimates are presented below in Table 3. For this final rule, we averaged the estimates for FY 2010, FY 2011, and FY 2012.

TABLE 3—ANNUAL IRF FACILITY-LEVEL ADJUSTMENT FACTOR ESTIMATES

| | FY 05 | FY 06 | FY 07 | FY 08 | FY 09 | FY 10 | FY 11 | FY 12 |
|----------------|--------|--------|--------|--------|--------|--------|--------|--------|
| LIP | 0.4172 | 0.5107 | 0.3865 | 0.4898 | 0.4866 | 0.1594 | 0.2702 | 0.5538 |
| Teaching | 1.5155 | 0.6732 | 1.0451 | 0.4045 | 1.5678 | 0.3597 | 0.6326 | 2.6930 |
| Rural | 0.1860 | 0.1856 | 0.1765 | 0.1898 | 0.2123 | 0.1608 | 0.1516 | 0.1356 |

Additionally, we investigated another commenter's suggestion that we reduce the annual fluctuation in the adjustment factors by performing the regression analysis on three years' worth of pooled discharge data instead of averaging each year's regression coefficients over three

years. We tried the approach that the commenter suggested, and it did not materially change our estimates.

Final Decision: After careful consideration of the public comments, we are finalizing our proposal to add an indicator variable for a facility's

freestanding/hospital-based status to the payment regression, and, with that change, to update the IRF facility-level adjustment factors for FY 2014 using the same methodology, with the exception of adding the indicator variable, that we used in updating the FY 2010 IRF

facility-level adjustment factors, including the 3-year moving average approach. This results in a rural adjustment of 14.9 percent, a LIP adjustment factor of 0.3177, and a teaching status adjustment factor of 1.0163 for FY 2014. These updates are effective October 1, 2013.

VI. FY 2014 IRF PPS Federal Prospective Payment Rates

A. Market Basket Increase Factor, Productivity Adjustment, and Other Adjustment for FY 2014

Section 1886(j)(3)(C) of the Act requires the Secretary to establish an increase factor that reflects changes over time in the prices of an appropriate mix of goods and services included in the covered IRF services, which is referred to as a market basket index. According to section 1886(j)(3)(A)(i) of the Act, the increase factor shall be used to update the IRF federal prospective payment rates for each FY. Sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(iii) of the Act required the application of a 0.3 percentage point reduction to the market basket increase factor for FY 2014. In addition, section 1886(j)(3)(C)(ii)(I) of the Act requires the application of a productivity adjustment, as described below. Thus, in the FY 2014 IRF PPS proposed rule, we proposed to update the IRF PPS payments for FY 2014 by a market basket increase factor based upon the most current data available, with a productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act as described below and a 0.3 percentage point reduction as required by sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(iii) of the Act.

For this final rule, we use the same methodology described in the FY 2012 IRF PPS final rule (76 FR 47836 at 47848 through 47863) to compute the FY 2014 market basket increase factor and labor-related share. In that final rule, we rebased the RPL market basket from a 2002 base year to a 2008 base year. Based on IHS Global Insight's second quarter 2013 forecast, the most recent estimate of the 2008-based RPL market basket increase factor for FY 2014 is 2.6 percent. IHS Global Insight (IGI) is an economic and financial forecasting firm that contracts with CMS to forecast the components of providers' market baskets.

In accordance with section 1886(j)(3)(C)(ii)(I) of the Act, and using the methodology described in the FY 2012 IRF PPS final rule (76 FR 47836, 47858 through 47859), we apply a productivity adjustment to the FY 2014 RPL market basket increase factor. The

statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable FY cost reporting period, or other annual period) (the "MFP adjustment"). The Bureau of Labor Statistics (BLS) is the agency that publishes the official measure of private nonfarm business MFP. We refer readers to the BLS Web site at <http://www.bls.gov/mfp> to obtain the historical BLS-published MFP data. The projection of MFP is currently produced by IGI, using the methodology described in the FY 2012 IRF PPS final rule (76 FR 47836, 47859). The most recent estimate of the MFP adjustment for FY 2014 (the 10-year moving average of MFP for the period ending FY 2014) is 0.5 percent, which was calculated using the methodology described in the FY 2012 IRF PPS final rule (76 FR 47836, 47858 through 47859) and is based on IGI's second quarter 2013 forecast.

Thus, in accordance with section 1886(j)(3)(C) of the Act, we base the FY 2014 market basket update, which is used to determine the applicable percentage increase for the IRF payments, on the most recent estimate of the FY 2008-based RPL market basket (currently estimated to be 2.6 percent based on IGI's second quarter 2013 forecast). We then reduce this percentage increase by the current estimate of the MFP adjustment for FY 2014 of 0.5 percentage point (the 10-year moving average of MFP for the period ending FY 2014 based on IGI's second quarter 2013 forecast), which was calculated as described in the FY 2012 IRF PPS final rule (76 FR 47836, 47859). Following application of the MFP, we further reduce the applicable percentage increase by 0.3 percentage point, as required by sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(iii) of the Act. Therefore, the current estimate of the FY 2014 IRF update is 1.8 percent (2.6 percent market basket update, less 0.5 percentage point MFP adjustment, less 0.3 percentage point legislative adjustment).

B. Secretary's Final Recommendation

For FY 2014, the Medicare Payment Advisory Commission (MedPAC) recommends that a 0 percent update be applied to IRF PPS payment rates. As discussed above, and in accordance with sections 1886(j)(3)(C) and 1886(j)(3)(D) of the Act, the Secretary is proposing to update IRF PPS payment rates for FY 2014 by an adjusted market basket increase factor of 1.8 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 2014.

We received 5 comments on the proposed market basket increase factor, MFP adjustment, other adjustments for FY 2014, and the Secretary's proposed recommendation, which are summarized below.

Comment: One commenter supported our proposal to update the IRF PPS payment rates for FY 2014 by the adjusted market basket estimate. Another commenter noted that MedPAC recommended a 0 percent update for IRFs for FY 2014, but recognized that CMS does not have the statutory authority to apply a different update factor to IRF PPS payment rates than is specified in statute. Several other commenters expressed concerns about the applicability of the MFP adjustment to the IRF setting, indicating that the unique services provided in IRFs do not lend themselves to the efficiency gains that are implied by the application of a MFP adjustment. These commenters recommended that we continue to monitor the impact of the MFP adjustment on IRFs and communicate our findings to the Congress.

Response: We appreciate the commenters' concerns. As these commenters noted, we are bound in these matters by the statute. However, we will continue to monitor the effects of the annual updates to the IRF PPS payment rates, and will communicate our findings as appropriate.

Comment: One commenter expressed concern about our use of some of the underlying cost categories, weights, and price proxies from the acute care hospital data, when the necessary RPL-specific data are not available, and suggested that we consider collecting additional information on the IRF cost reports prior to our next rebasing of the RPL market basket, so that we will not have to use the IPPS data for this purpose anymore.

Response: As stated in the FY 2012 IRF final rule (76 FR 47836, 47851), effective for cost reports beginning on or after May 1, 2010, we finalized a revised Hospital and Hospital Health Care Complex Cost Report, Form CMS 2552-10, which includes a new worksheet (Worksheet S-3, part V) which identifies the contract labor costs and benefit costs for the hospital complex and is applicable to sub-providers and units. Prior to any future rebasings, we plan to review any contract labor and benefit cost data submitted by RPL providers to determine the appropriateness of using this

information in the derivation of updated market basket cost weights.

Final Decision: After careful consideration of the public comments, we are finalizing our decision to update IRF PPS payment rates for FY 2014 based on the most recent estimate of the FY 2008-based RPL market basket (currently estimated to be 2.6 percent based on IGI's second quarter 2013 forecast). We then reduce this percentage increase by the current estimate of the MFP adjustment for FY 2014 of 0.5 percentage point (the 10-year moving average of MFP for the period ending FY 2014 based on IGI's

second quarter 2013 forecast), which was calculated as described in the FY 2012 IRF PPS final rule (76 FR 47836, 47859). Following application of the MFP adjustment, we further reduce the applicable percentage increase by 0.3 percentage point, as required by sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(iii) of the Act. Therefore, the FY 2014 IRF update is 1.8 percent (2.6 percent market basket update, less 0.5 percentage point MFP adjustment, less 0.3 percentage point legislative adjustment).

C. Labor-Related Share for FY 2014

The labor-related share for FY 2014 is updated using the methodology described in the FY 2012 IRF PPS final rule (76 FR 47836, 47860 through 47863). Using this method and IGI's second quarter 2013 forecast of the 2008-based RPL market basket, the IRF labor-related share for FY 2014 is the sum of the FY 2014 relative importance of each labor-related cost category. This figure reflects the different rates of price change for these cost categories between the base year (FY 2008) and FY 2014. As shown in Table 4, the FY 2014 labor-related share is 69.494 percent.

TABLE 4—FY 2014 IRF RPL LABOR-RELATED SHARE RELATIVE IMPORTANCE

| | FY 2014 Relative importance labor-related share |
|--|---|
| Wages and Salaries | 48.394 |
| Employee Benefits | 12.963 |
| Professional Fees: Labor-Related | 2.065 |
| Administrative and Business Support Services | 0.415 |
| All Other: Labor-Related Services | 2.080 |
| Subtotal | 65.917 |
| Labor-Related Portion of Capital Costs (.46) | 3.577 |
| Total Labor-Related Share | 69.494 |

Source: IHS Global Insight, Inc. 2nd quarter 2013 forecast; Historical Data through 1st quarter, 2013.

We received 1 comment on the proposed update to the IRF labor-related share, which is summarized below.

Comment: One commenter expressed general concern with the proposed decrease in the IRF labor-related share from FY 2013 to FY 2014.

Response: We believe that the methodology for determining the labor-related share is technically appropriate, as it estimates the proportion of IRF costs that are labor-intensive and vary with, or are influenced by, the local labor market. The methodology for determining the proposed IRF labor-related share for FY 2014 is the same general method that was used to derive the FY 2013 IRF PPS labor-related share. That is, the labor-related share is equal to the sum of the relative importance of each labor-related cost category in the RPL market basket. We calculate the labor-related relative importance for FY 2014 in four steps. First, we compute the FY 2014 price index level for the total market basket and each cost category of the market basket. Second, we calculate a ratio for each cost category by dividing the FY 2014 price index level for that cost category by the total market basket price index level. Third, we determine the FY 2014 relative importance for each cost category by multiplying this ratio by the

base year (FY 2008) weight. Finally, we add the FY 2014 relative importance for each of the labor-related cost categories. The purpose of the relative importance is to capture the different rates of price change for each of the market basket cost categories between the base year (FY 2008 for IRFs) and FY 2014. Therefore, to the extent an individual price proxy for a specific cost category is projected to grow faster from FY 2008 to FY 2014 relative to the proxies for other cost categories, the relative importance for that category in FY 2014 will be higher than the base year cost weight in FY 2008.

Final Decision: After consideration of the public comments received, we are finalizing our decision to update IRF labor-related share for FY 2014 using the methodology described in the FY 2012 IRF PPS final rule (76 FR 47836, 47860 through 47863) and IGI's second quarter 2013 forecast of the 2008-based RPL market basket. The FY 2014 labor-related share is 69.494 percent.

D. Wage Adjustment

Section 1886(j)(6) of the Act requires the Secretary to adjust the proportion of rehabilitation facilities' costs attributable to wages and wage related costs (as estimated by the Secretary from time to time) by a factor (established by the Secretary) reflecting the relative

hospital wage level in the geographic area of the rehabilitation facility compared to the national average wage level for those facilities. The Secretary is required to update the IRF PPS wage index on the basis of information available to the Secretary on the wages and wage-related costs to furnish rehabilitation services. Any adjustment or updates made under section 1886(j)(6) of the Act for a FY are made in a budget-neutral manner.

For FY 2014, we are maintaining the policies and methodologies described in the FY 2012 IRF PPS final rule (76 FR 47836, at 47863 through 47865) relating to the labor market area definitions and the wage index methodology for areas with wage data. Thus, we are using the CBSA labor market area definitions and the FY 2013 pre-reclassification and pre-floor hospital wage index data. In accordance with section 1886(d)(3)(E) of the Act, the FY 2013 pre-reclassification and pre-floor hospital wage index is based on data submitted for hospital cost reporting periods beginning on or after October 1, 2008, and before October 1, 2009 (that is, FY 2009 cost report data).

The labor market designations made by the OMB include some geographic areas where there are no hospitals and, thus, no hospital wage index data on

which to base the calculation of the IRF PPS wage index. We will continue to use the same methodology discussed in the FY 2008 IRF PPS final rule (72 FR 44299) to address those geographic areas where there are no hospitals and, thus, no hospital wage index data in which to base the calculation for the FY 2014 IRF PPS wage index.

In accordance with our established methodology, we have historically adopted any CBSA changes that are published in the OMB bulletin that corresponds with the hospital wage data used to determine the IRF PPS wage index. The OMB bulletins are available at <http://www.whitehouse.gov/omb/bulletins/index.html>.

In keeping with the established IRF PPS wage index policy, we will use the prior year's (FY 2013) pre-floor, pre-reclassified hospital wage index data to derive the FY 2014 applicable IRF PPS wage index. We anticipate using the FY 2014 pre-floor, pre-reclassified hospital wage index data to derive the applicable IRF PPS wage index for FY 2015. We note, however, that the FY 2014 pre-floor, pre-reclassified hospital wage index does not use OMB's new 2010 Census-based area delineations, which were outlined in the February 28, 2013 OMB Bulletin 13-01. This bulletin contains a number of significant changes. For example, there are new CBSAs, counties that change from urban to rural, counties that change from rural to urban, and existing CBSAs that are being split apart. The OMB Bulletin with these changes was not published in time for incorporation into the FY 2014 pre-floor, pre-reclassified hospital wage index, since the proposed rule was already in the advanced stages of development at that time and the changes and their ramifications would need to be extensively reviewed and verified prior to their inclusion in the rule. We therefore intend to consider the incorporation of these CBSA changes during the development of the FY 2015 hospital wage index. Assuming that we would continue to follow our established methodology for the IRF PPS wage index, this means that the 2010 Census-based CBSA changes would not be considered for inclusion in the IRF PPS wage index until FY 2016.

To calculate the wage-adjusted facility payment for the payment rates set forth in this final rule, we multiply the unadjusted Federal payment rate for IRFs by the FY 2014 labor-related share based on the FY 2008-based RPL market basket (69.494 percent) to determine the labor-related portion of the standard payment amount. We then multiply the labor-related portion by the applicable

IRF wage index from the tables in the addendum to this final rule. These tables are available through the Internet on the CMS Web site at <http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/>. Table A is for urban areas, and Table B is for rural areas.

Adjustments or updates to the IRF wage index made under section 1886(j)(6) of the Act must be made in a budget-neutral manner. We calculate a budget-neutral wage adjustment factor as established in the FY 2004 IRF PPS final rule (68 FR 45689), codified at § 412.624(e)(1), as described in the steps below. We use the listed steps to ensure that the FY 2014 IRF standard payment conversion factor reflects the update to the wage indexes (based on the FY 2009 hospital cost report data) and the labor-related share in a budget-neutral manner:

Step 1. Determine the total amount of the estimated FY 2013 IRF PPS rates, using the FY 2013 standard payment conversion factor and the labor-related share and the wage indexes from FY 2013 (as published in the July 30, 2012 FY 2013 IRF PPS notice (77 FR 44618)).

Step 2. Calculate the total amount of estimated IRF PPS payments using the FY 2013 standard payment conversion factor and the FY 2014 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 2014 budget-neutral wage adjustment factor of 1.0010.

Step 4. Apply the FY 2014 budget-neutral wage adjustment factor from step 3 to the FY 2013 IRF PPS standard payment conversion factor after the application of the adjusted market basket update to determine the FY 2014 standard payment conversion factor.

We received 3 comments on the proposed FY 2014 IRF PPS wage index, which are summarized below.

Comment: Several commenters recommended that we develop a new methodology for area wage adjustment that eliminates hospital wage index reclassifications for all hospitals and reduces the problems associated with annual fluctuations in wage indexes and across geographic boundaries. These commenters also recommended that we consider wage index policies under the current IPPS because IRFs compete in a similar labor pool as acute care hospitals. The commenters suggested that the IPPS wage index policies would allow IRFs to benefit from the IPPS reclassification and/or floor policies. The commenters 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: 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 Public Law 105-33 (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 final rule (70 FR 47880, 47926 through 47928).

Finally, although some commenters recommended that we adopt the IPPS wage index policies such as reclassification and floor policies, we note that the Medicare Payment Advisory Commission (MedPAC's) June 2007 report to the Congress, titled "Report to Congress: Promoting Greater Efficiency in Medicare," 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 that adopting the IPPS wage index policies, such as reclassification or floor, would not be prudent at this time because MedPAC suggests that the reclassification and exception policies in the IPPS wage index alter the wage index values for one-third of IPPS hospitals. As one commenter noted, we have research currently under way to examine alternatives to the wage index methodology, including the issues the commenters mentioned about ensuring that the wage index minimizes fluctuations, matches the costs of labor in the market, and provides for a single wage index policy. Section 3137(b) of the Affordable Care Act required us to submit a report to the Congress by December 31, 2011 that includes a plan to reform the hospital wage index system. The report that we submitted is available online at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Reform.html>.

We enlisted the help of Acumen, LLC to assist us in meeting the requirements of section 106(b)(2), Division B, Title I of the Tax Relief and Health Care Act of 2006 (Pub. L. 109-432, enacted on December 20, 2006) (TRCA). Acumen, LLC conducted a study of both the current methodology used to construct the Medicare wage index and the

recommendations reported to Congress by MedPAC. Parts 1 and 2 of Acumen's final report, which analyzes the strengths and weaknesses of the data sources used to construct the CMS and MedPAC indexes, is available online at <http://www.acumenllc.com/reports/cms>. The report took MedPAC's 2009 recommendations on the Medicare wage index classification system into account, and includes a proposal to revise the IPPS wage index system. MedPAC's recommendations were noted in the FY 2009 IPPS final rule (75 FR 48434 at 48563). The proposal considered each of the following:

- The use of Bureau of Labor Statistics data or other data or methodologies to calculate relative wages for each geographic area.
- Minimizing variations in wage index adjustments between and within MSAs and statewide rural areas.
- Methods to minimize the volatility of wage index adjustments while maintaining the principle of budget neutrality.
- The effect that the implementation of the proposal would have on health care providers in each region of the county.
- Issues relating to occupational mix, such as staffing practices and any evidence on quality of care and patient safety, including any recommendations for alternative calculations to the occupational mix.
- The provision of a transition period.

We plan to monitor the efforts to develop an alternative wage index system for the IPPS closely and determine the impact or influence they may have on the IRF PPS wage index.

Final Decision: After consideration of the public comments received, we have decided to continue to use the policies and methodologies described in the FY 2008 IRF PPS final rule relating to the wage index methodology for areas without wage data. For FY 2014, we are maintaining the policies and methodologies described in the FY 2012 IRF PPS final rule (76 FR 47836, at 47836 through 47865) relating to the labor market area definitions and the wage index methodology for areas with wage data. Therefore, this final rule continues to use the Core-Based Statistical Area (CBSA) labor market area definitions and the pre-reclassification and pre-floor hospital wage index data based on 2009 cost report data. However, we will continue to monitor the IPPS wage index to identify any policy changes that may be appropriate for IRFs.

We discuss the calculation of the standard payment conversion factor for FY 2014 in section VI.E. of this final rule.

E. Description of the IRF Standard Conversion Factor and Payment Rates for FY 2014

To calculate the standard payment conversion factor for FY 2014, as

illustrated in Table 5, we begin by applying the adjusted market basket increase factor for FY 2014 that was adjusted in accordance with sections 1886(j)(3)(C) and (D) of the Act, to the standard payment conversion factor for FY 2013 (\$14,343). Applying the 1.8 percent adjusted market basket increase factor for FY 2014 to the revised standard payment conversion factor for FY 2013 of \$14,343 yields a standard payment amount of \$14,601. Then, we apply the budget neutrality factor for the FY 2014 wage index and labor-related share of 1.0010, which results in a standard payment amount of \$14,616. We next apply the budget neutrality factors for the revised CMG relative weights of 1.0000, which results in a standard payment conversion factor of \$14,616 for FY 2014.

We then apply the budget neutrality factors for the facility adjustments. Applying the budget neutrality factor for the revised rural adjustment of 1.0025 results in a standard payment conversion factor of \$14,652. We then apply the budget neutrality factor for the revised LIP adjustment of 1.0171 resulting in a standard payment conversion factor of \$14,903. Lastly, we apply the budget neutrality factor for the revised teaching adjustment of 0.9962 which results in a final standard payment conversion factor for FY 2014 of \$14,846.

TABLE 5—CALCULATIONS TO DETERMINE THE FY 2014 STANDARD PAYMENT CONVERSION FACTOR

| Explanation for adjustment | Calculations |
|---|--------------|
| Standard Payment Conversion Factor for FY 2013 | \$14,343 |
| Market Basket Increase Factor for FY 2014 (2.6 percent), reduced by 0.3 percentage point in accordance with sections 1886(j)(3)(C) and (D) of the Act and a 0.5 percentage point reduction for the productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act | × 1.018 |
| Budget Neutrality Factor for the Wage Index and Labor-Related Share | × 1.0010 |
| Budget Neutrality Factor for the Revisions to the CMG Relative Weights | × 1.0000 |
| Budget Neutrality Factor for the Update to the Rural Adjustment Factor | × 1.0025 |
| Budget Neutrality Factor for the Update to the LIP Adjustment Factor | × 1.0171 |
| Budget Neutrality Factor for the Update to the Teaching Status Adjustment Factor | × 0.9962 |
| FY 2014 Standard Payment Conversion Factor | = \$14,846 |

After the application of the CMG relative weights described in Section IV of this final rule, to the FY 2014

standard payment conversion factor (\$14,846), the resulting unadjusted IRF

prospective payment rates for FY 2014 are shown in Table 6.

TABLE 6—FY 2014 PAYMENT RATES

| CMG | Payment rate Tier 1 | Payment rate Tier 2 | Payment rate Tier 3 | Payment rate no comorbidity |
|------------|---------------------|---------------------|---------------------|-----------------------------|
| 0101 | \$11,851.56 | \$10,616.37 | \$9,707.80 | \$9,262.42 |
| 0102 | 14,713.87 | 13,180.28 | 12,051.98 | 11,498.23 |
| 0103 | 17,233.24 | 15,436.87 | 14,115.58 | 13,466.81 |
| 0104 | 18,129.94 | 16,240.04 | 14,848.97 | 14,167.54 |
| 0105 | 21,192.67 | 18,983.58 | 17,357.94 | 16,560.71 |
| 0106 | 24,176.71 | 21,657.34 | 19,803.08 | 18,893.02 |
| 0107 | 27,294.37 | 24,448.39 | 22,356.59 | 21,329.25 |
| 0108 | 34,378.88 | 30,795.06 | 28,158.41 | 26,865.32 |

TABLE 6—FY 2014 PAYMENT RATES—Continued

| CMG | Payment rate Tier 1 | Payment rate Tier 2 | Payment rate Tier 3 | Payment rate no comorbidity |
|------|---------------------|---------------------|---------------------|-----------------------------|
| 0109 | 31,161.75 | 27,913.45 | 25,523.24 | 24,351.89 |
| 0110 | 40,651.32 | 36,412.78 | 33,295.12 | 31,767.47 |
| 0201 | 12,250.92 | 10,322.42 | 9,177.80 | 8,546.84 |
| 0202 | 15,661.05 | 13,196.61 | 11,734.28 | 10,926.66 |
| 0203 | 18,587.19 | 15,662.53 | 13,925.55 | 12,967.98 |
| 0204 | 19,414.11 | 16,360.29 | 14,546.11 | 13,545.49 |
| 0205 | 23,443.32 | 19,755.57 | 17,564.30 | 16,355.84 |
| 0206 | 28,908.13 | 24,360.80 | 21,658.83 | 20,168.29 |
| 0207 | 38,253.69 | 32,235.12 | 28,660.20 | 26,688.65 |
| 0301 | 16,306.85 | 14,033.92 | 12,573.08 | 11,627.39 |
| 0302 | 20,420.67 | 17,574.69 | 15,745.67 | 14,560.96 |
| 0303 | 24,078.73 | 20,722.05 | 18,566.41 | 17,169.40 |
| 0304 | 32,352.40 | 27,843.67 | 24,945.73 | 23,069.20 |
| 0401 | 16,838.33 | 13,995.32 | 13,031.82 | 11,652.63 |
| 0402 | 20,975.91 | 17,435.14 | 16,235.59 | 14,516.42 |
| 0403 | 34,375.91 | 28,572.61 | 26,605.52 | 23,789.23 |
| 0404 | 63,147.46 | 52,488.03 | 48,874.52 | 43,700.69 |
| 0405 | 51,949.12 | 43,181.08 | 40,207.42 | 35,951.07 |
| 0501 | 12,446.89 | 9,779.06 | 9,217.40 | 8,392.44 |
| 0502 | 16,464.21 | 12,933.84 | 12,190.05 | 11,100.35 |
| 0503 | 21,280.26 | 16,718.08 | 15,756.06 | 14,347.17 |
| 0504 | 24,592.40 | 19,320.58 | 18,208.62 | 16,580.01 |
| 0505 | 29,258.50 | 22,986.06 | 21,663.28 | 19,725.88 |
| 0506 | 40,853.22 | 32,095.57 | 30,248.73 | 27,543.78 |
| 0601 | 14,318.97 | 11,624.42 | 10,729.20 | 9,725.61 |
| 0602 | 19,261.20 | 15,637.29 | 14,431.80 | 13,080.81 |
| 0603 | 24,092.09 | 19,558.12 | 18,051.25 | 16,361.78 |
| 0604 | 32,190.58 | 26,133.41 | 24,118.81 | 21,862.22 |
| 0701 | 13,909.22 | 11,869.38 | 11,354.22 | 10,310.55 |
| 0702 | 18,011.17 | 15,370.06 | 14,703.48 | 13,351.01 |
| 0703 | 21,884.49 | 18,674.78 | 17,864.19 | 16,222.22 |
| 0704 | 27,785.77 | 23,710.55 | 22,681.72 | 20,597.34 |
| 0801 | 10,447.13 | 9,194.13 | 8,413.23 | 7,699.14 |
| 0802 | 13,739.97 | 12,092.07 | 11,066.21 | 10,126.46 |
| 0803 | 18,689.63 | 16,446.40 | 15,050.87 | 13,772.63 |
| 0804 | 16,536.96 | 14,553.53 | 13,318.35 | 12,187.08 |
| 0805 | 20,419.19 | 17,969.60 | 16,444.91 | 15,047.91 |
| 0806 | 24,767.58 | 21,796.90 | 19,945.60 | 18,251.67 |
| 0901 | 13,376.25 | 11,063.24 | 10,230.38 | 9,265.39 |
| 0902 | 17,935.45 | 14,834.12 | 13,719.19 | 12,424.62 |
| 0903 | 22,387.77 | 18,515.93 | 17,123.38 | 15,508.13 |
| 0904 | 29,200.60 | 24,151.47 | 22,335.81 | 20,229.16 |
| 1001 | 15,255.75 | 13,873.59 | 11,910.95 | 11,011.28 |
| 1002 | 19,414.11 | 17,654.86 | 15,157.77 | 14,013.14 |
| 1003 | 28,744.83 | 26,140.84 | 22,442.70 | 20,747.29 |
| 1101 | 18,110.64 | 16,563.68 | 15,294.35 | 14,929.14 |
| 1102 | 25,408.93 | 23,236.96 | 21,458.41 | 20,943.25 |
| 1201 | 14,035.41 | 13,971.57 | 12,537.45 | 11,467.05 |
| 1202 | 17,442.57 | 17,362.40 | 15,580.88 | 14,250.68 |
| 1203 | 21,789.47 | 21,688.52 | 19,463.11 | 17,801.84 |
| 1301 | 17,337.16 | 14,807.40 | 13,453.45 | 12,201.93 |
| 1302 | 22,306.12 | 19,050.39 | 17,308.95 | 15,699.65 |
| 1303 | 28,584.49 | 24,412.76 | 22,181.41 | 20,117.81 |
| 1401 | 13,166.92 | 10,782.65 | 9,731.55 | 8,814.07 |
| 1402 | 17,708.31 | 14,501.57 | 13,088.23 | 11,854.53 |
| 1403 | 21,646.95 | 17,727.61 | 15,999.53 | 14,491.18 |
| 1404 | 27,594.26 | 22,598.58 | 20,395.43 | 18,472.88 |
| 1501 | 15,036.03 | 12,819.52 | 11,584.33 | 11,095.90 |
| 1502 | 18,781.67 | 16,014.38 | 14,470.40 | 13,860.23 |
| 1503 | 22,799.00 | 19,439.35 | 17,565.79 | 16,824.97 |
| 1504 | 28,292.02 | 24,121.78 | 21,798.38 | 20,877.93 |
| 1601 | 15,895.61 | 13,187.70 | 12,362.26 | 11,340.86 |
| 1602 | 20,619.61 | 17,107.05 | 16,036.65 | 14,710.90 |
| 1603 | 26,078.48 | 21,635.08 | 20,282.61 | 18,606.49 |
| 1701 | 16,409.28 | 14,179.41 | 12,795.77 | 11,533.86 |
| 1702 | 20,643.36 | 17,838.95 | 16,097.52 | 14,510.48 |
| 1703 | 24,574.58 | 21,235.72 | 19,163.22 | 17,273.32 |
| 1704 | 31,184.02 | 26,948.46 | 24,317.75 | 21,918.63 |
| 1801 | 16,891.78 | 15,117.68 | 13,682.07 | 11,354.22 |
| 1802 | 25,992.38 | 23,262.20 | 21,054.60 | 17,472.26 |
| 1803 | 41,528.72 | 37,166.96 | 33,639.55 | 27,916.42 |
| 1901 | 16,087.13 | 13,788.96 | 13,134.26 | 12,939.77 |

TABLE 6—FY 2014 PAYMENT RATES—Continued

| CMG | Payment rate Tier 1 | Payment rate Tier 2 | Payment rate Tier 3 | Payment rate no comorbidity |
|------|---------------------|---------------------|---------------------|-----------------------------|
| 1902 | 31,559.63 | 27,050.90 | 25,765.23 | 25,382.21 |
| 1903 | 52,455.37 | 44,964.08 | 42,824.77 | 42,189.36 |
| 2001 | 13,178.79 | 10,788.59 | 9,933.46 | 9,066.45 |
| 2002 | 17,617.75 | 14,421.40 | 13,279.75 | 12,120.27 |
| 2003 | 22,190.32 | 18,164.08 | 16,725.50 | 15,266.14 |
| 2004 | 29,113.01 | 23,829.31 | 21,942.39 | 20,027.25 |
| 2101 | 32,591.42 | 23,195.39 | 22,433.79 | 21,001.15 |
| 5001 | | | | 2,283.31 |
| 5101 | | | | 9,823.60 |
| 5102 | | | | 21,298.07 |
| 5103 | | | | 11,361.64 |
| 5104 | | | | 29,224.35 |

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

Table 7 illustrates the methodology for adjusting the federal prospective payments (as described in sections VI.A. through VI.D. of this final rule). The following examples are based on two hypothetical Medicare beneficiaries, both classified into CMG 0110 (without comorbidities). The unadjusted federal prospective payment rate for CMG 0110 (without comorbidities) appears in Table 6.

Example: One beneficiary is in Facility A, an IRF located in rural Spencer County, Indiana, and another beneficiary is in Facility B, an IRF located in urban Harrison County, Indiana. Facility A, a rural non-teaching hospital has a Disproportionate Share Hospital (DSH) percentage of 5 percent (which would result in a LIP adjustment of 1.0156), a wage index of 0.8472, 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 0.8862, 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 6. Then, we multiply the labor-related share for FY 2014 (69.494 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 found in tables A and B. These tables are available through the Internet on the CMS Web site at <http://www.cms.hhs.gov/Medicare/Medicare->

Fee-for-Service-Payment/Inpatient RehabFacPPS/. The resulting figure is the wage-adjusted labor amount. Next, we compute the wage-adjusted federal payment by adding the wage-adjusted labor amount to the non-labor portion.

Adjusting the wage-adjusted federal payment by the facility-level adjustments involves several steps. First, we take the wage-adjusted Federal prospective payment and multiply it by the appropriate rural and LIP adjustments (if applicable). Second, to determine the appropriate amount of additional payment for the teaching status adjustment (if applicable), we multiply the teaching status adjustment (0.0784, in this example) by the wage-adjusted and rural-adjusted amount (if applicable). Finally, we add the additional teaching status payments (if applicable) to the wage, rural, and LIP-adjusted federal prospective payment rates. Table 7 illustrates the components of the adjusted payment calculation.

TABLE 7—EXAMPLE OF COMPUTING THE IRF FY 2014 FEDERAL PROSPECTIVE PAYMENT

| Steps | | Rural facility A (Spencer Co., IN) | Urban facility B (Harrison Co., IN) |
|-------|--|---------------------------------------|--|
| 1 | Unadjusted Federal Prospective Payment | \$31,767.47 | \$31,767.47 |
| 2 | Labor Share | × 0.69494 | × 0.69494 |
| 3 | Labor Portion of Federal Payment | = \$22,076.49 | = \$22,076.49 |
| 4 | CBSA Based Wage Index (shown in the Addendum, Tables 1 and 2) | × 0.8472 | × 0.8862 |
| 5 | Wage-Adjusted Amount | = \$18,703.20 | = \$19,564.19 |
| 6 | Non-labor Amount | + \$9,690.98 | + \$9,690.98 |
| 7 | Wage-Adjusted Federal Payment | = \$28,394.18 | = \$29,255.17 |
| 8 | Rural Adjustment | × 1.1493 | × 1.000 |
| 9 | Wage- and Rural-Adjusted Federal Payment | = \$32,633.43 | = \$29,255.17 |
| 10 | LIP Adjustment | × 1.0156 | × 1.0454 |
| 11 | FY 2014 Wage-, Rural- and LIP-Adjusted Federal Prospective Payment Rate | = \$33,142.51 | = \$30,583.35 |
| 12 | FY 2014 Wage- and Rural-Adjusted Federal Prospective Payment | \$32,633.43 | \$29,255.17 |
| 13 | Teaching Status Adjustment | × 0 | × 0.0784 |
| 14 | Teaching Status Adjustment Amount | = \$0.00 | = \$2,293.61 |
| 15 | FY 2014 Wage-, Rural-, and LIP-Adjusted Federal Prospective Payment Rate | + \$33,142.51 | + \$30,583.35 |
| 16 | Total FY 2014 Adjusted Federal Prospective Payment | = \$33,142.51 | = \$32,876.96 |

Thus, the adjusted payment for Facility A would be \$33,142.51, and the

adjusted payment for Facility B would be \$32,876.96.

We did not receive any comments specifically on the FY 2014 IRF PPS Federal prospective payment rates.

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

A. Update to the Outlier Threshold Amount for FY 2014

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 2012 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, 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 2014, we proposed to use FY 2012 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 2013. Based on an analysis of this updated data, we estimate that IRF outlier payments as a percentage of total estimated payments are approximately 2.5 percent in FY 2014. This estimated percentage changed more than usual between the proposed rule and the final rule due to the use of updated data for the final rule (from 2.8 percent in the proposed rule to 2.5 percent in the final rule). Our analysis indicates that this change was due to a larger-than-usual change in individual IRFs' CCRs between the proposed rule and the final rule. This may be the result of outlier reconciliation policies that we recently implemented for the IRF PPS that result in more current CCRs being used to calculate the outlier payments. Based on our updated estimates, then, we update the outlier threshold amount to \$9,272 to maintain estimated outlier payments at approximately 3 percent of total estimated aggregate IRF payments for FY 2014.

We received 4 comments on the update to the outlier threshold amount for FY 2014, which are summarized below.

Comment: Several commenters expressed support for the proposed update to the outlier threshold amount to maintain estimated IRF outlier payments for FY 2014 at 3 percent of total IRF PPS payments. However, several other commenters expressed concerns that actual IRF outlier payments in recent years have tended to fall below 3 percent of total IRF PPS payments. These commenters requested that we evaluate the IRF PPS outlier policy to ensure that it is working as intended, adopt similar changes in the IRF PPS outlier calculation that are proposed for the FY 2014 IPPS outlier calculation, and incorporate any unused outlier payments from years in which aggregate outlier payments are below the 3 percent target back into the IRF PPS base payments for subsequent years. One commenter also suggested that we lower the outlier pool from 3 percent to 1.5 or 2 percent, and add the money back into the IRF PPS base payment amount.

Response: We will continue to monitor our IRF outlier policies to ensure that they continue to compensate IRFs for treating unusually high-cost patients and, thereby, promote access to care for patients who are likely to require unusually high-cost care. At this time, we do not have any indications to suggest that the outlier pool would be

better set at 1.5 or 2 percent than at 3 percent.

We do not make adjustments to IRF PPS payment rates for the sole purpose of accounting for differences between projected and actual outlier payments. We use the best available data at the time to establish an outlier threshold for IRF PPS payments prior to the beginning of each fiscal year so that estimated outlier payments for that fiscal year will equal 3 percent of total estimated total IRF PPS payments. We evaluate the status of our outlier expenditures annually and if there is a difference from our projection, that information is used to make a prospective adjustment to lower or raise the outlier threshold for the upcoming fiscal year. We do not make retrospective adjustments. If outlier payments for a given year turn out to be greater than projected, we do not recoup money from hospitals; if outlier payments for a given year are lower than projected, we do not make an adjustment to account for the difference. Payments for a given discharge in a given fiscal year are generally intended to reflect or address the average costs of that discharge in that year; that goal would be undermined if we adjusted IRF PPS payments to account for "underpayments" or "overpayments" in IRF outliers in previous years.

We also note that the IPPS outlier payments are not calculated using the same methodology as the IRF PPS outlier calculations, so recently implemented and proposed changes to the IPPS methodology for calculating outlier payments would not be applicable for the IRF PPS unless we were to change our entire methodology for calculating IRF outlier payments to mirror the IPPS methodology, which we are not considering at this time.

Final Decision: Having carefully considered the public comments received, we are reducing the outlier threshold amount to \$9,272 to maintain estimated outlier payments at 3 percent of total estimated aggregate IRF payments for FY 2014. This update is effective October 1, 2013. We will continue to monitor trends in IRF outlier payments to ensure that they are working as intended to compensate IRFs for treating exceptionally high-cost IRF patients.

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

In accordance with the methodology stated in the FY 2004 IRF PPS final rule (68 FR 45674, 45692 through 45694), we apply a ceiling to IRFs' CCRs. Using the methodology described in that final rule, we update the national urban and

rural CCRs for IRFs, as well as the national CCR ceiling for FY 2014, 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 2014, as discussed below.
- Other IRFs for which accurate data to calculate an overall CCR are not available.

Specifically, for FY 2014, we estimate a national average CCR of 0.643 for rural IRFs, which we calculate by taking an average of the CCRs for all rural IRFs using their most recently submitted cost report data. Similarly, we estimate a national average CCR of 0.516 for urban IRFs, which we calculate by taking an average of the CCRs for all urban IRFs using their most recently submitted cost report data. We apply weights to both of these averages using the IRFs' estimated costs, meaning that the CCRs of IRFs with higher costs factor more heavily into the averages than the CCRs of IRFs with lower costs. For this final rule, we have used the most recent available cost report data (FY 2011). This includes all IRFs whose cost reporting periods begin on or after October 1, 2010, and before October 1, 2011. If, for any IRF, the FY 2011 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 2010) settled cost report for that IRF. We do not use cost report data from before FY 2004 for any IRF because changes in IRF utilization since FY 2004 resulting from the 60 percent rule and IRF medical review activities suggest that these older data do not adequately reflect the current cost of care.

In accordance with past practice, we will set the national CCR ceiling at 3 standard deviations above the mean CCR. Using this method, the national CCR ceiling is set at 1.57 for FY 2014. This means that, if an individual IRF's CCR exceeds this ceiling of 1.57 for FY 2014, we will replace the IRF's CCR with the appropriate national average CCR (either rural or urban, depending on the geographic location of the IRF). We estimate the national CCR ceiling by:

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

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

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

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

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

Final Decision: We did not receive any comments on the IRF CCR ceiling or urban/rural averages. Therefore, we are finalizing the national average urban CCR at 0.516, the national average rural CCR at 0.643, and the national CCR ceiling at 1.57 percent for FY 2014. These updates are effective October 1, 2013.

VIII. Refinements to the Presumptive Compliance Methodology

A. Background on the Compliance Percentage

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

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

The 1983 interim final rule stipulated that one of the criteria for being classified as an IRF was that, during the facility's most recently completed 12-month cost reporting period, the hospital must be primarily engaged in furnishing intensive rehabilitation services, as demonstrated by patient medical records, indicating that at least

75 percent of the IRF's patient population were treated for one or more of the 10 medical conditions specified in the regulation that typically required the intensive inpatient rehabilitation treatment provided in an IRF. These criteria, along with other related criteria, distinguished an inpatient rehabilitation hospital or unit from a hospital that furnished general medical or surgical services, as well as rehabilitation services. We believed then, as we do now, that by examining the types of conditions for which a hospital's inpatients are treated, and the proportion of patients treated for conditions that typically require intensive inpatient rehabilitation, we would be able to distinguish those hospitals in which the provision of rehabilitation services was primary rather than secondary. Thus, Medicare pays for rehabilitation services at IRFs at a higher rate than other hospitals because IRFs are designed to offer specialized inpatient rehabilitation care to patients with intensive needs.

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

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

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

- Severe or advanced osteoarthritis (osteoarthrosis or degenerative joint disease) involving three or more major joints (elbow, shoulders, hips, or knees) with joint deformity and substantial loss of range of motion, atrophy, significant functional impairment of ambulation and other activities of daily living, which has not improved after an appropriate, aggressive, and sustained course of outpatient therapy services or services in other less intensive rehabilitation settings immediately preceding the inpatient rehabilitation admission but has the potential to improve with more intensive rehabilitation. (A joint replaced by a prosthesis is no longer considered to have osteoarthritis, or other arthritis, even though this condition was the reason for the joint replacement.)

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

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

In 2002, we surveyed Medicare fiscal intermediaries to determine how they were enforcing the 75 percent rule. Although the 75 percent rule was one of the criteria that were used to distinguish an IRF from an acute care hospital from 1983 to 2004, we found evidence that different fiscal intermediaries were enforcing the rule differently. We found fiscal intermediaries were using inconsistent methods to determine whether IRFs were in compliance with the regulation, and that some IRFs were

not being reviewed for compliance at all. This led to concerns that some IRFs might have been out of compliance with the regulation and inappropriately classified as IRFs, while other IRFs may have been held to overly high standards. Because of these concerns we sought to establish a more uniform enforcement of the 75 percent rule.

In the May 16, 2003 IRF PPS proposed rule (68 FR 26786), we solicited comments on the regulatory requirements of the 75 percent rule. Though we did not, at that time, propose amending the regulatory requirements for the 75 percent rule located in then § 412.23(b)(2), we did propose to amend these requirements in the September 9, 2003 proposed rule titled, "Medicare Program; Changes to the Criteria for Being Classified as an Inpatient Rehabilitation Facility" (68 FR 53266). In that rule, we proposed some revisions to the 75 percent rule, including lowering the compliance percentage to 65 percent during a 3-year transition period for cost reporting periods between January 1, 2004 and January 1, 2007. Also, in response to comments on the September 9, 2003 proposed rule and as stated above, the May 7, 2004 final rule (69 FR 25752) expanded the number of medical conditions that would meet the compliance percentage from 10 to 13 and provided that patient comorbidities may also be included in determining an IRF's compliance with the requirements during the transition period.

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

Anticipating that IRFs needed some time to adjust and adapt their processes to the changes in the enforcement of the 75 percent rule, in the May 7, 2004 final rule, we provided IRFs with a 3-year phase-in period (cost reporting periods beginning on or after July 1, 2004 through July 1, 2007) to establish the

compliance threshold of 75 percent of the IRF's total patient population. The 3-year phase-in period was intended to begin with cost reporting periods on or after July 1, 2004 with the threshold at 50 percent of the IRF's population and gradually increase to 60 percent, then to 65 percent, and then to expire with cost reporting periods beginning on or after July 1, 2007, when the compliance percentage would once again be at 75 percent.

Section 5005 of the Deficit Reduction Act of 2005 (DRA, Pub. L. 109-171, enacted February 8, 2006) and section 1886(d)(1)(B) of the Act modified the provisions of the 75 percent rule originally specified in the May 7, 2004 final rule. To reflect these statutory changes, in the August 7, 2007 final rule (72 FR 44284), we revised the regulations to prolong the overall duration of the phased transition to the full 75 percent threshold by stipulating that an IRF must meet the full 75 percent compliance threshold as of its first cost reporting period that starts on or after July 1, 2008. We also extended the policy of using a patient's comorbidities to the extent they met the conditions as outlined in the regulations to determine compliance with the classification criteria at then § 412.23(b)(2)(1) to the first cost reporting period that starts on or after July 1, 2008.

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

Though an IRF must serve an inpatient population of whom at least 60 percent meet the compliance percentage criteria specified at § 412.29(b), the existing regulation allows for 40 percent of reasonable and

necessary admissions to an IRF to fall outside of the 13 qualifying medical conditions. Still, the “60 percent rule” is one of the primary ways we distinguish an IRF from an acute care hospital. As Medicare payments for IRF services are generally significantly higher than Medicare payments for similar services provided in acute care hospital settings, we believe that it is important to maintain and enforce the criteria for medical conditions that may be counted toward an IRF’s compliance calculation for the 60 percent rule to ensure that the higher Medicare payments are appropriately allocated to those providers that are providing IRF-level services.

B. Changes to the ICD–9–CM Codes That Are Used To Determine Presumptive Compliance

The presumptive compliance method is one of two ways that Medicare’s contractors may evaluate an IRF’s compliance with the 60 percent rule (the other method is called the medical review method). IRFs may only be evaluated using the presumptive compliance method if their Medicare Fee-for-Service and Medicare Advantage patient populations make up over half of their total patient population, so that the Medicare populations can be presumed to be representative of the IRF’s total patient population. If an IRF is eligible to have its compliance under the 60 percent rule measured using the presumptive compliance method, under the rule, it is given the option of whether the Medicare contractor will review all of the IRF’s discharges from that period, or all admissions from that period. All of its IRF–PAI assessments in the chosen category from the most recently completed 12 month compliance review period are then examined (with the use of a computer program) to determine whether they contain any of the ICD–9–CM diagnosis codes that are listed in the “ICD–9–CM Codes That Meet Presumptive Compliance Criteria” (which is also known as the presumptive methodology list). Each selected assessment is categorized as either meeting or not meeting the criteria for the medical conditions that may be counted towards the IRF’s 60 percent rule compliance calculation based on coded information about the primary reason the patient was admitted to the IRF (the impairment group) and the ICD–9–CM codes listed as either the etiologic diagnosis (the etiologic problem that led to the condition for which the patient is receiving rehabilitation) or one of the comorbidities listed on the assessment. An impairment group code is not an

ICD–9–CM code, but part of a separate unique set of codes specifically developed for the IRF PPS for assigning the primary reason for admission to an IRF. Those ICD–9–CM diagnosis codes that appear on the patient’s IRF–PAI assessment as either the etiologic diagnosis or comorbid conditions that are also listed in “ICD–9–CM Codes That Meet Presumptive Compliance Criteria” are deemed to demonstrate that the patient meets the criteria for the medical conditions that may be counted toward the IRF’s compliance percentage under the presumptive compliance method of calculating the compliance percentage. The current presumptive compliance list can be downloaded from the October 1, 2007 IRF Compliance Rule Specification Files on the Medicare IRF PPS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Criteria.html>. The ICD–9–CM Codes That Meet Presumptive Compliance Criteria that takes what we are finalizing in this rule into account can be downloaded from the Medicare IRF PPS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Data-Files.html>. We will build our ICD–10–CM version of the presumptive methodology list off of this document.

The underlying premise of the presumptive methodology list is that it represents particular diagnosis codes that, if applicable to a given patient, would more than likely mean that the patient required intensive rehabilitation services for treatment of one or more of the conditions specified at § 412.29(b)(2) or that they had a comorbidity that caused significant decline in functional ability such that, even in the absence of the admitting condition, the patient would require the intensive rehabilitation treatment that is unique to inpatient rehabilitation facilities and cannot be appropriately performed in another care setting.

Recently, we began a close examination of the list of ICD–9–CM codes that are currently deemed to meet the criteria for the medical conditions that may be counted toward an IRF’s compliance with the 60 percent rule under the presumptive compliance method to begin the process of converting this code list to ICD–10–CM. Upon this examination, we found that changes over time (including changes in the use of the individual codes, changes in clinical practice, changes in the frequency of various types of illness and disability, and changes to the application of 60 percent rule itself) supported our updating the ICD–9–CM

codes that are deemed appropriate to count toward a facility’s 60 percent rule compliance calculation. Such updates would ensure that the codes better reflect the regulations at § 412.29(b).

Our review included taking a fresh look at the regulations in § 412.29(b), which revealed that the following parts of the regulation were not being adequately addressed in the current application of the presumptive method of calculating compliance with the IRF 60 percent rule:

- The details of the requirements in paragraph § 412.29(b)(1), which specify that the IRF must serve “an inpatient population of whom at least 60 percent required intensive rehabilitation services for treatment of one or more of the conditions specified . . .”, and
- The details of the requirements regarding the specific conditions under which a patient’s comorbidity may be used to show that a patient meets the 60 percent rule criteria, specifically that, “The comorbidity has caused significant decline in functional ability in the individual that, even in the absence of the admitting condition, the individual would require the intensive rehabilitation treatment that is unique to inpatient rehabilitation facilities . . . and that cannot be appropriately performed in another care setting . . .”

These requirements must be met in conjunction with a patient having one of the 13 conditions listed in § 412.29(b)(2) for the case to meet the 60 percent rule compliance criteria. It is not enough for the patient to just have one of the 13 conditions. Mindful of these requirements, we took a fresh look at the ICD–9–CM codes on the presumptive methodology list.

Further, the regulations in § 412.29 also specify that the arthritis conditions only meet the 60 percent rule compliance criteria if certain severity and prior treatment criteria are met. It is impossible to discern from the ICD–9–CM codes alone whether or not the required severity and prior treatment criteria are met for those patients being treated for arthritis conditions. This type of information can only be assessed on medical review. Thus, we found that the presence of the ICD–9–CM code, by itself, cannot always allow us to presume that patients meet all of the requirements for being counted toward a facility’s meeting the 60 percent rule requirements. As such, we believe that certain ICD–9–CM codes currently on the presumptive methodology list do not necessarily demonstrate a patient’s meeting the medical condition (including severity and prior treatment) requirements for inclusion in a facility’s

60 percent compliance calculation under the presumptive compliance method, and, as such, should be removed from the presumptive methodology list to better reflect the regulations.

Therefore, we performed a clinical analysis of the ICD-9-CM code list to determine the clinical appropriateness of each individual ICD-9-CM code's inclusion on the list, and a statistical analysis of the ICD-9-CM diagnoses code list to enhance our understanding of how individual ICD-9-CM codes are being used by IRFs. Based on these analyses, we proposed specific revisions to the ICD-9-CM code list that are described below in sections VIII.B.1 through VIII.B.6 of this final rule.

We received 39 public comments on the proposed changes to the presumptive methodology list, which are summarized below.

Comment: Several commenters stated that section 5005 of the DRA of 2005, and section 115 of the MMSEA of 2007 "codified" the 13 qualifying medical conditions that were originally adopted in our May 7, 2004 final rule and that were still in the regulations in effect as of January 1, 2007, and froze the compliance threshold at 60 percent. These commenters also expressed the belief that CMS does not have the legal authority to make changes to the presumptive methodology list as proposed and must appeal to Congress to make such changes. One commenter stated that Congress "was clear in the statute" that for purposes of determining a facility's compliance under the presumptive compliance method, that CMS should utilize the May 7, 2004 final rule and the 13 qualifying medical conditions described in that final rule.

Response: While the commenters are correct that the DRA of 2005 and the MMSEA of 2007 both referenced the regulatory text that was adopted in the May 7, 2004 final rule, or the rule itself, we disagree with the assertion that the proposed changes to the "ICD-9-CM Codes That Meet Presumptive Compliance Criteria" list are in contravention of section 5005 of the DRA as amended by section 115 of MMSEA. Additionally, as we did not propose any changes to the compliance threshold (it remains at 60 percent), the comments regarding the 60 percent threshold are outside the scope of this rule.

Subsection (a) of section 5005 of the DRA stipulated that the Secretary should apply the applicable percent "in the classification criterion used under the IRF regulation (as defined in subsection (c)) to determine whether a

hospital or unit of a hospital is an inpatient rehabilitation facility under the Medicare program under title XVIII of the Social Security Act." Subsection (c) of section 5005 of the DRA then stated that "[f]or purposes of subsection (a), the term "IRF regulation" means the rule published in the **Federal Register** on May 7, 2004. . . ."

Even if we were to agree with commenters' assertions that this cross-reference froze the medical conditions that could be considered for the 75-percent compliance rule to the 13 medical conditions listed in the May 7, 2004 final rule, however, it would not follow that Congress froze the sub-regulatory means of verifying compliance with the severity and prior treatment requirements that were contained in that final rule. We disagree with any assertion that the proposed removal of certain ICD-9-CM codes from the sub-regulatory listing of codes that presumptively count toward the IRF compliance calculation under the presumptive compliance method would, in fact or effect, remove any of the 13 qualifying medical conditions under the classification criteria established in our May 7, 2004 final rule (69 FR 25752). Rather, it merely means that the medical review method would need to be used.

For example, the "arthritis" categories in the May 7, 2004 final rule only included those arthritis patients that meet the severity and pretreatment conditions specified in the regulations prior to the patient's admission to the IRF. See, the former 42 CFR § 412.23(b)(2)(iii)(L), which can be found at 69 FR 25772. As such, the severity and pretreatment requirements were part of the defined condition, and any sub-regulatory procedures to implement these regulatory conditions would have to take into account the need to ensure compliance with these severity and pretreatment requirements.

Furthermore, while the May 7, 2004 final rule noted that CMS would be issuing sub-regulatory guidance to its contractors that were to be tasked with the administration of the verification process for these requirements, the substance of such processes is not in the final rule. What are in the rule, however, are multiple statements that ICD-9-CM diagnosis codes alone would not, in the absence of additional clinical data, demonstrate compliance with the severity and pre-treatment requirements. Some other mechanism, such as medical review, was contemplated from the outset for these conditions (69 FR 25752, 25755 and 25761).

Thus, we have not proposed changes to the criteria established in the May 7,

2004 final rule. It remains as a list of 13 medical conditions, at times, paired with additional severity and prior treatment requirements. And, with the exception of discussion about imputing the Medicare portion of a facility's patient population compliance percentage to the entire population when the Medicare population represents the majority of that facility's patients, it did not discuss, let alone "codify" the methods we would use to verify IRFs' compliance percentages. Rather, we merely stated in that rule that we would issue instructions to the FIs that serve as the Medicare contractors and provide guidance to the clinical/medical FI personnel responsible for performing the compliance reviews to ensure that they use a method that consistently counts only cases with a diagnosis that both serves as the basis for intensive rehabilitation services and meets one of the 13 qualifying medical conditions; noted that we were still determining how best to provide guidance to the FIs on how to identify patients that fall into the 13 medical conditions; noted that we would not be providing ICD-9-CM codes in response to a commenter because diagnosis would be only one aspect of the FI's determination; and stated that FIs would also "review information to assess (1) the medical necessity of rehabilitation in an inpatient setting; (2) the severity of the specific condition(s); (3) the patient's function; and (4) the capacity of the patient to participate in intensive rehabilitation and benefit from it."

As such, we believe that the proposed removal of some of the ICD-9-CM codes in our sub-regulatory presumptive methodology list is consistent with the legislation and the May 7, 2004 regulation. We have not proposed the revision of the list of 13 medical conditions or the severity and prior treatment requirements that were paired with those conditions. For example, consistent with the severity and pretreatment requirements defined in the regulations (which are currently located at § 412.29(b)(2)(x) through § 412.29(b)(2)(xiii), we proposed the removal of the "arthritis" ICD-9-CM codes because those codes do not provide the pertinent information necessary to assess whether the applicable severity and prior treatment requirements for those conditions have been met. If and when the severity and pretreatment requirements are confirmed using the medical review method, however, patients with those arthritis conditions will be counted toward the IRF's compliance threshold.

In this manner, we administratively apply the regulation as codified and as outlined in the May 7, 2004 final rule. Ultimately, the code refinements to the ICD-9-CM Codes That Meet Presumptive Compliance Criteria list will ensure that the codes represent the types of medical conditions that we believe clearly, and without further evidence, can be found to indicate that the criteria for the medical conditions that may be counted toward the 60 percent rule compliance calculation have been met, and, therefore, that the presumptive compliance method can be used to include that individual in the IRF's compliance percentage.

Comment: Several commenters suggested that we delay these refinements to the presumptive compliance list until next year when the implementation of ICD-10-CM is planned. Commenters also stated that making these changes effective for discharges on or after October 1, 2013 will cause significant disruption for providers. One commenter asked for clarification regarding how the proposed changes would be implemented, specifically whether the prior list would be applied for the first part of a facility's fiscal year and the new list be applied for the second part. Several commenters asked that we provide a 6-month transition period to implement these changes.

Response: We considered the impact that our proposals would have on IRF providers if we were to make the changes effective for FY 2014 instead of in FY 2015 when we plan to move to ICD-10-CM. We believed that a gradual approach allowing IRF providers time to adjust their coding practices in response to the specific changes made to the presumptive methodology list before also moving to ICD-10-CM was the appropriate course of action. However, we recognize that IRF's may need more time to adjust to the changes to the presumptive methodology list. In recognition of these concerns, we will adopt these changes, but only apply the revised list to compliance review periods beginning on or after October 1, 2014. This will eliminate any problems associated with changing lists in the middle of a fiscal year.

Comment: One commenter supported our efforts to refine the list of ICD-9-CM codes in the presumptive methodology list. But, the commenter also stated that a better overall system would be one in which payment systems would be focused on patient-based criteria at the level of the episode of care or other broader site-neutral systems; however, within the current payment system, they supported CMS'

efforts to improve accuracy in determining the need for the intensive inpatient rehabilitation services that IRF's provide. Further, the commenter stated that by "requiring IRF's to use more detailed coding, we could potentially collect information on IRF patients that would differentiate them from patients with similar conditions who are treated in other settings (for example, skilled nursing facilities, home health agencies, or outpatient therapy providers)."

Response: We thank the commenter for their support of our efforts to refine the presumptive methodology list so that it reflects codes that truly indicate compliance with the 60 percent rule criteria for inclusion in the compliance calculation. Additionally, we thank the commenter for their suggestions as the agency continues research efforts into broader site-neutral payment systems.

Comment: Several commenters stated that they had concerns about the viability of the "60 percent rule." One commenter stated that the 60 percent rule should be repealed or modified in that the current classification criteria do not reflect the full range of factors that contribute to a patient's need for intensive inpatient rehabilitation. The commenter also stated that if we continue to use the 60 percent rule, then the list of 13 qualifying medical conditions under the 60 percent rule should be expanded to include patients with the following conditions: orthopedic/joint/limb replacement patients, post-transplant patients, patients with chronic pulmonary and cardiac conditions, and medically complex patients.

Response: We appreciate the commenters' suggestions, and will take these suggestions into account in future analyses. However, since we did not propose any modifications to the qualifying medical conditions for the 60 percent rule, these comments are beyond the scope of this final rule.

Comment: One commenter stated that we should clarify the alphabet designations for appendices associated with IRF-PAI completion because in our rules (this year and in past rulemakings) we have used the same alphabet character for more than one list.

Response: We agree that the alphabet designations used for appendices in the IRF PPS may lead to confusion because appendices for several tables are listed with the same alphabet character.

Appendix C: ICD-9-CM Codes That Meet Presumptive Compliance Criteria is used to determine an IRF's presumptive compliance with the 60 percent rule. However, there is also the

list of comorbidities (ICD-9-CM codes) that is used to determine placement in tiers, *Appendix C—List of Comorbidities*. Beginning with the publication of this rule, we will no longer use alphabet characters to identify these appendices. Beginning with this final rule and related sub-regulatory guidance, we will refer to the two lists by their titles, without the Appendix labels.

Comment: One commenter recommended that in lieu of removing the ICD-9-CM codes from the ICD-9-CM Codes That Meet Presumptive Compliance Criteria, CMS should establish modifiers that could be entered on the IRF-PAI to indicate that the patient meets the requirements for the medical conditions that may be included in the IRF's presumptive compliance method's compliance calculation. The commenter offered the following example that is used on claims: the KX modifier with respect to outpatient therapy services to indicate that a patient qualifies for an exception to the therapy caps on the claim. The commenter stated that using modifiers would ensure that "clinically appropriate" records would count under the presumptive compliance method compliance calculations without having to do medical review.

Response: We appreciate the commenter's suggestion. However, we note that the presumptive compliance method relies on information recorded on the IRF-PAI, rather than information from the IRF claim. The purpose of the IRF-PAI is to collect the clinical characteristics of the patient for use in care planning, payment, and quality reporting and therefore we believe it presents a more accurate and comprehensive record of the medical conditions of the patient, which is important when the record is then used to calculate the presumptive compliance percentage. Thus, we do not currently use and are not planning in the future to use, the IRF claim for the presumptive compliance method. Thus, a modifier applied to the coding on the claim, similar to the KX modifier for outpatient therapy services, is not useful in this context, and we do not currently have a similar mechanism for modifying codes on the IRF-PAI. However, we will take the commenter's suggestions into consideration. We believe that a delayed implementation of the changes to the presumptive compliance list of ICD-9-CM codes will allow us additional time to study ways to minimize the burden of the operational aspects of the changes to the presumptive compliance methodology.

Comment: Several commenters stated that we have incorrectly applied a medical necessity measurement (the coverage criteria) to the 60 percent rule. One commenter stated that we conflated individualized medical necessity review with the presumptive compliance method's review. Another commenter requested that we distinguish between the policies for IRF classification criteria and medical necessity coverage criteria in the final rule.

Response: We disagree with the commenters; we are not conflating the criteria for the medical conditions that may be counted under the presumptive method to determine compliance with the 60 percent rule with the coverage criteria. IRF coverage criteria are not used to determine IRF classification. As we stated in the August 7, 2009 final rule (74 FR 39762), we do not intend for any IRF to lose its classification status because an individual patient does not meet the coverage criteria. Failure to meet the coverage criteria in a particular case will only result in the denial of the IRF's claim for the services provided to that patient, not in a change in the classification of the facility.

Comment: Several commenters expressed concerns that, in the proposed rule, we changed our policy articulated in previous rules of distinguishing IRFs from other care settings by identifying certain conditions that "typically require" intensive inpatient rehabilitation. Specifically, commenters asserted that we have deviated from the policy standard of serving those with conditions that "typically required" an IRF-level of service. The commenters point to our statement in the proposed rule that "[i]t is not enough for the patient to just have one of the 13 conditions" to indicate that we proposed adding additional criteria to the medical conditions that may be counted under the presumptive compliance method. For example, the commenters believed that we had proposed adding a new criterion by indicating that beyond having one of the 13 medical conditions, we now proposed to require that patients need intensive inpatient rehabilitation services. According to the commenters, this is inconsistent with the history of the 60 percent rule and our own interpretations of the policy in previous rulemaking.

Response: We disagree with the commenters' assertions that we have introduced new criteria to the presumptive compliance method of determining whether an IRF has met the criteria for a given medical condition such that the individual with that

condition may be counted toward the IRF's 60 percent rule compliance percentage. Section 412.29 outlines the requirements for a facility to be classified for payment under the IRF PPS. Within this section, the regulations at § 412.29(b)(1) require the IRF to demonstrate that it "served an inpatient population of whom at least 60 percent required intensive rehabilitation services for treatment of one or more of the conditions specified at paragraph (b)(2)." . . . (emphasis added). As such, the "intensive rehabilitation service needs" criterion is part of the original criteria for the medical conditions that can be counted toward an IRF's 60 percent rule compliance rate. We also point out that this particular part of the regulation read the same in the May 7, 2004 final rule (then codified in § 412.23(b)(2)(i), now codified in § 412.29(b)(1)). Thus, our statement in the proposed rule was consistent with what has been our stated policy since the May 7, 2004 final rule.

We also disagree with any assertion that the proposed changes to the presumptive methodology list are an indication that we have departed from historical discussions outlined in the preamble of previous rules. As we stated previously, we are not revising the criteria that govern the 13 medical conditions that may be counted toward an IRF's 60 percent rule compliance percentage. In the preamble of the May 7, 2004 final rule, when discussing how CMS contractors would administratively identify patients with the 13 medical conditions, we specifically declined to provide a list of ICD-9-CM codes because ICD-9-CM codes alone are not always enough to ascertain whether someone falls into one of the 13 medical condition categories. As such, the regulations have never included such a list. Rather, we use a bifurcated sub-regulatory approach with a presumptive compliance method and a medical review compliance method. We continue to believe that the 13 medical conditions that are listed in regulation at § 412.29(b)(2) are conditions that "typically" require the level of intensive rehabilitation that provide the basis of need to differentiate the services offered in IRFs from those offered in other care settings.

Comment: One commenter requested that we make available the methodology that was used to assess the "clinical appropriateness" determinations for the ICD-9-CM codes that were proposed for removal.

Response: To analyze the "clinical appropriateness" of the ICD-9-CM codes on the list used to determine compliance under the presumptive

compliance method, we used the extensive clinical and coding expertise available within CMS's staff. Our clinical staff went through the current list code-by-code to determine whether, in their professional judgment, a particular ICD-9-CM code's use would indicate a patient's presumptive need for intensive inpatient rehabilitation for one of the 13 medical conditions listed in 412.29(b)(2), absent additional information about a particular patient's clinical condition and rehabilitation needs. The details of our clinical rationale for each of the proposed changes to the ICD-9-CM codes used to determine compliance percentages under the presumptive compliance method were presented in the FY 2014 IRF PPS proposed rule (78 FR 26880 at 26895 through 26906) and are further reflected in this final rule. We also used the public comments we received on the FY 2014 IRF PPS proposed rule (78 FR 26880) to further refine our clinical analysis, in that we used a lot of the input from commenters in forming our final decisions regarding which ICD-9-CM codes to retain on the list and which to proceed to remove from the list. As discussed in detail below, in some cases we agreed with the commenter's input and have added codes back to the list, as appropriate.

Comment: Several commenters requested that we make an IRF's presumptive testing data available to that IRF to allow the IRF to monitor its presumptive compliance with the 60 percent rule.

Response: Until now, we did not have the capability within our data system for securely communicating information about an IRF's individual IRF-PAI submissions back to that IRF. We are in the process of developing such a system, and will consider the feasibility of incorporating a report of an IRF's compliance percentage into this new system.

1. Non-Specific Diagnosis Codes

We believe that highly descriptive coding provides the best and clearest way to document the appropriateness of a given patient's admission, and would improve our ability to use the presumptive compliance method of calculating a facility's 60 percent rule compliance percentage. Therefore, whenever possible, we believe that the most specific code that describes a medical disease, condition, or injury should be used to document diagnoses on the IRF-PAI. Generally, "unspecified" codes are used when there is a lack of information about location or severity of medical conditions in the medical record.

However, site and/or severity of condition is often an important determinant in assessing whether a patient's principal or secondary diagnosis falls into the 13 qualifying medical conditions that may be counted toward the facility's 60 percent rule compliance percentage under the presumptive compliance method. For this reason, we believe that specific diagnosis codes that narrowly identify anatomical sites where disease, injury, or condition exist should be used when coding patients' conditions on the IRF-PAI whenever such codes are available. Furthermore, on the same note, we believe that one should also include on the IRF-PAI the more descriptive ICD-9-CM code that indicates the degree of injury in instances of burns. In accordance with these principles, we proposed to remove non-specific codes from the list, ICD-9-CM Codes That Meet Presumptive Compliance Criteria, in instances in which more specific codes are available as we believe imprecise codes would inappropriately categorize an overly broad segment of the patient population as having the conditions required for inclusion in a facility's presumptive compliance calculation, which would result in an inflated compliance percentage. If the IRF does not have enough information about the patient's condition to code the more specific codes on the IRF-PAI, we would expect the IRF to seek out additional information from the patient's acute care hospital medical record to determine the appropriate, more specific code to use. The list of ICD-9-CM codes that we proposed removing can be found in the May 8, 2013 proposed rule at 78 FR 26880, 26901 through 26906.

We received 18 comments on the proposed changes to the non-specific diagnosis codes listed in ICD-9-CM Codes That Meet Presumptive Compliance Criteria, which are summarized below.

Comment: Several commenters noted that IRFs are post-acute settings and that etiological documentation is based on the data received from the acute care hospital. They argued that, in some cases, the specificity demanded in coding as described in the proposed rule cannot be achieved because the information is not in the records that IRFs receive from the acute care setting. For example, for ICD-9-CM codes 433.91—Occlusion and stenosis of unspecified pre-cerebral artery with cerebral infarction—and 434.91—Cerebral artery occlusion, unspecified with cerebral infarction—, several commenters stated that a large proportion of ischemic strokes may not

be able to be identified as thrombotic or embolic. Several commenters stated that the ICD-9-CM code 434.91—Cerebral artery occlusion, unspecified with cerebral infarction—should not be removed from the presumptive methodology list because in order to be more specific the physiatrist would need to note whether the stroke was embolic or thrombotic in nature. The commenters stated that this is often unknown, even after radiological results.

Response: We recognize that the IRF builds its understanding of its patients that are admitted to the IRF from the acute care hospital in part from the acute care medical records, and that sometimes the information needed to code a more specific diagnosis is not available in those records. In the case of certain ICD-9-CM codes that we had proposed to remove from the presumptive compliance list, we agree with the commenters and have determined that the information necessary to appropriately code certain conditions may not always be available. To avoid diagnostic misclassification, we are revising our proposals in Table 7 of the proposed rule and will retain codes 433.91 and 434.91 on the list of codes that meet the presumptive compliance criteria. We may revisit this decision in the future, if information to code the more specific diagnosis codes becomes more readily available.

Though we agree with commenters that some information is either not available or may not always be found in the documentation sent by the acute care hospital and that this impacts the coding of some diagnoses, we do not agree that this is the case for all the diagnosis codes proposed for removal in Table 7 of the proposed rule or that the IRF would not be able to obtain the necessary information through other means in many instances. IRFs are required under the IRF coverage requirements to conduct thorough preadmission screenings on all prospective IRF patients prior to each IRF admission. During the preadmission screenings, a complete medical chart review is required, unless the patient is being assessed in person by the IRF personnel conducting the preadmission screening. Even if the patient is being assessed in person, a medical chart review is typically needed to gather all of the pertinent information to complete a thorough preadmission screening. Generally, diagnostic reports, radiological reports, and consultation notes, among other informational documentation are available in the acute care medical record to assist IRF staff in building a more complete clinical

picture so that diagnostic coding, whenever possible, can be more specific. Even if such information is not available in the acute care medical record, however, we believe that the IRF should make every effort to obtain the necessary information to code more specifically.

Comment: We received several comments on various non-specific diagnosis codes that the commenters stated should not be removed from the list. The commenters provided a variety of rationales for the continued use of these codes to meet the presumptive compliance criteria. For example, several commenters stated that the ICD-9-CM codes related to hip fracture should not be excluded from the list. The commenters stated that the specific information required to provide where the fracture occurred on the neck of the femur is often not available to IRF staff that do not have access to x-ray reports and that such specificity would not impact the type of treatment in the IRF. Several other commenters stated that we should reconsider the proposed removal of some non-specific traumatic brain injury codes. The commenters stated that the removal of these codes is "administratively unrealistic." The commenters also stated that for incidents of loss of consciousness of short duration this information, usually documented by on-site emergency technicians (when known), is no longer in the records by the time the patient is admitted to the IRF. One commenter argued that in cases of unobserved traumatic brain injury the duration of a patient's loss of consciousness may never be specifically determined. This commenter further stated that despite the absence of this information, the patient may still be clinically appropriate for intensive inpatient rehabilitation services.

Several commenters also argued that the identity of virus or bacteria associated with diagnoses such as ICD-9-CM codes 049.9—Unspecified non-arthropod-borne viral diseases of central nervous system—, 320.9—Meningitis due to unspecified bacterium—, 322.9—Meningitis, unspecified—, 323.9—Unspecified causes of encephalitis, myelitis, and encephalomyelitis cannot frequently be found in the medical records from the transferring hospital or in some cases may never be known. As such, the commenters suggest that these codes not be removed from the presumptive methodology list.

Several commenters stated that ICD-9-CM codes 343.9—Infantile cerebral palsy, unspecified should not be removed from the presumptive methodology list because many times

these patients are seen in IRFs as adults, when the patient's current clinical presentation may be different from their original presentation as infants. Moreover, the commenters argue, the adults may have no available medical records that state the appropriate cerebral palsy type. Similarly, these commenters argue that ICD-9-CM code 344.00—Quadriplegia, unspecified should not be removed from the presumptive methodology list because of the potential for a change from the original presentation that was the basis of appropriate classification of the level of completeness of the injury.

Response: Upon further review and after thoughtful consideration of the comments we received, we have determined that several codes that we proposed to remove from the ICD-9-CM Codes That Meet Presumptive Compliance Criteria list should be retained. Thus, in this final rule we will not remove these codes from the presumptive methodology list. The ICD-9-CM codes that we proposed for removal from the ICD-9-CM Codes That Meet Presumptive Compliance Criteria list, but we have determined should be retained, are listed in Table 8. We also note here that we inadvertently included 4 codes in Table 7 of the proposed rule that were never on the ICD-9-CM Codes That Meet Presumptive Compliance Criteria list. The codes are as follows: 804.00—Closed fractures involving skull or face with other bones, without mention of intracranial injury, unspecified state of

consciousness—, 804.09—Closed fractures involving skull of face with other bones, without mention of intracranial injury, with concussion, unspecified—, 851.90—Other and unspecified cerebral laceration and contusion, with open intracranial wound, unspecified state of consciousness—, 851.99—Other and unspecified cerebral laceration and contusion, with open intracranial wound, with concussion, unspecified.

Comment: Several commenters expressed concerns about our proposal to remove ICD-9-CM code 356.9—Unspecified hereditary and idiopathic peripheral neuropathy (IPN) from the ICD-9-CM Codes That Meet Presumptive Compliance Criteria list because “IPN is one of the most common chronic neurologic disorders in America.” One commenter further stated that the precise etiology of a neuropathy has little effect on a patient's rehabilitation, and that there are a limited number of codes that can be used to specify the type of neuropathy.

Response: We believe that the fact that ICD-9-CM code 356.9—Unspecified hereditary and idiopathic peripheral neuropathy (IPN)—is such a commonly used code for multiple types of chronic neurological disorders in the U.S. means that it is too broad a diagnosis to enable us to determine whether a patient coded with this code meets the criteria for the medical conditions that may be counted toward an IRF's 60 percent rule compliance

percentage or not. We believe that some patients coded with this code could meet the requirements in 412.29(b)(1), but others would not. That is, we believe that it is impossible to tell from the possible application of this code to such a broad and diverse population of patients whether patients coded with this diagnosis code require intensive rehabilitation services for treatment of one or more of the conditions specified at 42 CFR 412.29(b)(2). Our analysis shows that the percent of patients in IRFs that are coded with this diagnosis code has increased substantially over time (from 2.7 percent of all IRF patients in FY 2004 to 4.5 percent in FY 2012), with more dramatic increases occurring within specific IRF providers. This finding may be the result of an increase in the patient population for which this code applies, an increase in the percent of patients with these conditions being admitted to the IRF, or upcoding on the part of IRFs. Regardless, we believe that this code does not provide enough information for us to determine whether a patient coded with this diagnosis code would meet the requirements at 42 CFR 412.29(b). Thus, we believe that the most appropriate course of action at this time is to remove this code from the presumptive methodology list. However, we note that patients that are coded with this diagnosis code may, where appropriate upon medical review, be found to meet the criteria for the medical conditions that may be counted toward a facility's 60 percent rule compliance percentage.

TABLE 8—ICD-9-CM CODES RETAINED IN “ICD-9-CM CODES THAT MEET PRESUMPTIVE COMPLIANCE CRITERIA” **

| ICD-9-CM Code | Diagnosis |
|---------------|---|
| 049.9 | Unspecified non-arthropod-borne viral diseases of central nervous system. |
| 320.9 | Meningitis due to unspecified bacterium. |
| 322.9 | Meningitis, unspecified. |
| 323.9 | Unspecified causes of encephalitis, myelitis, and encephalomyelitis. |
| 343.9 | Infantile cerebral palsy, unspecified. |
| 344.00 | Quadriplegia, unspecified. |
| 433.91 | Occlusion and stenosis of unspecified precerebral artery with cerebral infarction. |
| 434.91 | Cerebral artery occlusion, unspecified with cerebral infarction. |
| 800.00 | Closed fracture of vault of skull without mention of intracranial injury, unspecified state of consciousness. |
| 800.10 | Closed fracture of vault of skull with cerebral laceration and contusion, unspecified state of consciousness. |
| 800.20 | Closed fracture of vault of skull with subarachnoid, subdural, and extradural hemorrhage, unspecified state of consciousness. |
| 800.30 | Closed fracture of vault of skull with other and unspecified intracranial hemorrhage, unspecified state of consciousness. |
| 800.40 | Closed fracture of vault of skull with intracranial injury of other and unspecified nature, unspecified state of consciousness. |
| 800.50 | Open fracture of vault of skull without mention of intracranial injury, unspecified state of consciousness. |
| 800.60 | Open fracture of vault of skull with cerebral laceration and contusion, unspecified state of consciousness. |
| 800.70 | Open fracture of vault of skull with subarachnoid, subdural, and extradural hemorrhage, unspecified state of consciousness. |
| 800.80 | Open fracture of vault of skull with other and unspecified intracranial hemorrhage, unspecified state of consciousness. |
| 800.90 | Open fracture of vault of skull with intracranial injury of other and unspecified nature, unspecified state of consciousness. |
| 801.00 | Closed fracture of base of skull without mention of intra cranial injury, unspecified state of consciousness. |
| 801.10 | Closed fracture of base of skull with cerebral laceration and contusion, unspecified state of consciousness. |
| 801.20 | Closed fracture of base of skull with subarachnoid, subdural, and extradural hemorrhage, unspecified state of consciousness. |
| 801.30 | Closed fracture of base of skull with other and unspecified intracranial hemorrhage, unspecified state of consciousness. |
| 801.40 | Closed fracture of base of skull with intracranial injury of other and unspecified nature, unspecified state of consciousness. |
| 801.50 | Open fracture of base of skull without mention of intracranial injury, unspecified state of consciousness. |
| 801.60 | Open fracture of base of skull with cerebral laceration and contusion, unspecified state of consciousness. |

TABLE 8—ICD-9-CM CODES RETAINED IN “ICD-9-CM CODES THAT MEET PRESUMPTIVE COMPLIANCE CRITERIA” **—
Continued

| ICD-9-CM Code | Diagnosis |
|---------------|--|
| 801.70 | Open fracture of base of skull with subarachnoid, subdural, and extradural hemorrhage, unspecified state of consciousness. |
| 801.80 | Open fracture of base of skull with other and unspecified intracranial hemorrhage, unspecified state of consciousness. |
| 801.90 | Open fracture of base of skull with intracranial injury of other and unspecified nature, unspecified state of consciousness. |
| 803.00 | Other closed skull fracture without mention of intracranial injury, unspecified state of consciousness. |
| 803.10 | Other closed skull fracture with cerebral laceration and contusion, unspecified state of consciousness. |
| 803.20 | Other closed skull fracture with subarachnoid, subdural, and extradural hemorrhage, unspecified state of consciousness. |
| 803.30 | Other closed skull fracture with other and unspecified intracranial hemorrhage, unspecified state of unconsciousness. |
| 803.40 | Other closed skull fracture with intracranial injury of other and unspecified nature, unspecified state of consciousness. |
| 803.50 | Other open skull fracture without mention of injury, unspecified state of consciousness. |
| 803.60 | Other open skull fracture with cerebral laceration and contusion, unspecified state of consciousness. |
| 803.70 | Other open skull fracture with subarachnoid, subdural, and extradural hemorrhage, unspecified state of consciousness. |
| 803.80 | Other open skull fracture with other and unspecified intracranial hemorrhage, unspecified state of consciousness. |
| 803.90 | Other open skull fracture with intracranial injury of other and unspecified nature, unspecified state of consciousness. |
| 804.10 | Closed fractures involving skull or face with other bones, with cerebral laceration and contusion, unspecified state of consciousness. |
| 804.20 | Closed fractures involving skull or face with other bones with subarachnoid, subdural, and extradural hemorrhage, unspecified state of consciousness. |
| 804.30 | Closed fractures involving skull or face with other bones, with other and unspecified intracranial hemorrhage, unspecified state of consciousness. |
| 804.40 | Closed fractures involving skull or face with other bones, with intracranial injury of other and unspecified nature, unspecified state of consciousness. |
| 804.60 | Open fractures involving skull or face with other bones, with cerebral laceration and contusion, unspecified state of consciousness. |
| 804.70 | Open fractures involving skull or face with other bones with subarachnoid, subdural, and extradural hemorrhage, unspecified state of consciousness. |
| 804.80 | Open fractures involving skull or face with other bones, with other and unspecified intracranial hemorrhage, unspecified state of consciousness. |
| 804.90 | Open fractures involving skull or face with other bones, with intracranial injury of other and unspecified nature, unspecified state of consciousness. |
| 820.00 | Closed fracture of intracapsular section of neck of femur, unspecified. |
| 820.10 | Open fracture of intracapsular section of neck of femur, unspecified. |
| 820.30 | Open fracture of trochanteric section of neck of femur, unspecified. |
| 851.00 | Cortex (cerebral) contusion without mention of open intracranial wound, unspecified state of consciousness. |
| 851.10 | Cortex (cerebral) contusion with open intracranial wound, unspecified state of consciousness. |
| 851.20 | Cortex (cerebral) laceration without mention of open intracranial wound, unspecified state of consciousness. |
| 851.30 | Cortex (cerebral) laceration with open intracranial wound, unspecified state of consciousness. |
| 851.40 | Cerebellar or brain stem contusion without mention of open intracranial wound, unspecified state of consciousness. |
| 851.50 | Cerebellar or brain stem contusion with open intracranial wound, unspecified state of consciousness. |
| 851.60 | Cerebellar or brain stem laceration without mention of open intracranial wound, unspecified state of consciousness. |
| 851.70 | Cerebellar or brain stem laceration with open intracranial wound, unspecified state of consciousness. |
| 851.80 | Other and unspecified cerebral laceration and contusion, without mention of open intracranial wound, unspecified state of consciousness. |
| 852.00 | Subarachnoid hemorrhage following injury without mention of open intracranial wound, unspecified state of consciousness. |
| 852.10 | Subarachnoid hemorrhage following injury with open intracranial wound, unspecified state of consciousness. |
| 852.20 | Subdural hemorrhage following injury without mention of open intracranial wound, unspecified state of consciousness. |
| 852.30 | Subdural hemorrhage following injury with open intracranial wound, unspecified state of consciousness. |
| 852.40 | Extradural hemorrhage following injury without mention of open intracranial wound, unspecified state of consciousness. |
| 852.50 | Extradural hemorrhage following injury with open intracranial wound, unspecified state of consciousness. |
| 853.00 | Other and unspecified intracranial hemorrhage following injury without mention of open intracranial wound, unspecified state of consciousness. |
| 853.10 | Other and unspecified intracranial hemorrhage following injury with open intracranial wound, unspecified state of consciousness. |
| 854.00 | Intracranial injury of other and unspecified nature without mention of open intracranial wound, unspecified state of consciousness. |
| 854.10 | Intracranial injury of other and unspecified nature with open intracranial wound, unspecified state of consciousness. |

** This table includes ICD-9-CM codes that were proposed (Table 7) in the May 8, 2013 proposed rule for removal from “ICD-9-CM Codes That Meet Presumptive Compliance Criteria,” but we have determined should be retained.

2. Arthritis Codes

Our analysis of the list of ICD-9-CM codes that are currently included in the presumptive methodology list revealed utilization patterns that indicated that these codes were used far more frequently than we had anticipated. We also realized that such codes did not

provide any information as to whether the patients met the severity and prior treatment requirement portions of the criteria for the medical conditions that may be counted toward an IRF's compliance percentage under the presumptive compliance method. We did not adopt any and all arthritis conditions in the May 7, 2004 final rule

(69 FR 25752). Rather, we only provided for those patients with certain kinds of arthritic conditions that met defined severity and prior treatment requirements. We anticipated that less severe arthritic conditions could be satisfactorily managed outside of IRFs since these cases would not require the intensive therapy provided in the

inpatient rehabilitation setting. As we realized on reflection that there is no way to tell base on an arthritis ICD-9-CM code alone whether an individual met the severity and prior treatment requirements outlined in regulation, we realized that factors beyond the ICD-9-CM code would need to be reviewed to establish whether these IRF patients should be included in the IRF's compliance percentage.

Specifically, the regulations under § 412.29(b)(2)(x) through § 412.29(b)(2)(xii), describe the following three (3) "arthritis" medical conditions that, if present, and all of the described circumstances are met, would make a patient eligible for inclusion in the presumptive compliance calculation of the IRF's compliance percentage. The 3 medical conditions are as follows:

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

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

- Severe or advanced osteoarthritis (osteoarthritis or degenerative joint disease) involving two or more major weight bearing joints (elbow, shoulders, hips, or knees, but not counting a joint with a prosthesis) with joint deformity and substantial loss of range of motion, atrophy of muscles surrounding the joint, significant functional impairment of ambulation and other activities of daily living that have not improved after the patient has participated in an appropriate, aggressive, and sustained course of outpatient therapy services or services in other less intensive rehabilitation settings immediately preceding the inpatient rehabilitation

admission but have the potential to improve with more intensive rehabilitation. (A joint replaced by a prosthesis is no longer is considered to have osteoarthritis, or other arthritis, even though this condition was the reason for the joint replacement.)

As stated above, the inclusion of patients with these medical conditions in the presumptive compliance calculation of the IRF's compliance percentage is conditioned on those patients meeting the described severity and prior treatment requirements. However, the ICD-9-CM diagnosis codes that reflect these arthritis and arthropathy conditions do not provide any information about whether these additional elements of the regulatory criteria were met. We therefore believe that additional information beyond the presence of the code is necessary to determine if the medical record would support inclusion of individuals with the arthritis and arthropathy conditions outlined in our regulations under § 412.29(b)(2)(x) through § 412.29(b)(2)(xii) in the presumptive compliance calculation of the facility's compliance percentage. Thus, we proposed to remove the ICD-9-CM diagnosis codes associated with the medical conditions outlined in our regulations under § 412.29(b)(2)(x) through § 412.29(b)(2)(xii) from the presumptive methodology list.

We expect that the MACs will be able, upon medical review, to include those patients in a facility's 60 percent rule compliance after it has confirmed the severity and prior treatment portions of the criteria. As such, IRFs would continue to be able to have these individuals included in the medical review calculation of their compliance percentages. In Table 9, we list the ICD-9-CM codes associated with the medical conditions listed under § 412.29(b)(2)(x) through § 412.29(b)(2)(xii) that we will remove from the list, ICD-9-CM Codes That Meet Presumptive Compliance Criteria.

We received 11 comments on the proposed changes to arthritis diagnosis codes listed in ICD-9-CM Codes That Meet Presumptive Compliance Criteria, which are summarized below.

Comment: One commenter suggested that the proposed changes to the presumptive methodology list and the removal of the arthritis codes will increase the use of the medical review method, which is more burdensome for both CMS and for IRFs. Several commenters suggested that the facility should not have to undergo a "full medical review" if it failed to meet the required compliance percentage using the presumptive compliance method.

Instead, they suggested use of a "limited medical review" in which only arthritis and systemic vasculidities cases would be reviewed. The commenters further stated that, should a sufficient number of cases from the "limited review" be determined to meet criteria, these "passing" records would be added to the "numerator" of the presumptive calculation result to arrive at a compliance percentage equal at least 60 percent. In this manner the facility would be deemed compliant without needing a "full medical review." However, if the IRF failed to meet criteria with this "limited review," the MAC could then perform a "full medical review."

Response: We acknowledge that because of the removal of the arthritis codes from the list of codes that are used to determine presumptive compliance under the "60 percent" rule, some facilities may not be able to reach the minimum compliance percentage using presumptive compliance method. In the May 8, 2013 proposed rule, we suggested that upon medical review (in accordance with chapter 3, section 140.1.4 of the Medicare Claims Processing Manual (Pub. 100-04)), after which the MAC will have been able to determine that severity and pretreatment requirements have been met, these patients would be included in the calculation of a facility's 60 percent rule compliance percentage. Assuming providers make no other changes, we estimate that the removal of the arthritis and arthropathy codes will result in approximately 40 facilities failing to meet the 60 percent threshold using the presumptive compliance method, and would have to instead be evaluated under the medical review method. We assume that all of these facilities would obtain a satisfactory compliance percentage after medical review, as we assume that the patients that will be coded with the to-be removed arthritis and arthropathy codes will meet the severity and prior treatment requirements. Thus, we believe that few, if any facilities will ultimately lose their IRF classification by virtue of these changes.

We appreciate the commenter's suggestions regarding the use of a modified medical review limited to only arthritis and systemic vasculidities cases to determine if patients have met severity and pretreatment requirements, in lieu of full medical review carried out in accordance with chapter 3, section 140.1.3(D), of the Medicare Claims Processing Manual (Pub. 100-04). We will use the time afforded by our one-year delay (that is, the application of the changes to the list will not apply to

compliance review periods beginning before October 1, 2014) to consider the feasibility of minimizing any burdens created by the operational aspects of this policy.

Comment: One commenter expressed concern that in response to our proposal to remove arthritis codes from the ICD-9-CM Codes That Meet Presumptive Compliance Criteria list and no longer count them as part of the presumptive methodology, IRFs will seek to avoid “unnecessary” medical review by modifying their admission criteria so as to limit the admission of patients with arthritis conditions. The commenter also stated that our proposed removal of the arthritis codes from the list of presumptive ICD-9-CM codes that meet compliance criteria “was as if” we removed arthritis and arthropathy conditions from the 13 qualifying medical conditions outlined in regulation.

Response: Although we agree that it is plausible that some IRFs might seek to avoid the possibility of medical review by limiting admission of patients with arthritis conditions, this is not our intent. Our intent behind this policy is to ensure that we have enough information to ensure patients with arthritis conditions who are counted as meeting the compliance criteria in 412.29(b) are appropriately meeting the severity and prior treatment requirements, as per the regulation. We disagree that the proposed changes to the presumptive methodology list equates with the removal of arthritis and arthropathy conditions from the 13 qualifying medical conditions outlined in regulation. As discussed in the proposed rule’s preamble and in prior discussion in this preamble, when we adopted the arthritis and arthropathy conditions in the May 7, 2004 final rule, we limited the conditions to those that met defined severity and prior treatment requirements, and that were sufficiently severe as to require intensive inpatient rehabilitation services. As discussed above, ICD-9-CM diagnosis codes alone do not provide sufficient information to establish whether these pretreatment and severity requirements have been met. More detailed information is necessary to determine if the patient meets the pretreatment and severity requirements. Verification using the medical review compliance method will allow an IRF to have these patients included in their compliance percentage. Thus, arthritis conditions will continue to be included in the calculation of compliance percentages in accordance with the 13 qualifying medical conditions in the regulations.

3. Some Congenital Anomaly Diagnosis Codes

Though congenital deformity is one of the 13 medical conditions that may, subject to the limitations spelled out in the regulations, qualify for inclusion in the calculation of an IRF’s compliance percentage under the 60 percent rule, certain congenital anomalies represent such serious conditions that a patient with one of these conditions would generally not be expected to be able to meaningfully participate in an intensive rehabilitation therapy program. For example, Craniorachischisis (ICD-9-CM code 740.1) is a congenital malformation where the neural tube from the midbrain down to the upper sacral region of the spinal cord remains open. The neural tube is the embryo’s precursor to the central nervous system, which comprises the brain and spinal cord. Similarly, Iniencephaly (ICD-9-CD code 740.2) is a congenital malformation in which parts of the brain do not form and the patient does not have a neck. Because beneficiaries with these diagnoses likely would generally not be expected to be able to actively participate in an intensive rehabilitation program, we do not believe that we can include such cases in an IRF’s presumptive compliance percentage. That said, as we noted in the proposed rule, if a patient with one of these conditions were able to participate in the intensive rehabilitation services provided in an IRF, then the MAC would be able to count that case toward an IRF’s 60 percent rule compliance percentage upon medical review. Thus, we proposed the removal of these congenital deformity codes, and others that present similar concerns that were discussed in the proposed rule from the presumptive compliance list.

We received 4 comments on the proposed changes to the congenital anomaly diagnosis codes, which are summarized below.

Comment: The commenters supported our proposal to remove the specified congenital anomaly conditions from the presumptive methodology list. These commenters noted that these conditions are rare and agreed that patients with these conditions would be unlikely to require or to meaningfully participate in intensive inpatient rehabilitation services.

Response: We thank the commenters for supporting our efforts to refine the presumptive methodology list so that the list truly represents diagnoses that would be expected to indicate that an individual meets the medical condition criteria, and that they should be

included in an IRF’s compliance percentage under the presumptive compliance method of calculating a compliance percentage. All of the congenital anomaly diagnosis codes that we are removing from ICD-9-CM Codes That Meet Presumptive Compliance Criteria list are listed in Table 9.

4. Unilateral Upper Extremity Amputations Diagnosis Codes

Though amputation is generally one of the 13 medical conditions that qualify for inclusion in the an IRF’s compliance calculation for the 60 percent rule, we proposed the removal of certain ICD-9-CM codes for unilateral upper extremity amputations from the presumptive methodology list, ICD-9-CM Codes That Meet Presumptive Compliance Criteria, because we believe that it is impossible to determine, from the presence of such ICD-9-CM codes alone, whether a patient with such a unilateral upper extremity amputation has a condition for which he or she would need intensive rehabilitation services for treatment of one or more of the conditions specified in § 412.29(b)(2). We expect that some patients with these upper extremity amputations will not require close medical supervision by a physician or weekly interdisciplinary team conferences to achieve their goals, while others may require these services. But we generally believe that rehabilitation associated with unilateral upper extremity amputations would not need to be accompanied by the close medical management provided in IRFs, as long as the patient does not have any additional comorbidities that have caused significant decline in his or her functional ability that, in the absence of the unilateral upper extremity amputation, would necessitate treatment in an IRF. That is to say, a patient’s need for intensive rehabilitation services provided in an IRF depends on other conditions which cannot be solely identified through the presence of a unilateral upper extremity amputation ICD-9-CM code. If the patient has comorbidities that would necessitate treatment in an IRF, then those comorbidities would qualify the patient for inclusion under the presumptive compliance method of calculating compliance with the 60 percent rule if one or more of the comorbidities are on the presumptive methodology list. If the codes for such a patient’s comorbidities do not appear in the presumptive compliance list, the patient can still be considered for inclusion in the IRF’s compliance percentage following medical review and confirmation that they meet the

criteria for one or more of the medical conditions in the regulations. Thus, we proposed to remove the unilateral upper extremity amputation from the presumptive methodology list.

We received 5 comments on the proposed changes to unilateral upper extremity amputation diagnosis codes listed in ICD-9-CM Codes That Meet Presumptive Compliance Criteria, which are summarized below.

Comment: Several commenters supported our proposal to remove unilateral upper extremity amputation codes from ICD-9-CM Codes That Meet Presumptive Compliance. The commenters agreed with our assessment that a patient's need for intensive inpatient rehabilitative services for the treatment of one or more of these conditions would depend on the presence of additional comorbidities that caused significant decline in his or her functional ability to the extent that the patient would necessitate treatment in an IRF. However, one commenter disagreed with the proposal because an inpatient setting offering an intensive rehabilitation therapy program would be appropriate for the acute phase of wound healing, edema control, and desensitization and pain control that these patients may require.

Response: We agree that unilateral upper extremity amputation patients have ongoing therapy needs and may require medical aftercare once discharged from an acute hospital stay. However, as long as the patient does not have any other comorbidities that have caused significant decline in his or her functional ability that, in the absence of the unilateral upper extremity amputation, would require treatment in an IRF, we do not believe that the patient could be presumed to meet the regulatory requirements for inclusion in an IRF's compliance percentage.

5. Miscellaneous Diagnosis Codes That Do Not Require Intensive Rehabilitation Services for Treatment

We have identified additional ICD-9-CM diagnosis codes in the presumptive methodology list, ICD-9-CM Codes That Meet Presumptive Compliance Criteria, which do not, in the absence of additional confirmatory information, indicate a patient's need for intensive rehabilitation services or that they have met any severity or prerequisite treatment requirements for the medical conditions that may be counted toward an IRF's compliance percentage. We therefore proposed removal of the following ICD-9-CM codes from the list, ICD-9-CM Codes That Meet Presumptive Compliance Criteria.

- *Tuberculous (abscess, meningitis, and encephalitis or myelitis) and Tuberculoma (of the meninges, brain, or spinal cord) where a bacterial or histological examination is unspecified or was not done (see Table 7 in the proposed rule for a list of the specific codes)*—Appropriate patient care dictates that the IRF physician must attempt to ascertain the means by which the organism, whether it be bacteriologic or histologic, was tested. We expect the IRF physician to make a good faith effort to determine the type of diagnostic test which identified the tuberculous organism. In the circumstances where this is impossible (that is, documentation no longer exists), appropriate codes remain on the presumptive methodology list. However, we expect the IRF physician to make a good faith effort to determine the type of diagnostic test which identified the tuberculous organism. We therefore proposed to remove these unspecified codes from the list, ICD-9-CM Codes That Meet Presumptive Compliance Criteria.

- *Postherpetic polyneuropathy (053.13)*—This is a condition characterized by severe pain, which typically requires pain medication or other pain control therapies but does not typically require the intensive inpatient rehabilitation services of an IRF. In fact, the prescriptive hands-on therapeutic interventions provided in an IRF could exacerbate the patient's pain. For these reasons, we proposed the removal of this code from ICD-9-CM Codes That Meet Presumptive Compliance Criteria.

- *Louping ill (063.1)*—This ICD-9-CM code refers to an acute viral disease primarily of sheep that is not endemic to the United States. Louping ill disease has been recognized in Scotland for centuries, but only 39 cases of human infection have been described and none of these cases have been observed in the United States. Louping ill is a disease which has many manifestations, not all requiring inpatient rehabilitation hospital services. We believe that the ICD-9-CM code for this diagnosis does not provide the information necessary for us to determine presumptively whether the patient has met the criteria for the medical conditions that may be counted toward an IRF's compliance percentage. However, as with all of the codes that we proposed removing from the list, ICD-9-CM Codes That Meet Presumptive Compliance Criteria, if someone with this diagnosis were to be admitted to an IRF, medical review could be used to confirm whether the regulatory criteria have been met.

- *Brain death (348.82)*—We believe that it is unlikely that a patient with this condition would require the intensive inpatient rehabilitation services provided in an IRF. For this reason, we proposed the removal of this code from ICD-9-CM Codes That Meet Presumptive Compliance Criteria.

- *Myasthenia gravis without (acute) exacerbation (358.00)*—Although we believe that a patient experiencing an acute attack of Myasthenia Gravis could potentially require the intensive inpatient rehabilitative services of an IRF (these individuals are coded with ICD-9 code 358.01 "Myasthenia gravis with (acute) exacerbation"), we proposed the removal of non-acute myasthenia gravis from the list, ICD-9-CM Codes That Meet Presumptive Compliance Criteria because such patients would not be experiencing an acute exacerbation of the condition and most likely would not require the intensive inpatient rehabilitation services provided in an IRF.

- *Other specified myotonic disorder (359.29)*—codes patients with Myotonia fluctuans, myotonia permanens, and paramyotonia congenital which are conditions that are exacerbated by exercise. The intensive inpatient rehabilitation services of an IRF would be expected to exacerbate these conditions, so such care would likely be contraindicated. Therefore, we proposed the removal of this code from the list, ICD-9-CM Codes That Meet Presumptive Compliance Criteria.

- *Periodic paralysis (359.3)*—The treatment for periodic paralysis involves pharmaceutical interventions and lifestyle changes that control exercise and activity, but patients with this condition do not generally require the intensive inpatient rehabilitation services of an IRF. In fact, it is unclear how the intensive inpatient rehabilitation services provided in an IRF would effectively treat this condition. Thus, we proposed the removal of this code from the list, ICD-9-CM Codes That Meet Presumptive Compliance Criteria.

- *Brachial plexus lesions (353.0)*—Care and treatment for this condition, which affects an upper extremity in a manner that typically does not require close medical supervision by a physician or weekly interdisciplinary team meetings to reach the patient's goals, would not be expect to require the intensive inpatient rehabilitation services provided in an IRF. Therefore, we proposed the removal of this code from the list, ICD-9-CM Codes That Meet Presumptive Compliance Criteria.

- *Neuralgic amyotrophy (353.5)*—This condition is also known as

Parsonage-Turner syndrome or brachial plexus neuritis. It is a distinct peripheral nervous system disorder characterized by attacks of extreme neuropathic pain and rapid multifocal weakness and atrophy in the upper limbs. Patients with this condition do not typically require close medical supervision by a physician or weekly interdisciplinary team meetings to reach the patient's therapy goals. Thus, patients with this condition do not typically require the intensive inpatient rehabilitation services provided in an IRF. Therefore, we proposed the removal of this code from the list, ICD-9-CM Codes That Meet Presumptive Compliance Criteria.

- *Other nerve root and plexus disorders* (353.8)—This code does not, in the absence of additional information, reveal whether a patient is in need of intensive rehabilitation services for treatment of one or more of the conditions specified in the regulations. More descriptive codes should be used so as to document the appropriateness of a patient's IRF admission, and potentially, their inclusion in the IRF's compliance percentage. For example, Lumbosacral plexus lesions (353.1) could substitute for Other nerve root and plexus disorders (353.8). Patients with lumbosacral plexus lesions, however, do not typically require the intensive inpatient rehabilitation services provided in an IRF. Therefore, we proposed the removal of this code from

the list, ICD-9-CM Codes That Meet Presumptive Compliance Criteria.

We received 3 comments on the proposed changes to the miscellaneous diagnosis codes that we proposed removing from the presumptive methodology list in the proposed rule. These are summarized below.

Comment: The commenters agreed with the proposed removal of the miscellaneous diagnosis codes that were discussed in the May 8, 2013 proposed rule.

Response: We appreciate the commenters support and thank them for their comments.

6. Additional Diagnosis Codes

During our review of the diagnosis codes on the presumptive methodology list we did not identify any ICD-9-CM codes that would be appropriate to add to the list. However, we welcomed public comment regarding ICD-9-CM diagnosis codes that are not currently on the presumptive methodology list that stakeholders believe should be added. We noted that any such suggested codes would have to code for one of the medical conditions listed at § 412.29(b)(2) (including any severity or pretreatment requirements), and require intensive inpatient rehabilitation.

We received one comment suggesting additional diagnosis codes not currently listed in ICD-9-CM Codes That Meet Presumptive Compliance Criteria..

Comment: The commenter suggested that we add ICD-9-CM code 348.31—Metabolic encephalopathy and ICD-9-

CM code 331.83—Parkinson's Dementia—to the list of qualifying codes.

Response: We agree that code ICD-9-CM code 348.31—Metabolic encephalopathy— should be added to the list with the other toxic encephalopathy codes to ensure that IRFs can code to the highest level of specificity. We will add this code to the list of ICD-9-CM Codes That Meet Presumptive Compliance Criteria. However, we disagree with the commenter's suggestion to add Parkinson's Dementia to the list of codes because we cannot determine "presumptively" whether these patients would be able to meaningfully participate in an intensive inpatient rehabilitation program.

Final Decision: After carefully considering the comments that we received on the proposed changes to the ICD-9-CM in the presumptive methodology list, we are revising the list of ICD-9-CM codes to be removed from "ICD-9-CM Codes That Meet Presumptive Compliance Criteria" as follows: We are removing the codes listed in Table 9 of this final rule. We are also adding ICD-9-CM code 348.31—Metabolic encephalopathy to the presumptive methodology list. The revisions to the list of diagnosis codes that are used to determine presumptive compliance under the "60 percent rule" are effective for compliance review periods beginning on or after October 1, 2014.

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

| ICD-9-CM Code | Diagnosis |
|---------------|---|
| 013.00 | Tuberculous meningitis, unspecified. |
| 013.01 | Tuberculous meningitis, bacteriological or histological examination not done. |
| 013.10 | Tuberculoma of meninges, unspecified. |
| 013.11 | Tuberculoma of meninges, bacteriological or histological examination not done. |
| 013.20 | Tuberculoma of brain, unspecified. |
| 013.21 | Tuberculoma of brain, bacteriological or histological examination not done. |
| 013.30 | Tuberculous abscess of brain, unspecified. |
| 013.31 | Tuberculous abscess of brain, bacteriological or histological examination not done. |
| 013.40 | Tuberculoma of spinal cord, unspecified. |
| 013.41 | Tuberculoma of spinal cord, bacteriological or histological examination not done. |
| 013.50 | Tuberculous abscess of spinal cord, unspecified. |
| 013.51 | Tuberculous abscess of spinal cord, bacteriological or histological examination not done. |
| 013.60 | Tuberculous encephalitis or myelitis, unspecified. |
| 013.61 | Tuberculous encephalitis or myelitis, bacteriological or histological examination not done. |
| 047.9 | Unspecified viral meningitis. |
| 053.13 | Postherpetic polyneuropathy. |
| 062.9 | Mosquito-borne viral encephalitis, unspecified. |
| 063.1 | Louping ill. |
| 063.9 | Tick-borne viral encephalitis, unspecified. |
| 324.9 | Intracranial and intraspinal abscess of unspecified site. |
| 335.10 | Spinal muscular atrophy, unspecified. |
| 335.9 | Anterior horn cell disease, unspecified. |
| 336.9 | Unspecified disease of spinal cord. |
| 341.9 | Demyelinating disease of central nervous system, unspecified. |
| 342.00 | Flaccid hemiplegia and hemiparesis affecting unspecified side. |
| 342.10 | Spastic hemiplegia and hemiparesis affecting unspecified side. |

TABLE 9—ICD-9-CM CODES REMOVED FROM “ICD-9-CM CODES THAT MEET PRESUMPTIVE COMPLIANCE CRITERIA”—Continued

| ICD-9-CM Code | Diagnosis |
|---------------|---|
| 342.80 | Other specified hemiplegia and hemiparesis affecting unspecified side. |
| 342.90 | Hemiplegia, unspecified, affecting unspecified side. |
| 342.91 | Hemiplegia, unspecified, affecting dominant side. |
| 342.92 | Hemiplegia, unspecified, affecting nondominant side. |
| 343.3 | Congenital monoplegia. |
| 344.5 | Unspecified monoplegia. |
| 348.82 | Brain death. |
| 353.0 | Brachial plexus lesions. |
| 353.2 | Cervical root lesions, not elsewhere classified. |
| 353.3 | Thoracic root lesions, not elsewhere classified. |
| 353.4 | Lumbosacral root lesions, not elsewhere classified. |
| 353.5 | Neuralgic amyotrophy. |
| 353.8 | Other nerve root and plexus disorders. |
| 354.5 | Mononeuritis multiplex. |
| 356.9 | Unspecified hereditary and idiopathic peripheral neuropathy. |
| 358.00 | Myasthenia gravis without (acute) exacerbation. |
| 359.29 | Other specified myotonic disorder. |
| 359.3 | Periodic paralysis. |
| 432.9 | Unspecified intracranial hemorrhage. |
| 438.20 | Late effects of cerebrovascular disease, hemiplegia affecting unspecified side. |
| 438.30 | Late effects of cerebrovascular disease, monoplegia of upper limb affecting unspecified side. |
| 438.31 | Late effects of cerebrovascular disease, monoplegia of upper limb affecting dominant side. |
| 438.32 | Late effects of cerebrovascular disease, monoplegia of upper limb affecting nondominant side. |
| 438.40 | Late effects of cerebrovascular disease, monoplegia of lower limb affecting unspecified side. |
| 438.50 | Late effects of cerebrovascular disease, other paralytic syndrome affecting unspecified side. |
| 446.0 | Polyarteritis nodosa. |
| 711.20 | Arthropathy in Behcet's syndrome, site unspecified. |
| 711.21 | Arthropathy in Behcet's syndrome, shoulder region. |
| 711.22 | Arthropathy in Behcet's syndrome, upper arm. |
| 711.23 | Arthropathy in Behcet's syndrome, forearm. |
| 711.24 | Arthropathy in Behcet's syndrome, hand. |
| 711.25 | Arthropathy in Behcet's syndrome, pelvic region and thigh. |
| 711.26 | Arthropathy in Behcet's syndrome, lower leg. |
| 711.27 | Arthropathy in Behcet's syndrome, ankle and foot. |
| 711.28 | Arthropathy in Behcet's syndrome, other specified sites. |
| 711.29 | Arthropathy in Behcet's syndrome, multiple sites. |
| 713.0 | Arthropathy associated with other endocrine and metabolic disorders. |
| 713.1 | Arthropathy associated with gastrointestinal conditions other than infections. |
| 713.2 | Arthropathy associated with hematological disorders. |
| 713.3 | Arthropathy associated with dermatological disorders. |
| 713.4 | Arthropathy associated with respiratory disorders. |
| 713.6 | Arthropathy associated with hypersensitivity reaction. |
| 713.7 | Other general diseases with articular involvement. |
| 714.0 | Rheumatoid arthritis. |
| 714.1 | Felty's syndrome. |
| 714.2 | Other rheumatoid arthritis with visceral or systemic involvement. |
| 714.32 | Pauciarticular juvenile rheumatoid arthritis. |
| 714.81 | Rheumatoid lung. |
| 714.89 | Other specified inflammatory polyarthropathies. |
| 714.9 | Unspecified inflammatory polyarthropathy. |
| 715.11 | Osteoarthritis, localized, primary, shoulder region. |
| 715.12 | Osteoarthritis, localized, primary, upper arm. |
| 715.15 | Osteoarthritis, localized, primary, pelvic region and thigh. |
| 715.16 | Osteoarthritis, localized, primary, lower leg. |
| 715.21 | Osteoarthritis, localized, secondary, shoulder region. |
| 715.22 | Osteoarthritis, localized, secondary, upper arm. |
| 715.25 | Osteoarthritis, localized, secondary, pelvic region and thigh. |
| 715.26 | Osteoarthritis, localized, secondary, lower leg. |
| 715.31 | Osteoarthritis, localized, not specified whether primary or secondary, shoulder region. |
| 715.32 | Osteoarthritis, localized, not specified whether primary or secondary, upper arm. |
| 715.35 | Osteoarthritis, localized, not specified whether primary or secondary, pelvic region and thigh. |
| 715.36 | Osteoarthritis, localized, not specified whether primary or secondary, lower leg. |
| 716.01 | Kaschin-Beck disease, shoulder region. |
| 716.02 | Kaschin-Beck disease, upper arm. |
| 716.05 | Kaschin-Beck disease, pelvic region and thigh. |
| 716.06 | Kaschin-Beck disease, lower leg. |
| 716.11 | Traumatic arthropathy, shoulder region. |
| 716.12 | Traumatic arthropathy, upper arm. |
| 716.15 | Traumatic arthropathy, pelvic region and thigh. |
| 716.16 | Traumatic arthropathy, lower leg. |

TABLE 9—ICD-9-CM CODES REMOVED FROM “ICD-9-CM CODES THAT MEET PRESUMPTIVE COMPLIANCE CRITERIA”—Continued

| ICD-9-CM Code | Diagnosis |
|---------------|---|
| 716.21 | Allergic arthritis, shoulder region. |
| 716.22 | Allergic arthritis, upper arm. |
| 716.25 | Allergic arthritis, pelvic region and thigh. |
| 716.26 | Allergic arthritis, lower leg. |
| 716.51 | Unspecified polyarthropathy or polyarthritis, shoulder region. |
| 716.52 | Unspecified polyarthropathy or polyarthritis, upper arm. |
| 716.55 | Unspecified polyarthropathy or polyarthritis, pelvic region and thigh. |
| 716.56 | Unspecified polyarthropathy or polyarthritis, lower leg. |
| 719.30 | Palindromic rheumatism, site unspecified. |
| 719.31 | Palindromic rheumatism, shoulder region. |
| 719.32 | Palindromic rheumatism, upper arm. |
| 719.33 | Palindromic rheumatism, forearm. |
| 719.34 | Palindromic rheumatism, hand. |
| 719.35 | Palindromic rheumatism, pelvic region and thigh. |
| 719.36 | Palindromic rheumatism, lower leg. |
| 719.37 | Palindromic rheumatism, ankle and foot. |
| 719.38 | Palindromic rheumatism, other specified sites. |
| 719.39 | Palindromic rheumatism, multiple sites. |
| 720.0 | Ankylosing spondylitis. |
| 720.81 | Inflammatory spondylopathies in diseases classified elsewhere. |
| 720.89 | Other inflammatory spondylopathies. |
| 721.91 | Spondylosis of unspecified site, with myelopathy. |
| 722.70 | Intervertebral disc disorder with myelopathy, unspecified region. |
| 740.1 | Craniorachischisis. |
| 740.2 | Encephalocele. |
| 741.00 | Spina bifida with hydrocephalus, unspecified region. |
| 741.90 | Spina bifida without mention of hydrocephalus, unspecified region. |
| 742.1 | Microcephalus. |
| 754.30 | Congenital dislocation of hip, unilateral. |
| 754.31 | Congenital dislocation of hip, bilateral. |
| 754.32 | Congenital subluxation of hip, unilateral. |
| 755.20 | Unspecified reduction deformity of upper limb. |
| 755.21 | Transverse deficiency of upper limb. |
| 755.22 | Longitudinal deficiency of upper limb, not elsewhere classified. |
| 755.23 | Longitudinal deficiency, combined, involving humerus, radius, and ulna (complete or incomplete). |
| 755.24 | Longitudinal deficiency, humeral, complete or partial (with or without distal deficiencies, incomplete). |
| 755.25 | Longitudinal deficiency, radioulnar, complete or partial (with or without distal deficiencies, incomplete). |
| 755.26 | Longitudinal deficiency, radial, complete or partial (with or without distal deficiencies, incomplete). |
| 755.27 | Longitudinal deficiency, ulnar, complete or partial (with or without distal deficiencies, incomplete). |
| 755.28 | Longitudinal deficiency, carpals or metacarpals, complete or partial (with or without incomplete phalangeal deficiency). |
| 755.30 | Unspecified reduction deformity of lower limb. |
| 755.4 | Reduction deformities, unspecified limb. |
| 755.51 | Congenital deformity of clavicle. |
| 755.53 | Radioulnar synostosis. |
| 755.61 | Coxa valga, congenital. |
| 755.62 | Coxa vara, congenital. |
| 755.63 | Other congenital deformity of hip (joint). |
| 756.50 | Congenital osteodystrophy, unspecified. |
| 800.09 | Closed fracture of vault of skull without mention of intracranial injury, with concussion, unspecified. |
| 800.19 | Closed fracture of vault of skull with cerebral laceration and contusion, with concussion, unspecified. |
| 800.29 | Closed fracture of vault of skull with subarachnoid, subdural, and extradural hemorrhage, with concussion, unspecified. |
| 800.39 | Closed fracture of vault of skull with other and unspecified intracranial hemorrhage, with concussion, unspecified. |
| 800.49 | Closed fracture of vault of skull with intracranial injury of other and unspecified nature, with concussion, unspecified. |
| 800.59 | Open fracture of vault of skull without mention of intracranial injury, with concussion, unspecified. |
| 800.69 | Open fracture of vault of skull with cerebral laceration and contusion, with concussion, unspecified. |
| 800.79 | Open fracture of vault of skull with subarachnoid, subdural, and extradural hemorrhage, with concussion, unspecified. |
| 800.89 | Open fracture of vault of skull with other and unspecified intracranial hemorrhage, with concussion, unspecified. |
| 800.99 | Open fracture of vault of skull with intracranial injury of other and unspecified nature, with concussion, unspecified. |
| 801.09 | Closed fracture of base of skull without mention of intracranial injury, with concussion, unspecified. |
| 801.19 | Closed fracture of base of skull with cerebral laceration and contusion, with concussion, unspecified. |
| 801.29 | Closed fracture of base of skull with subarachnoid, subdural, and extradural hemorrhage, with concussion, unspecified. |
| 801.39 | Closed fracture of base of skull with other and unspecified intracranial hemorrhage, with concussion, unspecified. |
| 801.49 | Closed fracture of base of skull with intracranial injury of other and unspecified nature, with concussion, unspecified. |
| 801.59 | Open fracture of base of skull without mention of intracranial injury, with concussion, unspecified. |
| 801.69 | Open fracture of base of skull with cerebral laceration and contusion, with concussion, unspecified. |
| 801.79 | Open fracture of base of skull with subarachnoid, subdural, and extradural hemorrhage, with concussion, unspecified. |
| 801.89 | Open fracture of base of skull with other and unspecified intracranial hemorrhage, with concussion, unspecified. |
| 801.99 | Open fracture of base of skull with intracranial injury of other and unspecified nature, with concussion, unspecified. |
| 803.09 | Other closed skull fracture without mention of intracranial injury, with concussion, unspecified. |
| 803.19 | Other closed skull fracture with cerebral laceration and contusion, with concussion, unspecified. |

TABLE 9—ICD-9-CM CODES REMOVED FROM “ICD-9-CM CODES THAT MEET PRESUMPTIVE COMPLIANCE CRITERIA”—Continued

| ICD-9-CM Code | Diagnosis |
|---------------|--|
| 803.29 | Other closed skull fracture with subarachnoid, subdural, and extradural hemorrhage, with concussion, unspecified. |
| 803.39 | Other closed skull fracture with other and unspecified intracranial hemorrhage, with concussion, unspecified. |
| 803.49 | Other closed skull fracture with intracranial injury of other and unspecified nature, with concussion, unspecified. |
| 803.59 | Other open skull fracture without mention of intracranial injury, with concussion, unspecified. |
| 803.69 | Other open skull fracture with cerebral laceration and contusion, with concussion, unspecified. |
| 803.79 | Other open skull fracture with subarachnoid, subdural, and extradural hemorrhage, with concussion, unspecified. |
| 803.89 | Other open skull fracture with other and unspecified intracranial hemorrhage, with concussion, unspecified. |
| 803.99 | Other open skull fracture with intracranial injury of other and unspecified nature, with concussion, unspecified. |
| 804.19 | Closed fractures involving skull or face with other bones, with cerebral laceration and contusion, with concussion, unspecified. |
| 804.29 | Closed fractures involving skull or face with other bones with subarachnoid, subdural, and extradural hemorrhage, with concussion, unspecified. |
| 804.39 | Closed fractures involving skull or face with other bones, with other and unspecified intracranial hemorrhage, with concussion, unspecified. |
| 804.49 | Closed fractures involving skull or face with other bones, with intracranial injury of other and unspecified nature, with concussion, unspecified. |
| 804.69 | Open fractures involving skull or face with other bones, with cerebral laceration and contusion, with concussion, unspecified. |
| 804.79 | Open fractures involving skull or face with other bones with subarachnoid, subdural, and extradural hemorrhage, with concussion, unspecified. |
| 804.89 | Open fractures involving skull or face with other bones, with other and unspecified intracranial hemorrhage, with concussion, unspecified. |
| 804.99 | Open fractures involving skull or face with other bones, with intracranial injury of other and unspecified nature, with concussion, unspecified. |
| 806.00 | Closed fracture of C1–C4 level with unspecified spinal cord injury. |
| 806.05 | Closed fracture of C5–C7 level with unspecified spinal cord injury. |
| 806.10 | Open fracture of C1–C4 level with unspecified spinal cord injury. |
| 806.15 | Open fracture of C5–C7 level with unspecified spinal cord injury. |
| 806.20 | Closed fracture of T1–T6 level with unspecified spinal cord injury. |
| 806.25 | Closed fracture of T7–T12 level with unspecified spinal cord injury. |
| 806.30 | Open fracture of T1–T6 level with unspecified spinal cord injury. |
| 806.35 | Open fracture of T7–T12 level with unspecified spinal cord injury. |
| 806.60 | Closed fracture of sacrum and coccyx with unspecified spinal cord injury. |
| 806.70 | Open fracture of sacrum and coccyx with unspecified spinal cord injury. |
| 820.8 | Closed fracture of unspecified part of neck of femur. |
| 820.9 | Open fracture of unspecified part of neck of femur. |
| 839.10 | Open dislocation, cervical vertebra, unspecified. |
| 850.5 | Concussion with loss of consciousness of unspecified duration. |
| 851.09 | Cortex (cerebral) contusion without mention of open intracranial wound, with concussion, unspecified. |
| 851.19 | Cortex (cerebral) contusion with open intracranial wound, with concussion, unspecified. |
| 851.29 | Cortex (cerebral) laceration without mention of open intracranial wound, with concussion, unspecified. |
| 851.39 | Cortex (cerebral) laceration with open intracranial wound, with concussion, unspecified. |
| 851.49 | Cerebellar or brain stem contusion without mention of open intracranial wound, with concussion, unspecified. |
| 851.59 | Cerebellar or brain stem contusion with open intracranial wound, with concussion, unspecified. |
| 851.69 | Cerebellar or brain stem laceration without mention of open intracranial wound, with concussion, unspecified. |
| 851.79 | Cerebellar or brain stem laceration with open intracranial wound, with concussion, unspecified. |
| 851.89 | Other and unspecified cerebral laceration and contusion, without mention of open intracranial wound, with concussion, unspecified. |
| 852.09 | Subarachnoid hemorrhage following injury without mention of open intracranial wound, with concussion, unspecified. |
| 852.19 | Subarachnoid hemorrhage following injury with open intracranial wound, with concussion, unspecified. |
| 852.29 | Subdural hemorrhage following injury without mention of open intracranial wound, with concussion, unspecified. |
| 852.39 | Subdural hemorrhage following injury with open intracranial wound, with concussion, unspecified. |
| 852.49 | Extradural hemorrhage following injury without mention of open intracranial wound, with concussion, unspecified. |
| 852.59 | Extradural hemorrhage following injury with open intracranial wound, with concussion, unspecified. |
| 853.09 | Other and unspecified intracranial hemorrhage following injury without mention of open intracranial wound, with concussion, unspecified. |
| 853.19 | Other and unspecified intracranial hemorrhage following injury with open intracranial wound, with concussion, unspecified. |
| 854.09 | Intracranial injury of other and unspecified nature without mention of open intracranial wound, with concussion, unspecified. |
| 854.19 | Intracranial injury of other and unspecified nature with open intracranial wound, with concussion, unspecified. |
| 887.0 | Traumatic amputation of arm and hand (complete) (partial), unilateral, below elbow, without mention of complication. |
| 887.1 | Traumatic amputation of arm and hand (complete) (partial), unilateral, below elbow, complicated. |
| 887.2 | Traumatic amputation of arm and hand (complete) (partial), unilateral, at or above elbow, without mention of complication. |
| 887.3 | Traumatic amputation of arm and hand (complete) (partial), unilateral, at or above elbow, complicated. |
| 887.4 | Traumatic amputation of arm and hand (complete) (partial), unilateral, level not specified, without mention of complication. |
| 887.5 | Traumatic amputation of arm and hand (complete) (partial), unilateral, level not specified, complicated. |
| 941.00 | Burn of unspecified degree of face and head, unspecified site. |
| 941.02 | Burn of unspecified degree of eye (with other parts of face, head, and neck). |
| 941.09 | Burn of unspecified degree of multiple sites [except with eye] of face, head, and neck. |
| 942.00 | Burn of unspecified degree of trunk, unspecified site. |
| 942.01 | Burn of unspecified degree of breast. |
| 942.02 | Burn of unspecified degree of chest wall, excluding breast and nipple. |
| 942.03 | Burn of unspecified degree of abdominal wall. |

TABLE 9—ICD-9-CM CODES REMOVED FROM “ICD-9-CM CODES THAT MEET PRESUMPTIVE COMPLIANCE CRITERIA”—Continued

| ICD-9-CM Code | Diagnosis |
|---------------|---|
| 942.04 | Burn of unspecified degree of back [any part]. |
| 942.05 | Burn of unspecified degree of genitalia. |
| 942.09 | Burn of unspecified degree of other and multiple sites of trunk. |
| 943.00 | Burn of unspecified degree of upper limb, except wrist and hand, unspecified site. |
| 943.01 | Burn of unspecified degree of forearm. |
| 943.02 | Burn of unspecified degree of elbow. |
| 943.03 | Burn of unspecified degree of upper arm. |
| 943.04 | Burn of unspecified degree of axilla. |
| 943.05 | Burn of unspecified degree of shoulder. |
| 943.06 | Burn of unspecified degree of scapular region. |
| 943.09 | Burn of unspecified degree of multiple sites of upper limb, except wrist and hand. |
| 943.30 | Full-thickness skin [third degree, not otherwise specified] of upper limb, unspecified site. |
| 943.40 | Deep necrosis of underlying tissues [deep third degree] without mention of loss of a body part, of upper limb, unspecified site. |
| 943.50 | Deep necrosis of underlying tissues [deep third degree] with loss of a body part, of upper limb, unspecified site. |
| 944.30 | Full-thickness skin loss [third degree, not otherwise specified] of hand, unspecified site. |
| 944.40 | Deep necrosis of underlying tissues [deep third degree] without mention of loss of a body part, hand, unspecified site. |
| 944.50 | Deep necrosis of underlying tissues [deep third degree] with loss of a body part, of hand, unspecified site. |
| 945.00 | Burn of unspecified degree of lower limb [leg], unspecified site. |
| 945.01 | Burn of unspecified degree of toe(s) (nail). |
| 945.02 | Burn of unspecified degree of foot. |
| 945.03 | Burn of unspecified degree of ankle. |
| 945.04 | Burn of unspecified degree of lower leg. |
| 945.05 | Burn of unspecified degree of knee. |
| 945.06 | Burn of unspecified degree of thigh [any part]. |
| 945.09 | Burn of unspecified degree of multiple sites of lower limb(s). |
| 945.20 | Blisters, epidermal loss [second degree] of lower limb [leg], unspecified site. |
| 945.40 | Deep necrosis of underlying tissues [deep third degree] without mention of loss of a body part, lower limb [leg], unspecified site. |
| 945.50 | Deep necrosis of underlying tissues [deep third degree] with loss of a body part, of lower limb [leg], unspecified site. |
| 949.4 | Deep necrosis of underlying tissue [deep third degree] without mention of loss of a body part, unspecified. |
| 949.5 | Deep necrosis of underlying tissues [deep third degree] with loss of a body part, unspecified. |
| 997.60 | Unspecified complication of amputation stump. |

IX. Non-Quality Related Revisions to IRF-PAI Sections

Under section 1886(j)(2)(D) of the Act, the Secretary is authorized to require rehabilitation facilities that provide inpatient hospital services to submit such data as the Secretary deems necessary to establish and administer the prospective payment system under subsection P. The collection of patient data is indispensable for the successful development and implementation of the IRF payment system. In the August 7, 2001 final rule, the inpatient rehabilitation facility patient assessment instrument (IRF-PAI) was adopted as the standardized patient assessment instrument under the IRF prospective payment system (PPS). The IRF-PAI was established, and is still used to gather data to classify patients for payment under the IRF PPS. As discussed in section XIV of this final rule, it is also now used to collect certain data for the IRF Quality Reporting Program. IRFs are currently required to complete an IRF-PAI for every Medicare Part A or C patient who is admitted to, or discharged from an IRF. (We note that Medicare Part B was inappropriately listed in the proposed

rule. We are clarifying that IRFs are not required to submit the IRF-PAI for Medicare Part B patients.)

Although there have been significant advancements in the industry, no IRF PPS payment-related changes have been made to the IRF-PAI form since its implementation in FY 2002. In the FY 2014 IRF PPS proposed rule, we proposed amending certain response code options, adding additional data points, removing certain outdated items and changing certain references to ensure that our policies reflect the current data needs of the IRF PPS program.

A. Revisions

We proposed to amend the response codes on the following items in the IRF-PAI:

- Item 15A: Admit From (Formerly item 15)
- Item 16A: Pre-Hospital Living Situation (Formerly item 16)
- Item 44D: Patient's Discharge Destination/Living Setting (Formerly item 44A)

To minimize possible confusion due to the use of different sets of status codes on the IRF-PAI and the CMS-

1450 (also referred to as the UB-04) claim form, we believe that the IRF-PAI status codes should be updated to mirror those used on the UB-04 claim form. We also believed this update would help with consistency, ultimately decreasing the rate of coding submission errors on the UB-04 claim form. We believed that would provide response options that mirror other commonly used instruments in the Medicare context allowing providers to use only one common set of response codes. We proposed to amend the response options for the three items listed above to:

- 01—Home (private home/apt., board/care, assisted living, group home)
- 02—Short-term General Hospital
- 03—Skilled Nursing Facility (SNF)
- 50—Hospice
- 62—Another Inpatient Rehabilitation Facility
- 63—Long-Term Care Hospital (LTCH)
- 64—Medicaid Nursing Facility
- 65—Inpatient Psychiatric Facility
- 66—Critical Access Hospital
- 99—Not Listed

We also proposed to update the options for responding to item 20B: Secondary Source. While not expressly stated in the preamble, but evident from

the web-posted draft of the IRF-PAI that was cross-referenced in the proposed rule, we also proposed to amend the response codes for 20A: Primary Source as well. As we noted in the proposed rule, we find that the current response options for these data elements result in the collection of patient information that we do not currently need to operate the IRF PPS and the IRF quality programs. Therefore, we limit our data collections to those which are currently needed, and in an effort to decrease burden on IRFs through the implementation of simplified response options, we proposed to limit the secondary source response options to the following:

- 02—Medicare—Fee for Service
- 51—Medicare—Medicare Advantage
- 99—Not Listed

B. Additions

Further, we proposed to add (or expand) the following items to the IRF-PAI:

- Item 25A: Height
- Item 26A: Weight
- Item 24: Comorbid Conditions (15 additional spaces)
- Item 44C: Was the patient discharged alive?
- Signature of Persons Completing the IRF-PAI

Items 25A: Height and 26A: Weight, are important items to collect for using in the classification of facilities for payment under the IRF-PPS as well as for the risk adjustment of quality measures (as described in section XIV of this final rule). In the regulations at section 412.29(b)(2), we specify a list of comorbid conditions that, if certain conditions are met, may qualify a patient for inclusion in an IRF's 60 percent rule compliance percentage. For example, a patient with a lower-extremity joint replacement comorbidity could qualify as an IRF patient under the 60 percent rule compliance percentage if they have one or more of the following:

- A bilateral joint replacement
- Is over the age of 85
- Has a BMI greater than 50.

The patient's BMI is calculated using height and weight. By adding a patient's height and weight information to the IRF-PAI, we will for the first time have enough information on the number and types of patients being treated for a lower-extremity joint replacement with a BMI greater than 50 for purposes of analyzing the effects of the 60 percent rule.

We also proposed to add 15 additional spaces for providers to document patients' comorbid medical

conditions at item 24: Comorbid Conditions (located in the medical information section of the IRF-PAI). The IRF-PAI currently has ten spaces available for providers to enter ICD codes for comorbid conditions. Including the 15 additional proposed spaces for this item will give providers a total of 25 spaces on the IRF-PAI. Such expansion will enable IRFs to code with greater specificity which may result in accounting for additional comorbidities. Further identification of patient characteristics may assist in care planning, payment assignment, and presumptive compliance method calculations. Furthermore, in order to stay aligned, we believe that the number of data elements allowed on the IRF-PAI for item 24: Comorbid Conditions, should mirror the number of spaces currently available for providers to document patients' comorbidities on the UB-04 claim. Additionally, the ICD-10 coding scheme will become effective on October 1, 2014, and is much more specific than the current ICD-9 coding. Therefore, when the agency moves from ICD-9 to ICD-10 coding, providers may need the additional spaces to code because of the greater specificity under ICD-10.

Furthermore, we proposed to add a new item 44C: "Was the patient discharged alive?" to the discharge information section on the IRF-PAI. Adding this item as a standalone item would allow facilities that reply "no" to 44C to skip items 44D, 44E, and 45, which describe a living patient's discharge destination. This will also reduce the burden on the time it takes providers to complete the IRF-PAI. Facilities that respond "yes" to item 44C will complete items 44D, 44E and 45 as they apply to the patient. We believe that adding this question as a standalone item would provide greater clarity for providers when documenting patient information on the IRF-PAI.

We also proposed to add a page to the IRF-PAI dedicated as the signature page for persons completing the IRF-PAI. As of the effective date of the IRF Coverage Requirements (see the August 7, 2009 FY 2010 IRF PPS final rule (74 FR 39762)) a patient's IRF-PAI must be maintained in their medical record at the IRF (electronic or paper format), and the information in the IRF-PAI must correspond with all of the information provided in the patient's IRF medical record. We received multiple public comments on the FY 2010 IRF PPS proposed rule regarding the requirement to include the IRF-PAI in the medical record. Commenters questioned whether IRFs would need to adhere to the conditions of participation in

§ 482.24(c)(1) that require all patient medical record entries must be legible, complete, dated, timed, and authenticated in written or electronic form by the person responsible for providing or evaluating the service provided, consistent with hospital policies and procedures. When we responded (at http://cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Downloads/IRF-Training-call_version_1.pdf) that IRFs would need to adhere to § 482.24(c)(1), providers responded by asking for a place on the IRF-PAI where they would be able to document the required authentication. The addition of a signature page for persons completing the IRF-PAI would fulfill providers' request to have an organized way to document who in the IRF has completed an IRF-PAI item and/or section when the information was completed. We also believe that the addition of a signature page for those completing the IRF-PAI will ensure that providers are satisfying both the IRF coverage requirements and the conditions of participation requirements.

C. Deletions

We proposed to delete the following items from the IRF-PAI:

- Item 18: Pre-Hospital Vocational Category
- Item 19: Pre-Hospital Vocational Effort
- Item 25: Is patient comatose at admission?
- Item 26: Is patient delirious at admission?
- Item 28: Clinical signs of dehydration

Because we no longer believe that these items are necessary and in the interest of reducing burden on providers, we would like to delete them.

Items 18: Pre-Hospital Vocational Category and 19: Pre-Hospital Vocational Effort (currently located in the admission identification section on the IRF-PAI) are not used for payment or quality purposes. While these items will be removed from the IRF-PAI, we note that these data elements could be significant in a treatment context. For example, we believe that these data elements could be relevant during the care planning/discharge process, as well as during interdisciplinary team meetings. Therefore, we would expect them to appear in the patient's medical record.

We also note, that items 25: Is patient comatose at admission, 26: Is patient delirious at admission, and 28: Clinical signs of dehydration (currently located in the medical information section on the IRF-PAI) are voluntary items that

are not used for our payment or quality program purposes. Therefore, we do not believe it is necessary to collect this information on the IRF-PAI.

Furthermore, to the extent such information would be relevant to the provision of patient care; this information should be captured in either the transfer documentation from the referring physician, or the patients' initial assessment documentation. As such, continuing to require this information on the IRF-PAI would be duplicative since the items should be well documented in the patients' medical record from their stay at the facility.

D. Changes

We proposed to replace all references to the ICD-9-CM code(s) in the IRF-PAI with references to ICD code(s). This change would allow CMS to forgo making additional changes to the IRF-PAI when the adopted ICD code(s) change.

Proposed Technical Correction

We proposed technical corrections at items 44D, 44E and 45 to conform to the additions above. We believe that adding language to these items indicating that the question can be skipped depending upon how item 44C is answered, will help reduce submission errors for providers when filling out the IRF-PAI.

A draft of the IRF-PAI, with the revisions proposed in the proposed rule was made available for download on the IRF PPS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/IRFPAL.html>.

We received 18 comments on the proposed changes to the non-quality related revisions to IRF-PAI sections, which are summarized below.

Comment: Overall, the majority of commenters commended CMS for assessing the non-quality related portions of the IRF-PAI for refinements.

Response: We appreciate the support from the commenters regarding the changes to the IRF-PAI. We believe that the IRF-PAI changes will promote efficiency and clarity for providers as well as ensure that our policies reflect the current data needs required to support the IRF PPS program.

Comment: Many of the commenters supported our proposal to align the status codes on the IRF-PAI with those used on the UB-04 claim form. Commenters agreed that the proposed changes would help providers avoid coding errors. More specifically, two commenters commended our proposed removal of the status code 13 (sub-acute care) stating that the term is not clearly

defined and is more commonly used as a marketing term.

Response: We appreciate the support from commenters regarding the proposed changes to the IRF-PAI. We believe that streamlining claim submission codes and IRF-PAI status codes will ease the administrative burden for providers as well as reduce coding errors.

Comment: One commenter suggested that we should delete item 44E: Was patient discharged with Home Health Services, and instead add code 06-Home under care of organized home health service organization, to item 44D: Patient's discharge destination/living setting. Likewise, another commenter recommended that we remove the proposed new item 44C: Was the patient discharged alive and add the status code option 20-Expired. Additionally, another commenter supported our proposal to add 50-Hospice as a status code option, however, suggested that CMS should add the status code option 51-Hospice (Institutional Facility). The commenters suggested that these status code options would more accurately reflect the UB-04 claim form.

Response: As we mentioned in the proposed rule, many of the changes we made on the non-quality related IRF-PAI items were to initiate standardization between IRF claims and the IRF-PAI when coding patients. Our intent in mirroring the IRF-PAI status codes with the UB-04 claim form codes was to help providers avoid future coding errors. After reviewing the comments submitted, we agree with most of the commenters suggestions to add several status code options to further mirror the UB-04 claim form. In addition to finalizing the proposed status code changes, we will also add the following status code options, which are identical to the options on the UB-04 claim form to items 15A: Admit From; 16A: Pre-hospital Living Setting; and 44D: Patient's discharge destination/living setting:

04—Intermediate Care Facility
06—Home under care of organized home health service organization
51—Hospice (Institutional Facility)
61—Within institution to swing bed

We do not agree with the commenters suggestion to remove item 44C: Was the patient discharged alive, and add 20-Expired as a status code option. Although the status code would mirror the UB-04 claim form, we do not believe "expired" is an adequate response when providers are answering a question regarding the patient's discharge destination. If a patient expires while in the IRF, they are not

discharged from the facility therefore, we would still need item 44C: Was the patient discharged alive. Additionally, adding this item as a standalone item allows clear delineation of a section of the IRF-PAI that providers would not have to report if the reply to 44C is "no". Items 44D and 45, which describe a living patient's discharge destination, can then be skipped. Finally, in light of the addition of status code option 06—Home under care of organized home health service organization; we will remove item 44E: Was patient discharged with Home Health Services live, as this item would be redundant for providers to answer.

Comment: One commenter suggested that we should consider creating a new status code option 08-subacute (SNF with continued therapy plan of care/skilled needs).

Response: We appreciate the commenter's suggestion and will consider creating a new status code option 08-Subacute (SNF with continued therapy plan of care/skilled needs) during future rulemaking. However, our intentions of changing the status code options on the IRF-PAI were to mirror those on the UB-04 claim form, and this suggestion does not conform to those changes as it is not currently necessary for IRF payment or quality reporting.

Comment: Several commenters expressed concern that the coding changes to the IRF-PAI for items 15A: Admitted From; 16A: Pre-Hospital Living Situation; and 44D: Patient's Discharge Destination, are not optimal and suggested that we retain the current IRF-PAI coding options for these items. The commenters stated that the data collected by IRFs in response to these items provide valuable information for quality review and operational management. Limiting the response options too severely, the commenters indicated, would impair an IRF's ability to collect and retain valuable information for payers other than Medicare.

Response: We appreciate the commenters suggestion as we continue to believe that the status code changes are necessary to provide better clarity and alignment with the UB-04 claim form, ultimately reducing coding submission errors. Although we have removed some status code options, we do not believe that we are preventing or deterring IRFs from continuing to collect patient information and document it within the medical record.

Comment: One commenter disagreed with our proposal to group the existing status codes for private home, board/care, assisted living and group home

together under the proposed status code 01—Home (private home/apt., board/care, assisted living, group home) and to completely remove the code options for transitional living and intermediate care from items 15A: Admitted From; 16A: Pre-Hospital Living Situation; and 44D: Patient's Discharge Destination. The commenter recommended that if the proposed status code changes are finalized, we should consider adding transitional living and intermediate care under the status code 01—Home.

Response: As we have previously mentioned, our goal in proposing to change some of the status code options on the IRF-PAI is to be as consistent as possible with the UB-04 claim form. Therefore, we disagree with the commenters' suggestion to ungroup the existing status codes for private home, board/care, assisted living, and group home under the proposed status code 01—Home. But we do agree with the commenter that intermediate care and transitional living are status code options that should be included in the IRF-PAI. Therefore, we will add status code 04—Intermediate care. Furthermore, we will include transitional living as one of the locations listed in status code 01—Home to the response options.

Comment: Several commenters expressed concerns with our proposed change to limit the status code options in item 22B: Secondary Source, to only 02—Medicare-Fee For Service; 51 Medicare-Medicare Advantage; and 99 Not Listed, stating that IRFs would lose the ability to track other payer sources beyond Medicare. One commenter suggested that if we remove the majority of the code options in item 20B: Secondary Source, then we should display the current comprehensive list of payment sources under item 20A: Primary Source. Additionally, the commenter recommended that we add Medicaid Expansion and the Health Insurance Marketplace as status code options. Another commenter stated that decreasing the number of code options will not really save time and burden for providers.

Response: We respectfully disagree with the commenters and continue to believe that decreasing the number of code options will allow providers to code more accurately and reduce burden. However, even if this is not the case, we do not have authority to collect the various information requests the commenters suggested since the information is not currently relevant for administration of the IRF PPS or for the IRF Quality Reporting Program. According to the Privacy Act at 5 U.S.C. 552a(e)(1), an "agency that maintains a

system of records shall—(1) maintain in its records only such information about an individual as is relevant and necessary to accomplish a purpose of the agency required to be accomplished by statute or executive order of the President." When an IRF uploads the IRF-PAI data, it is entered into CMS's Privacy Act System of Records. As the status code options removed from the secondary source item are currently irrelevant to both the IRF payment system and the IRF Quality Reporting Program, we do not have statutory authority to continue to collect this information. Furthermore, we do not believe that we are limiting IRFs from continuing to collect and document payer source information by way of their own internal mechanisms. Furthermore, as we previously mentioned, it was our intent to include item 20A: Primary Source regarding this update, as the list of status code options identified in the Payer Information section relates to both items 20A and 20B. Additionally, the draft version of the IRF-PAI that went on display with the proposed rule very clearly depicts the changes; therefore, we will finalize our proposals as they were described in the proposed rule and the draft IRF-PAI.

Comment: The majority of commenters supported the additional 15 extra spaces in item 24: Comorbid Conditions, and the new items 25A: Height and 26A Weight. One commenter suggested that items 25A and 26A would be more beneficial if time parameters such as "admission" or "discharge" were placed on the measure. One commenter suggested that adding items 25A: Height; 26A Weight; and 27: Swallowing Status, to the IRF-PAI would be redundant, as this information is already in the patient's medical record. This commenter also requested clarification as to whether these items would be mandatory or optional requirements on the IRF-PAI.

Response: We appreciate the support from the commenters regarding the proposed addition of the 15 extra spaces in item 24: Comorbid Conditions, and the new items 25A: Height and 26A Weight. We believe these items are pertinent information to add to the IRF-PAI and allow additional information to be collected after the transition to the more specific ICD-10-CM codes. We note that the proposed items 25A: Height and 26A: Weight already indicate "on admission" as a time parameter. Additionally, items 25A: Height and 26A: Weight will be mandatory items on the IRF-PAI, as these items are needed for payment and quality measurement purposes. CMS did not propose any changes to item 27:

Swallowing Status, therefore, it will remain a voluntary item.

We disagree with the commenter's statement that items 25A and 26A are redundant, as all of the information on the IRF-PAI must also be included in some form in the medical record. We require this information on the IRF-PAI so that it may be submitted to us to enable the implementation of the IRF PPS and the IRF quality reporting program. Therefore, we are finalizing both of these items as they were proposed.

Comment: The majority of commenters supported the addition of a signature page to the IRF-PAI. A few commenters suggested that we allow an electronic signature to satisfy this new requirement. One commenter suggested that we add a prompt on the signature page for "time" in order to comply with the requirements at 482.24(c)(1).

Response: We appreciate the commenters' suggestions regarding the proposed signature page in the IRF-PAI. In order to stay consistent with our current procedures, providers should reference the clarification to our coverage requirements regarding the use of electronic signatures located at (<http://cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Downloads/ElecSysClar.pdf>).

Should a formal policy be established for the development of Medicare's formal electronic signature policies, we may need to revise or further clarify these criteria to ensure that it is in accordance with those policies.

Additionally, we agree with the commenters' suggestion that a "time" prompt should be added to the signature page. Therefore, we will add an additional column for providers to indicate the time that they completed an item and/or section of the IRF-PAI.

Comment: A few commenters requested that we clarify and/or provide more specific instructions for completing the proposed signature page in the IRF-PAI. One commenter was unclear as to why multiple signatures are required, as the information on the IRF-PAI is documented and authenticated within the medical record documentation. Another commenter requested clarification regarding the use of the word "submit" when referring to the sentence, "I also certify that I am authorized to submit this information by this facility on its behalf." The commenter acknowledged that anyone who contributes to the IRF-PAI is, in effect, involved in the submitting of data to us. However, in common parlance, "submit" often refers to the actual act of electronically submitting the final product to us.

Response: We plan to provide more specific instructions for completing the signature page in the IRF-PAI training manual that will accompany the revised IRF-PAI form. We understand the commenter's concerns regarding the attestation statement on the signature page, and we are deleting the statement, "I also certify that I am authorized to submit this information by this facility on its behalf." Removal of this statement from the attestation should clarify what providers are attesting to, and alleviate any concerns.

Comment: Several commenters expressed concern that the proposed addition of the signature page is burdensome and unnecessary because staff entries in the electronic health record are already stamped with date and time, in addition to the name and credentials of the person entering the information. These commenters stated that it would be burdensome to track down individuals to sign an additional sheet of paper.

Response: When the coverage requirements became effective January 1, 2010, providers requested a place on the IRF-PAI where they could sign, date, and record the time in order to comply with the hospital conditions of participation (CoPs). We are taking this opportunity to acknowledge those requests made by the industry. Additionally, the signature item clarifies for the provider and CMS that the requirement has been met.

Comment: One commenter requested that we provide a definition for the new discharge status code 64—Medicaid Nursing Facility.

Response: Medicaid coverage of nursing facility services is available only for services provided in a nursing home licensed and certified by the state survey agency as a Medicaid Nursing Facility (NF). Medicaid nursing facility services are available only when other payment options are unavailable and the individual is eligible for the Medicaid program. For more information please reference the link provided: <http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Delivery-Systems/Institutional-Care/Nursing-Facilities-NF.html>.

Comment: One commenter recommended that the IRF-PAI changes be delayed one year to coincide with the implementation of ICD-10, so that providers can incorporate all of the changes at one time. This commenter suggested that a delayed effective date for the IRF-PAI changes would decrease burden by only having to make updates to information systems once.

Response: We proposed an effective date of October 1, 2014, for all of the finalized IRF-PAI changes. In concert with stakeholder recommendations, we are finalizing this proposal which will help alleviate burden on providers. We believe that the October 1, 2014 effective date will provide IRF's with an adequate amount of time to make necessary changes to information systems as well as provide extensive education for clinicians.

Final Decision: Based on careful consideration of the comments that we received on the proposed non-quality related updates to the IRF-PAI for FY 2014, we are finalizing the following items:

- The status code options for Items 15A: Admit From, 16A: Pre-hospital Living Situation and 44D: Patient's Discharge Destination/Living Setting will be 01—Home (private home/apt., board/care, assisted living, group home, transitional living); 02—Short-term General Hospital; 03—Skilled Nursing Facility (SNF); 04—Intermediate Care; 06—Home under care of organized home health service organization; 50—Hospice (Home); 51—Hospice (Institutional Facility); 61—Within institution to swing bed; 62—Another Inpatient Rehabilitation Facility; 63—Long-Term Care Hospital (LTCH); 64—Medicaid Nursing Facility; 65—Inpatient Psychiatric Facility; 66—Critical Access Hospital; 99—Not Listed

- The status code options for Items 20A: Primary Source and 20B: Secondary Source will be 02—Medicare-Fee for Service; 51—Medicare-Medicare Advantage; 99—Not Listed

- The additions will include Item 24: Comorbid Conditions (15 additional spaces); item 25A: Height; item 26A: Weight; Signature of Persons Completing the IRF-PAI (with the addition of a "time" prompt); 44C: Was the patient discharged alive?

- The deletions will include items 18: Pre-Hospital Vocational Category; 19: Pre-Hospital Vocational Effort; 25: Is the patient comatose at admission; 26: Is the patient delirious at admission; 28: Clinical signs of dehydration; 44E: Was patient discharged with Home Health Services

- Using the language ICD code(s) on the IRF-PAI

- The technical corrections at items 44D: Patient's discharge destination/living setting and 45: Discharge to Living With

- The revised IRF-PAI will become effective for IRF discharges occurring on or after October 1, 2014. All final changes to the IRF-PAI will be

represented when it is posted with the final rule.

X. Technical Corrections to the Regulations at § 412.130

In the FY 2012 IRF PPS final rule (76 FR 47869 through 47873), we revised the regulations for inpatient rehabilitation facilities at § 412.23(b), § 412.25(b), § 412.29, and § 412.30 to update and simplify the policies, to eliminate unnecessary repetition and confusion, and to enhance consistency with the IRF coverage requirements. Among other revisions, we removed the regulations that were formerly in § 412.30, and revised and consolidated the requirements regarding "new" IRFs and "new" IRF beds that previously existed in § 412.30 into the revised regulations at § 412.29(c). However, we have recently discovered that § 412.130, which outlines the policies regarding retroactive adjustments for incorrectly excluded hospitals and units, was not updated to reflect the changes to § 412.30 and § 412.29. Specifically, § 412.130 still references regulations in § 412.30 that were revised and consolidated into § 412.29(c). Further, it still references regulations that were formerly in § 412.23(b)(2), but were moved into § 412.29(b) in the FY 2012 IRF PPS final rule (76 FR 47869 through 47873).

We proposed to make the following technical corrections to the regulations in § 412.130 to conform with the revisions to the regulations in § 412.23(b), § 412.29, and § 412.30 that were implemented in the FY 2012 IRF PPS final rule (76 FR 47869 through 47873):

- Replace the current reference to "§ 412.23(b)(8)" in § 412.130(a)(1) with the new reference to § 412.29(c),

- Replace all of the current references to "§ 412.23(b)(2)" in § 412.130(a)(1), (2), and (3) with the new reference to § 412.29(b),

- Replace the current reference to "§ 412.30(a)" in § 412.130(a)(2) with the new reference to § 412.29(c), and

- Replace the current reference to "§ 412.30(c)" in § 412.130(a)(3) with the new reference to § 412.29(c).

We did not receive any comments on the proposed technical corrections to the regulations at § 412.130. Thus, we are finalizing the technical corrections as proposed, effective for IRF discharges occurring on or after October 1, 2013.

XI. Revisions to the Conditions of Payment for IRF Units Under the IRF PPS

The regulations at § 412.25 specify the requirements for an IRF unit to be excluded from the inpatient prospective

payment system (IPPS) specified in § 412.1(a)(1) and to instead be paid under the IRF PPS specified in § 412.1(a)(3). The requirements at § 412.25 are unique to IRF units of hospitals, whereas the requirements at § 412.29 apply to both freestanding IRF hospitals and IRF units of hospitals. Among the requirements at § 412.25 is the requirement (at § 412.25(a)(1)(iii)) that the institution of which the IRF unit is a part must have “enough beds that are not excluded from the prospective payment systems to permit the provision of adequate cost information, as required by § 413.24(c) of this chapter.” We have not previously specified how many such beds the hospital, of which the IRF unit is a part, must have to meet this requirement. However, we have recently received questions from providers about whether one or two hospital beds that are certified for payment under the IPPS, in some cases beds that are rarely used for patient care, would meet the requirement at § 412.25(a)(1)(iii). We believe this does not meet the requirement at § 412.25(a)(1)(iii), which provides for the hospital of which the IRF unit is a part to be an IPPS hospital, which we believe is not demonstrated by the presence of just one or two hospital beds.

In addition, from a fairness and quality of care perspective, we are particularly concerned about the application of the regulations in § 412.29(g), which require freestanding IRF hospitals to have a full-time director of rehabilitation, but only require IRF units of acute care hospitals (and CAHs) to have a director of rehabilitation for 20 hours per week. We believe that it is unfair to other freestanding IRF hospitals and potentially problematic from a quality of care standpoint for an IRF that is effectively operating as a freestanding IRF hospital, even though it is technically classified as an IRF unit, to be allowed to have a director of rehabilitation only 20 hours per week.

Further, we are unclear how the IRF unit that is part of a hospital with only one or two beds would be able to meet another requirement, at § 412.25(a)(7), that specifies that an IRF unit must have beds that are “physically separate from (that is, not commingled with) the hospital’s other beds.” The requirement at § 412.25(a)(7) means that there is some sort of physical separation that distinguishes the IRF unit from the rest of the hospital beds. We believe that it is unlikely that this requirement would be met in the situation in which the hospital of which the IRF unit is a part only has one or two beds, in some cases

beds that are rarely used for patient care.

Thus, we proposed to specify at § 412.25(a)(1)(iii) a minimum number of hospital beds that the IPPS hospital must have to meet the requirements at § 412.25(a)(1)(iii) for having an IRF unit. We note that, though § 412.25(a)(1)(iii) also applies to inpatient psychiatric facilities (IPFs), these facilities have their own requirements at § 412.27 for payment under the IPF PPS that we are not changing in this proposed rule. IPFs should continue following the regulations at § 412.27.

We proposed to specify in § 412.25(a)(1)(iii) that the institution of which the IRF unit is a part must have at least 10 staffed and maintained hospital beds that are not excluded from the IPPS, or at least 1 staffed and maintained hospital bed for every 10 certified IRF beds, whichever number is greater. If the institution is not able to meet this requirement, then the IRF unit should instead be classified as an IRF hospital. We also proposed to exclude CAHs that have IRF units from these requirements, as CAHs already have very specific bed size restrictions.

We received 3 comments on the proposed revisions to the conditions of payment for IRF units under the IRF PPS, which are summarized below.

Comment: Several commenters noted that the conversion from an IRF unit to a freestanding IRF hospital to meet the new proposed requirements could pose problems for a facility in meeting certain state licensing and/or state certificate of need requirements. These commenters suggested that these state-level requirements could be “burdensome, difficult and expensive” for the IRF.

Response: Although the conversion from an IRF unit to a freestanding IRF hospital is a simple administrative task within Medicare, which does not necessitate any new surveys, any changes to the IRF’s Medicare provider agreement, or any changes to the IRF’s payment status under Medicare, we recognize that the conversion may take longer to complete under state laws. Thus, we are implementing this change on a one-year delay, so that it will be effective for IRF discharges occurring on or after October 1, 2014, to give IRFs who are affected by this change ample time to conform to state certificate of need or other state licensure laws.

Final Decision: After considering the comments that we received on the proposed revision to the conditions of payment for IRF units under the IRF PPS, we are finalizing the change to § 412.25(a)(1)(iii) to specify that the institution of which the IRF unit is a

part must have at least 10 staffed and maintained hospital beds that are not excluded from the IPPS, or at least 1 staffed and maintained hospital bed for every 10 certified IRF beds, whichever number is greater. We exclude CAHs that have IRF units from these requirements, as CAHs already have very specific bed size restrictions. We are implementing this change effective for IRF discharges occurring on or after October 1, 2014 (a one-year delay in the effective date) to give IRFs affected by this change adequate time to comply with state certificate of need or other state licensure laws.

XII. Clarification of the Regulations at § 412.630

In the original rule establishing a prospective payment system for Medicare payment of inpatient hospital services provided by a rehabilitation hospital or by a rehabilitation unit of a hospital, we stated that that there would be no administrative or judicial review, under sections 1869 and 1878 of the Act or otherwise, of the establishment of case-mix groups, the methodology for the classification of patients within these groups, the weighting factors, the prospective payment rates, outlier and special payments and area wage adjustments. See FY 2002 IRF PPS final rule (66 FR 41316, 41319). Our intent was to honor the full breadth of the preclusion of administrative or judicial review provided by section 1886(j)(8) of the Act. However, the regulatory text reflecting the preclusion of review has been at times improperly interpreted to allow review of adjustments authorized under section 1886(j)(3)(v) of the Act. Because we interpret the preclusion of review at § 1886(j)(8) of the Act to apply to all payments authorized under section 1886(j)(3) of the Act, we do not believe that there should be administrative or judicial review of any part of the prospective rate. Accordingly, we are clarifying our regulation at § 412.630 by deleting the word “unadjusted” so that the regulation will clearly preclude review of “the Federal per discharge payment rates.” This clarification will provide for better conformity between the regulation and the statutory language.

As such, in accordance with sections 1886(j)(7)(A), (B), and (C) of the Act, we are revising the regulations at § 412.630 to clarify that administrative or judicial review under sections 1869 or 1878 of the Act, or otherwise, is prohibited with regard to the establishment of the methodology to classify a patient into the case-mix groups and the associated weighting factors, the federal per discharge payment rates, additional

payments for outliers and special payments, and the area wage index.

We received 2 comments on the proposed clarification of the regulations at § 412.630, which are summarized below.

Comment: The commenters expressed concerns with our proposal to revise the regulations at 42 CFR 412.630 to clarify that the Medicare statute precludes administrative and judicial review of the Federal per discharge payment rates, including the LIP adjustment. One commenter stated that the proposal is not a “clarification” that can be applied to pending cases, is inconsistent with the statute, runs afoul of the presumption of judicial review, fails to give proper notice of the regulatory change, and is unconstitutional.

Response: We disagree with the commenter’s statements. Our proposed change serves to clarify the regulation so that it clearly reflects the preclusion of review found in the statute. It also removes any doubt as to the conformity of the regulation to the preclusion of review found in the statute, which by its own terms is applicable to all pending cases regardless of whether it is reflected in regulations or not.

We also strongly disagree with the commenter’s reading of the statute. Section 1886(j)(8) of the statute broadly precludes review of “the prospective payment rates under paragraph (3),” that is, section 1886(j)(3). Within this section, subsection 1886(j)(3)(A) authorizes certain adjustments to the IRF payment rates and, within that, subsection 1886(j)(3)(A)(v) authorizes adjustments to the rates by such other factors as the Secretary determines are necessary to properly reflect variations in necessary costs of treatment among rehabilitation facilities.” The LIP adjustment is made under authority of section 1886(j)(3)(A)(v). As that provision is contained within section 1886(j)(3), and the IRF payment rates under section 1886(j)(3) are precluded from review by section 1886(j)(8), the LIP adjustment falls squarely within the statutory preclusion of review. Such preclusion overcomes any presumption of reviewability that might generally apply, and it is not unconstitutional for Congress (which has the power to define the jurisdiction of the federal courts) to preclude review of certain issues as it has done here. Several virtually identical preclusions of review in other sections of the Medicare statute have been repeatedly upheld and applied by federal courts. Finally, as to notice, the proposed rule itself served as notice of our intention to revise the regulation. In addition, as discussed below, the longstanding language of the statute

itself provides sufficient notice to apply the preclusion.

Comment: One commenter stated that our proposal cannot be a clarification because we have allowed review of matters concerning the LIP adjustment for many years. This commenter further stated that any preclusion of review should apply only to the “formulas” used in the IRF payment rates, and that to preclude review would prevent providers from correcting errors in their payments and would result in two separate methods being used to pay IRFs and hospitals paid under the inpatient prospective payment system (IPPS).

Response: We disagree with these comments. The preclusion of review has been effective since its enactment as part of the IRF prospective payment system in 2002. No regulation or revision of any regulation was necessary for the statutory preclusion to become effective, regardless of whether we or our contractors may have participated in review of IRF LIP matters in the past without making a jurisdictional objection. To the extent that such erroneous participation may have occurred, it does not override the mandate of the statute or prevent us from immediately applying the statutory preclusion of review.

In addition, the preclusion applies to all aspects of the IRF PPS payment rates, not just the formulas. Courts have applied nearly identical preclusion provisions in other parts of the Medicare statute to prevent review of all subsidiary aspects of the matter or determination protected from review. Finally, while precluding review of the IRF LIP adjustment may prevent correction of certain errors, we can only conclude that Congress has made the judgment that such a result is an appropriate trade-off for the gains in efficiency and finality that are achieved by precluding review. Similarly, although applying the preclusion here may result in certain questions being reviewable for an IPPS hospital but not an IRF, this is a judgment that Congress has made. We note that there is a preclusion of review provision in the IPPS statute also, at section 1886(d)(7). The precise contours of these preclusive provisions were for Congress to draw.

Final Decision: After careful review of the comments we received on the clarification of the regulations at § 412.630, we are adopting our proposal to revise the regulations at 42 CFR 412.630 to clarify that the Medicare statute precludes administrative and judicial review of the Federal per discharge payment rates under section 1886(j)(3), including the LIP adjustment.

This revision to the regulation is effective October 1, 2013.

XIII. Revision to the Regulations at § 412.29

According to the regulations at § 412.29(d), to be excluded from the inpatient prospective payment system (IPPS) and instead be paid under the IRF PPS, a facility must “have in effect a preadmission screening procedure under which each prospective patient’s condition and medical history are reviewed to determine whether the patient is likely to benefit significantly from an intensive inpatient hospital program. This procedure must ensure that the preadmission screening is reviewed and approved by a rehabilitation physician prior to the patient’s admission to the IRF.” The latter sentence of this regulation is based on the preadmission screening requirement for Medicare coverage of IRF services in § 412.622(a)(4)(i)(D). The requirement was repeated in both places for consistency.

However, in § 412.622(a)(4)(i)(D), we specify that this requirement applies to patients “for whom the IRF seeks payment” from Medicare. We believe that the analogous requirement in § 412.29(d) should also clearly state that it applies only to patients for whom the IRF is seeking payment directly from Medicare. Other payer sources, such as private insurance, have their own IRF admission requirements, and we do not believe that it would be appropriate to interfere with or duplicate the requirements that other payer sources may already have in place. Thus, we proposed to amend § 412.29(d) to clarify that the IRF’s preadmission screening procedure must ensure that the preadmission screening for a Medicare Part A Fee-for-Service patient is reviewed and approved by a rehabilitation physician prior to the patient’s admission to the IRF. We continue to believe that the basic preadmission screening procedure itself is an important element of providing quality IRF care to all patients and, thus, we will require that the basic preadmission screening procedure requirement remain in place for all patients regardless.

We received 5 comments on the revision to the regulations at § 412.29(d), which are summarized below.

Comment: Several commenters expressed support for the proposed revisions to the regulations at § 412.29, which clarify that we require rehabilitation physician review and concurrence of a patient’s preadmission screening prior to the IRF admission

only for Medicare Fee-for-Service beneficiaries. The commenters indicated that this proposed regulation change would greatly relieve the burden on IRFs that treat a large proportion of non-Medicare patients, for whom other admission requirements typically apply. These commenters also requested that we amend the Rehabilitation Unit and Rehabilitation Hospital Criteria Worksheets and the Attestation Statement (State Operations Manual Exhibit 127, Attestation Statement) to appropriately reflect this change to the regulations.

Response: We appreciate the stakeholder community bringing this issue to our attention, thereby giving us the opportunity to alleviate unintended provider burden. We encourage stakeholders to bring these types of issues to our attention, as we are always willing to consider suggestions that can improve the Medicare program while at the same time reducing the regulatory burden on providers. We will ensure that the appropriate adjustments are made to the Worksheets and the Attestation Statement in accordance with the change to the regulations.

Comment: One commenter recommended that we further clarify the distinction between Medicare Conditions of Payment and the IRF coverage requirements. The commenter suggested that a table distinguishing the two requirements would be useful to providers.

Response: We thank the commenter for the suggestion, and will take this into consideration for future stakeholder outreach in this area.

Final Decision: Based on consideration of the comments received on the proposed change to § 412.29(d), we are finalizing this change, effective for IRF discharges occurring on or after October 1, 2013.

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

A. Background and Statutory Authority

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

Beginning in FY 2014, section 1886(j)(7)(A)(i) of the Act requires the reduction of the applicable IRF PPS annual increase factor, as previously modified under section 1886(j)(3)(D) of the Act, by 2 percentage points for any IRFs that fail to submit data to the

Secretary in accordance with requirements established by the Secretary for that fiscal year. Section 1886(j)(7)(A)(ii) of the Act notes that this reduction may result in the increase factor being less than 0.0 for a fiscal year, and in payment rates under this subsection for a fiscal year being less than the payment rates for the preceding fiscal year. Any reduction based on failure to comply with the reporting requirements is, in accordance with section 1886(j)(7)(B) of the Act, limited to the particular fiscal year involved. The reductions are not to be cumulative and will not be taken into account in computing the payment amount under section (j) for a subsequent fiscal year.

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

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

We have generally adopted NQF-endorsed measures in our reporting programs. However, section 1886(j)(7)(D)(ii) of the Act provides that “in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed, so long as due consideration is given to measures that have been endorsed or adopted by a consensus-based organization identified by the Secretary.” Under section 1886(j)(7)(D)(iii) of the Act, the Secretary was required to publish the selected measures that will be applicable to the FY 2014 IRF PPS no later than October 1, 2012.

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

We seek to promote higher quality and more efficient health care for all patients who receive care in acute and

post-acute care settings. Our efforts are, in part, effectuated by quality reporting programs coupled with the public reporting of data collected under those programs. The initial framework of the IRF QRP was established in the FY 2012 IRF PPS final rule (76 FR 47873).

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

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

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

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

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

- Updates to the CAUTI measure to reflect the NQF’s expansion of this measure to the IRF setting, replacing our previous adoption of an application of the measure for the IRF QRP;
- A policy that would allow any measure adopted for use in the IRF QRP to remain in effect until the measure was actively removed, suspended, or replaced (and specifically applied this policy to the CAUTI and pressure ulcer measures that had already been adopted for use in the IRF QRP); and
- A sub-regulatory process to incorporate NQF updates to IRF quality

¹ The version of the CAUTI measure that was adopted in the FY 2012 IRF PPS final rule (76 FR 47874 through 47876) was titled “Catheter-Associated Urinary Tract Infection [CAUTI] Rate Per 1,000 Urinary Catheter Days for ICU patients. However, shortly after the FY 2012 IRF PPS final rule was published, this measure was submitted by the CDC (measure steward) to the NQF for a measure maintenance review. The CDC asked for changes to the measure, including expansion of the scope of the measure to non-ICU patient care locations and additional healthcare facility settings, including IRFs. The name of the measure was changed to reflect the character of the revised CAUTI measure. This measure is now titled “National Health Safety Network (NHSN) Catheter Associated Urinary Tract Infection (CAUTI) Outcome Measure.”

measure specifications that do not substantively change the nature of the measure.

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

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

In the CY 2013 OPPI/ASC final rule we adopted the current version of NQF #0138 NHSN Catheter Associated Urinary Tract Infection (CAUTI) Outcome Measure (replacing an application of this measure which we initially adopted in the FY 2012 IRF PPS (76 FR 47874 through 47886). The NQF endorsed measure applies to the FY 2015 IRF PPS annual increase factor and all subsequent annual increase factors (77 FR 68504 through 68505).

Since the publication of the CY 2013 OPPI/ASC final rule, the NHSN CAUTI measure has not changed. Furthermore, we have not removed, suspended, or replaced this measure and it remains an active part of the IRF QRP. Additional information about this measure can be found at <http://www.qualityforum.org/QPS/0138>. Our procedures for data submission for this measure have also remained the same. IRFs should continue to submit their CAUTI measure data to the Centers for Disease Control and Prevention (CDC) NHSN.

Details regarding submission of IRF CAUTI data to NHSN can be found at the NHSN Web site at <http://www.cdc.gov/nhsn/inpatient-rehab/index.html>.

We received several comments related to this previously finalized measure, NQF #0138, and some other previously finalized measures, raising some questions about our current policies. While we greatly appreciate the commenters' views on such previously finalized measures and policies, we did not make any proposals relating to them in the FY 2014 IRF PPS proposed rule (78 FR 26880). As such, we will not, in general, be addressing them here. However, we will consider all of these views for future rulemaking and program development. We have responded, however, to a few comments in which commenters asked only for a clarification related to an existing policy and/or measure.

Comment: Several commenters, including MedPAC, expressed that CMS should focus on measures that reflect the success of rehabilitation care, mentioning specifically functional improvement and/or discharge to community. One commenter suggested these measures be used instead of the “process of care measures related to urinary tract infections and pressure ulcers”.

Response: We appreciate the commenter's suggestion. We would like to thank MedPAC and the other commenters for their comments. We also agree that a discharge to community measure would likely be very important to beneficiaries and serve as a useful corollary to the 30-day readmissions measure we proposed in the FY 2014 IRF PPS proposed rule, because it reflects whether a patient returns home, rather than returning directly to the acute hospital or another inpatient facility. We have developed a strategic plan related to the types of quality measures that we will propose over the next several rulemaking cycles. Patient experience of care and care coordination measures, such as a discharge to community measure, are included in this plan. We have previously discussed a measure of discharge to community in one of the IRF-QRP Technical Expert Panels. We also agree with MedPAC's suggestion that adding quality measures that assess functional improvement should be a priority for the IRFQRP. At this time, our quality measure development contractor is completing the development of quality measures that specifically focus on outcomes related to improvement of a patient's functional status, and these measures have been

presented to the Measures Application Partnership (MAP) to determine whether the MAP at least supports the direction of the concept behind these measures (since the measures are not yet complete). The MAP and its functions are described in detail at <http://www.qualityforum.org/map/>. The development of these measures has necessitated several years of work, involving testing, revisions, and expert review. However, we are now close to being in our final stages of the development of these measures, and will present them to the MAP this year. Before proposing to adopt these measures, we want to take all steps necessary to ensure that the introduction of functional measurement into the IRF-QRP is comprehensive in design so as to be meaningful to our beneficiaries, Medicare and our stakeholders.

Comment: One commenter expressed concern about changes made by the CDC to the CAUTI infection definitions in 2013, and the pending review with further changes to the definition likely in early 2014. This commenter believed that instability of data between baseline years and into CY 2014 can be expected due to the changes in the CAUTI definitions. One commenter expressed support for the continued use of the CAUTI measure, but suggested that training could help to support a smooth transition when the new reporting definitions are introduced. The commenter further encouraged CMS to provide any training necessary that will support a smooth transition when new reporting definitions are introduced.

Response: According to the measure steward, Centers for Disease Control and Prevention (CDC), NHSN's definition of CAUTI did not change in 2013, and the revised criteria in 2013 for what constitutes a healthcare-associated infection (HAI) amounts to providing operational guidance—already widely in use before the guidance was published—that makes identifying HAIs more consistent across reporting healthcare facilities. There was no change in the NQF measure specification; the CAUTI measure remains the same. As a result, CAUTI data reported for infections occurring in 2013 can be compared to the CAUTI baseline established using CAUTI data reported for infections occurring in 2009. In short, there was no significant change in the measure and the changes in HAI criteria have no bearing on reporting obligations. We will continue to work with the NHSN to provide provider training on any changes affecting the IRF QRP.

Comment: One commenter expressed concern about the adequacy of the risk adjustment of the CAUTI measure, especially with regard to its impact on IRFs caring for patients with a spinal cord injury.

Response: With regard to risk adjustment, the CAUTI measure relies on robust statistical analysis to inform its risk adjustment methodologies to ensure that the measure is accurately reported. We will work with the CDC to continue to collect data and to explore the possibility of refining the CAUTI measure through NQF measure maintenance and future rulemaking, if the change is substantive, as more data is collected.

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

In the CY 2103 OPPTS/ASC final rule (77 FR 68500 through 68507) we finalized adoption of a non-risk-adjusted application of this measure

using the current version of the IRF-PAI. To adopt the NQF-endorsed version of this measure, we must update the existing IRF-PAI to include the additional data elements necessary to risk adjust this measure. We also delayed public reporting of pressure ulcer measure results until we amend the IRF-PAI to add the data elements necessary for risk adjusting NQF #0678 (77 FR 68507). We are not making any changes to the application of measure #0678 finalized in the CY 2013 OPPTS/ASC final rule for the FY 2015 and FY 2016 IRF PPS annual increase factors. Furthermore, we have not removed, suspended, or replaced this measure for those specific annual increase factors and the application of NQF #0678 remains an active part of the IRF QRP for that purpose. Additional information about this measure can be found at <http://www.qualityforum.org/QPS/0678>. Our procedures for data submission for this measure also have remained the same. IRFs should continue to collect and submit pressure ulcer measure data

during CY 2013 using the IRF-PAI released on October 1, 2012 for the FY 2015 IRF PPS annual increase factor. Further, IRFs should continue to collect and submit pressure ulcer measure data during the first three quarters of CY 2014 using the IRF-PAI released on October 1, 2012 for the FY 2016 IRF PPS annual increase factor.

In the May 8, 2013 proposed rule (78 FR 26909 through 26924), we did propose to adopt a revised version of the IRF-PAI starting October 1, 2014 for the FY 2017 PPS annual increase factor and subsequent fiscal years annual increase factors. We noted that the proposed revisions to the IRF-PAI would allow collection of data elements necessary for risk adjustment of NQF #0678, which is required by the NQF endorsed version of the measure. We also proposed to replace the current application of NQF #0678 and adopt instead the NQF endorsed version of this measure. We have discussed these proposed changes in more detail in section C. below.

TABLE 10—QUALITY MEASURES FINALIZED IN THE CY 2013 OPPTS/ASC FINAL RULE AFFECTING THE FY 2015 IRF ANNUAL INCREASE FACTOR AND SUBSEQUENT YEAR INCREASE FACTORS

| NQF measure ID | Measure title |
|-------------------------------|---|
| NQF #0138 | National Health Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure.+ |
| Application of NQF #0678 | Percent of Residents or Patients with Pressure Ulcers That are New or Worsened (Short-Stay).* |

+ Using CDC/NHSN.
* Using October 1, 2012 release of IRF-PAI.

C. New IRF QRP Quality Measures Affecting the FY 2016 and FY 2017 IRF PPS Annual Increase Factor, and Subsequent Year Increase Factors

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

In the May 8, 2013 proposed rule (78 FR 26909 through 26924), we noted that the successful development of an IRF quality reporting program that promotes the delivery of high-quality healthcare services in IRFs is our paramount concern. We discussed many of the factors we had taken into account in selecting measures to propose in the May 8, 2013 proposed rule (78 FR 26909 through 26924), and we refer readers there for details about our selection process. We do wish to note here that, in our measure selection activities for the IRF QRP, we must take into consideration input we receive from a multi-stakeholder group, the Measure Applications Partnership (MAP), which is convened by the NQF as part of a pre-rulemaking process that we have established and are required to follow under section 1890A of the Act. The

MAP is a public-private partnership comprised of multi-stakeholder groups convened by the NQF for the primary purpose of providing input to CMS on the selection of certain categories of quality and efficiency measures, as required by section 1890A(a)(3) of the Act. By February 1st of each year, the NQF must provide MAP input to CMS. We have taken the MAP's input into consideration in selecting measures for this rule. Input from the MAP is located at http://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx. We also take into account national priorities, such as those established by the National Priorities Partnership (NPP) at http://www.qualityforum.org/Setting_Priorities/NPP/National_Priorities_Partnership.aspx, the HHS Strategic Plan at <http://www.hhs.gov/secretary/about/priorities/priorities.html>, and the National Strategy for Quality Improvement in Healthcare at <http://www.ahrq.gov/workingforquality/nqs/nqs2012annlrpt.pdf>. To the extent practicable, we have sought to adopt measures that have been endorsed by a national consensus organization,

recommended by multi-stakeholder organizations, and developed with the input of providers, purchasers/payers, and other stakeholders.

2. New Measures for the FY 2016 and FY 2017 Annual Increase Factors

For the FY 2016 IRF PPS annual increase factor, in addition to retaining the previously discussed CAUTI and Pressure Ulcer measures, we proposed in the May 8, 2013 proposed rule (78 FR 26909 through 26924), to adopt one new measure: Influenza Vaccination Coverage among Healthcare Personnel Measure (NQF #0431). In addition, for the FY 2017 IRF PPS annual increase factor, we proposed to adopt three quality measures: (1) All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from Inpatient Rehabilitation Facilities, (2) Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680), and (3) the NQF endorsed version of Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short-Stay) (NQF

#0678). We discuss these measures in more detail below in this final rule.

2. New Quality Measures for Quality Data Reporting Affecting the FY 2016 IRF PPS Annual Increase Factor

a. IRF QRP Measure #1: Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431)

In the FY 2014 IRF PPS proposed rule (78 FR 26880), we proposed to adopt the CDC developed Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) measure that is currently collected by the CDC via the NHSN. This measure reports on the percentage of IRF health care personnel (HCP) who receive the influenza vaccination. We noted that this measure was included on the CMS' List of Measures under Consideration for December 1, 2012 and that this measure was reviewed by the MAP and was included in the MAP input that was transmitted to CMS on February 1, 2013, as required by section 1890A(a)(3) of the Act. The MAP fully supported the use of this measure in the IRF setting, indicating it promotes alignment across quality reporting programs (for example, with Long-Term Care Hospital Quality Reporting Program (LTCHQR Program) and Hospital Inpatient Quality Reporting Program (Hospital IQR)) and addresses a core measure concept.

Health care personnel are at risk for both acquiring influenza from patients and transmitting it to patients, and health care personnel often come to work when ill.² One early report of health care personnel influenza infections during the 2009 H1N1 influenza pandemic estimated 50 percent of infected health care personnel had contracted the influenza virus from patients or coworkers in the healthcare setting.³

The CDC Advisory Committee on Immunization Practices (ACIP) guidelines recommends that all health care personnel get an influenza vaccination every year to protect themselves and patients.⁴ Even though levels of influenza vaccination among health care personnel have slowly increased over the past 10 years, less

than 50 percent of health care personnel each year received the influenza vaccination until the 2009 and 2010 season, when an estimated 62 percent of health care personnel got a seasonal influenza vaccination. In the 2010 and 2011 season, 63.5 percent of health care personnel reported an influenza vaccination. Increased influenza vaccination coverage among health care personnel is expected to result in reduced morbidity and mortality related to influenza virus infection among patients, aligning with the NQS's aims of better care and healthy people/communities. This measure has been finalized for reporting in the Hospital IQR Program, LTCHQR Program, and the Ambulatory Surgical Center Quality Reporting Program (ASCQR Program).

We refer readers to the NHSN Manual, Healthcare Personnel Safety Component Protocol Module, Influenza Vaccination and Exposure Management Modules, which is available at the CDC Web site at <http://www.cdc.gov/nhsn/inpatient-rehab/hcp-vacc/index.html> for measure specifications and additional details.

In the FY 2014 IRF PPS proposed rule (78 FR 26909 through 26924), we proposed that the Influenza Vaccination Coverage Among Healthcare Personnel measure (NQF #0431) have its own reporting period to align with the influenza vaccination season, which is defined by the CDC as October 1st (or when the vaccine becomes available) through March 31st. We further proposed that IRFs will submit their data for this measure to the NHSN (<http://www.cdc.gov/nhsn/>). The National Healthcare Safety Network (NHSN) is a secure Internet-based healthcare-associated infection tracking system maintained by the CDC and can be utilized by all types of health care facilities in the United States, including IRFs. NHSN collects data via a web-based tool hosted by the CDC.

Information on the NHSN system, including protocols, report forms, and guidance documents can be found at the provided web link: <http://www.cdc.gov/nhsn/>. NHSN will submit data to CMS on behalf of the facility. We also proposed that for the FY 2016 IRF PPS annual increase factor data collection will cover the period from October 1, 2014 (or when the vaccine becomes available) through March 31, 2015 (78 FR 26909 through 26924).

Details related to the use of NHSN for data submission and information on definitions, numerator data, denominator data, data analyses, and measure specifications for the Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) measure can be found at <http://www.cdc.gov/nhsn/>

[inpatient-rehab/hcp-vacc/index.html](http://www.cdc.gov/nhsn/inpatient-rehab/hcp-vacc/index.html). Because IRFs are already using the NHSN for the submission of CAUTI data, the administrative burden related to data collection and submission for this measure under the IRF QRP should be minimal.

While IRFs can enter information in NHSN at any point during the influenza season for the healthcare personnel (HCP) influenza vaccination measure NQF #0431, data submission is only required once per influenza season, unlike the other measure finalized for the IRF QRP that utilizes NHSN (CAUTI measure NQF #0138). For example, IRFs can choose to submit HCP influenza vaccination data on a monthly basis. However, each time an IRF submits these data, it will be asked to provide a cumulative total of vaccinations for the "current" influenza season. Thus, entering this information at the end of the influenza season would yield the same total number of vaccinations. The NHSN system will not track the individual number of vaccinations on a monthly basis, but, rather, will track the cumulative total of vaccinations for the "current" influenza season. We proposed that the final deadline associated with this measure should align with the other CMS deadline for IRF HAI (CAUTI) reporting into NHSN, which is May 15th. IRF QRP data collection timelines and submission deadlines are discussed below.

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

We sought public comments on the Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) measure for the FY 2016 IRF PPS annual increase factor and subsequent years. The responses to public comments on our adopting NQF #0431 are discussed below in this section of the final rule.

Comment: Several commenters expressed unconditional agreement with our proposal to adopt the Influenza Vaccination Coverage among Healthcare Personnel measure in the IRF QRP. However, a majority of commenters

² Wilde JA, McMillan JA, Serwint J, *et al*. Effectiveness of influenza vaccine in healthcare professionals: A randomized trial. *JAMA*. 1999; 281:908–913.

³ Harriman K, Rosenberg J, Robinson S, *et al*. Novel influenza A (H1N1) virus infections among health-care personnel—United States, April–May 2009. *MMWR Morb Mortal Wkly Rep*. 2009; 58(23): 641–645.

⁴ Fiore AE, Uyeki TM, Broder K, *et al*. Prevention and control of influenza with vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2010. *MMWR Recomm Rep*. 2010. 59(08): 1–62.

expressed a conditional support for this measure in which they support the use of the measure by IRFs that are freestanding hospitals, but do not support the use of this measure by IRF units that are affiliated with an acute care facility. These commenters believe that IRF units should be excluded from this measure because most IPPS hospitals include IRF unit employees in reporting health care personnel influenza vaccination rates to NHSN under the IPPS Quality Reporting program.

Response: The intent of NQF measure #0431 is to incentivize full influenza vaccination coverage of all healthcare workers (HCWs) within a specific kind of facility and to measure the extent to which that goal is accomplished within that facility. We regard an IRF unit that is affiliated with an acute care facility to be its own separate type of facility, with its own responsibility for HCW vaccination and data submission. The submission of data by an IRF unit that is affiliated with an acute care facility will constitute location-specific reporting to NHSN for the HCWs who

have worked within that specific unit. These IRF units will need to account for any staff that work within the unit for one day or more between Oct 1st and March 31st of a flu season and fall within the 3 required categories of staff as defined by the NHSN protocol, including payroll employees, licensed independent practitioners, and students/trainees/volunteers. The acute care facility will have the same requirements for submission of data, but will need to cover all of its inpatient care units, which will include any existing IRF units that are affiliated with an acute care facility, and will essentially be reporting facility-wide counts. The data submitted for these two separate requirements will never be summed together.

Comment: Many of the commenters requested that CMS clarify that the data collection period for the influenza vaccine begins on October 1st and not at an earlier date, should the influenza vaccination become available at any time before October 1st.

Response: NHSN specifies the reporting period for influenza vaccine

coverage in its protocol. Vaccine coverage reporting, that is, measure numerator data, is required based on data collected from Oct 1 or whenever the vaccine becomes available. This statement ensures that if the vaccine is available early, any vaccines given before Oct 1 can be credited toward vaccination coverage, and if the vaccine is late, then the vaccination counts are to begin as soon as possible after Oct 1.

For the denominator count, IRFs will need to account for any staff that work within the unit for 1 day or more between Oct 1st and March 31st of a flu season and fall within the 3 required categories of staff as defined by the NHSN protocol, including payroll employees, licensed independent practitioners, and students/trainees/volunteers.

Final Decision: Having carefully considered the comments we received on the Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431), we are finalizing the adoption of this measure for use in the IRF QRP.

TABLE 11—SUMMARY OF QUALITY MEASURES AFFECTING THE FY 2016 IRF PPS ANNUAL INCREASE FACTOR

Continued Measure Affecting the FY 2015 Annual Increase Factor and Subsequent Year Annual Increase Factors:

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

Continued Measure Affecting the FY 2015 and FY 2016 Annual Increase Factors:

- Application of NQF #0678: Percent of Residents with Pressure Ulcers That are New or Worsened (Short-Stay). *

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

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

+ Using CDC NHSN.

* Using October 1, 2012 release of IRF–PAI.

3. Quality Measures for Quality Data Reporting Affecting the FY 2017 IRF PPS Annual Increase Factor and Subsequent Years

In the FY 2014 IRF PPS proposed rule (78 FR 26909 through 26924), we proposed to adopt 2 additional quality measures and replace an existing quality measure for the IRF QRP for the FY 2017 annual increase factor and subsequent year increase factors. The new measures we proposed are: (1) All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from Inpatient Rehabilitation Facilities, and (2) Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680). In addition, we proposed to replace the non-risk adjusted application of Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (short-stay) (NQF #0678) with adoption of the NQF-endorsed version of this measure. A summary of the public

comments received and our responses to comments are discussed below.

a. IRF QRP Measure #1: All-Cause Unplanned Readmission Measure for 30 Days Post Discharge From Inpatient Rehabilitation Facilities

In the May 8, 2013 proposed rule (78 FR 26909 through 26924), we proposed to adopt an All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from Inpatient Rehabilitation Facilities. This measure estimates the risk-standardized rate of unplanned, all-cause hospital readmissions for cases discharged from an IRF who were readmitted to a short-stay acute care hospital or LTCH, within 30 days of an IRF discharge. We noted that this is a claims-based measure which will not require reporting of new data by IRFs, and hence, will not be used to determine IRF reporting compliance for the IRF QRP.

Addressing unplanned hospital readmissions is a high priority for HHS and CMS as our focus continues on

promoting patient safety, eliminating healthcare associated infections, improving care transitions, and reducing the cost of healthcare. Readmissions are costly to the Medicare program and have been cited as sensitive to improvements in coordination of care and discharge planning for patients.⁵ Although the literature on readmissions is mainly concerned with discharges from short-term acute hospitals, the same issues of discharge planning, communications and coordination arise at discharge from other inpatient facilities.

IRFs provide intensive rehabilitation services to patients after an injury, illness, or surgery. According to MedPAC, the average length of stay for most patients in an IRF is 13.1 days.⁶ In 2010, almost 360,000 Medicare Fee-for-Service (FFS) beneficiaries received care

⁵ Federal Register/Vol. 76, No. 160/Thursday, August 18, 2011/Rules and Regulations, C1a.

⁶ MedPAC, Report to Congress, Medicare Payment Policy, March, 2012. http://www.medpac.gov/chapters/Mar12_Ch09.pdf.

in IRFs and cost the Medicare FFS program over \$6 billion dollars. The unadjusted readmission rate to an IPPS hospital in the 30 days following an IRF discharge was about 15 percent.⁷ With such a large proportion of patients being readmitted to a hospital level of care, we proposed a risk-adjusted measure of readmission rate, the All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from Inpatient Rehabilitation Facilities. An IRF's readmission rate is affected by complex and critical aspects of care, such as communication between providers or between providers and patients; prevention of, and response to, complications; patient safety; and coordinated transitions to the community or a less intense level of care. While disease-specific measures of readmission are useful in identifying deficiencies in care for specific groups of patients, they account for only a small minority of total readmissions. By contrast, a facility-wide, all-cause readmission reflects a broader assessment of the quality of care in IRFs, and may consequently better promote quality improvement and inform consumers about quality.

While some readmissions are unavoidable, such as those resulting from the inevitable progression of disease or worsening of chronic conditions, readmissions may also result from poor quality of care or inadequate transitions between care settings. Randomized controlled trials in short-stay acute care hospitals have shown that improvement in the following areas can directly reduce hospital readmission rates: Quality of care during the initial admission; improvement in communication with patients, their caregivers and their clinicians; patient education; pre-discharge assessment; and coordination of care after discharge. Successful randomized trials have reduced 30-day readmission rates by 20 to 40 percent.^{8 9 10 11 12 13 14} and a 2011 meta-

⁷ Bernard SL, Dalton K, Lenfestey N F, Jarrett NM, Nguyen KH, Sorensen AV, Thaker S, West ND. Study to support a CMS Report to Congress: Assess feasibility of extending the hospital-acquired conditions—present on admission IPPS payment policy to non-IPPS payment environments. Prepared for the Centers for Medicare & Medicaid Services (CMS Contract No. HHSM-500-T00007). 2011.

⁸ Jack BW, Chetty VK, Anthony D, Greenwald JL, Sanchez GM, Johnson AE, et al. A reengineered hospital discharge program to decrease rehospitalization: a randomized trial. *Ann Intern Med* 2009;150(3):178–87.

⁹ Coleman EA, Smith JD, Frank JC, Min SJ, Parry C, Kramer AM. Preparing patients and caregivers to participate in care delivered across settings: the Care Transitions Intervention. *J Am Geriatr Soc* 2004;52(11):1817–25.

analysis of randomized clinical trials found evidence that interventions associated with discharge planning helped to reduce readmission rates,¹⁵ illustrating how hospitals may influence readmission rates through best practices.

Because many studies have shown readmissions to be related to quality of care, and that interventions have been able to reduce 30-day readmission rates, we believe it is appropriate to include an all-condition readmission rate as a quality measure in the IRF QRP. Promoting quality improvements leading to successful transitions of care for patients moving from the IRF setting to the community or another post-acute care setting, and reducing preventable facility-wide readmission rates, is consistent with the National Quality Strategy priorities of safer, better coordinated care and lower costs.

Our approach to developing this measure is not the same as, but is in many ways very similar to NQF-endorsed Hospital-Wide (HWR) Risk-Adjusted All-Cause Unplanned Readmission Measure (NQF #1789) (http://www.qualityforum.org/Publications/2012/07/Patient_Outcomes_All-Cause_Readmissions_Expedited_Review_2011.aspx) finalized for the Hospital IQR Program in the FY 2013 IPPS/LTCH PPS Final Rule (FR 77 53521 through 53528). To the extent appropriate, we have harmonized the IRF measure with the HWR measure and other measures of readmission rates developed for post-acute care (PAC) settings, including LTCHs. We have

¹⁰ Courtney M, Edwards H, Chang A, Parker A, Finlayson K, Hamilton K. Fewer emergency readmissions and better quality of life for older adults at risk of hospital readmission: a randomized controlled trial to determine the effectiveness of a 24-week exercise and telephone follow-up program. *J Am Geriatr Soc* 2009;57(3):395–402.

¹¹ Garasen H, Windspoll R, Johnsen R. Intermediate care at a community hospital as an alternative to prolonged general hospital care for elderly patients: a randomized controlled trial. *BMC Public Health* 2007;7:68.

¹² Koehler BE, Richter KM, Youngblood L, Cohen BA, Prengler ID, Cheng D, et al. Reduction of 30-day post discharge hospital readmission or emergency department (ED) visit rates in high-risk elderly medical patients through delivery of a targeted care bundle. *J Hosp Med* 2009;4(4):211–218.

¹³ Naylor M, Broton D, Jones R, Lavizzo-Mourey R, Mezey M, Pauly M. Comprehensive discharge planning for the hospitalized elderly. A randomized clinical trial. *Ann Intern Med* 1994;120(12):999–1006.

¹⁴ Naylor MD, Broton D, Campbell R, Jacobsen BS, Mezey MD, Pauly MV, et al. Comprehensive discharge planning and home follow-up of hospitalized elders: a randomized clinical trial. *JAMA* 1999;281(7):613–20.

¹⁵ Naylor MD, Aiken LH, Kurtzman ET, Olds DM, Hirschman KB. The Importance of Transitional Care in Achieving Health Reform. *Health Affairs* 2011; 30(4):746–754.

provided more details about these measures and our attempts to harmonize with them below.

The All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from Inpatient Rehabilitation Facilities measure assesses returns to short-stay acute care hospitals or LTCHs within 30 days of discharge from an IRF to the community or another care setting of lesser intensity. Patient readmissions are tracked using Medicare claims data for 30 days after discharge, to the date of patient death, if the patient dies within 30 days of discharge. Because patients differ in complexity and morbidity, the measure is risk-adjusted for patient case-mix. The measure also excludes planned readmissions, because these are not considered to be indicative of poor quality of care on the part of the IRF.

A model developed by a CMS measure development contractor predicts admission rates while accounting for patient demographics, primary condition in the prior short stay, comorbidities, and a few other patient factors. While estimating the predictive power of patient characteristics, the model also estimates a facility specific effect common to patients treated at that facility. Similar to the Hospital IQR Program hospital-wide readmission measure, the IRF QRP measure is the ratio of the number of risk-adjusted predicted unplanned readmissions for each individual IRF, including the estimated facility effect, to the average number of risk-adjusted predicted unplanned readmissions for the same patients treated at the average IRF. A ratio above one indicates a higher than expected readmission rate, or lower level of quality, while a ratio below one indicates a lower than expected readmission rate, or higher level of quality. (The methodology report detailing the development of the IPPS hospital-wide measure and the NQF report may be downloaded from: http://www.qualityforum.org/Publications/2012/07/Patient_Outcomes_AllCause_Readmissions_Expedited_Review_2011.aspx.)

The patient population includes IRF patients who:

- Were discharged alive from the IRF.
- Had 12 months of Medicare Part A, Fee-for-Service coverage prior to the IRF stay.
- Had 30 days of Medicare Part A, Fee-for-Service coverage post discharge.
- Had an acute care facility (IPPS, CAH or psychiatric hospital) stay within the 30 days prior to the IRF stay.
- Were aged 18 years or above when admitted to the IRF.

As with the Hospital IQR Program hospital-wide readmission measure, patients with medical treatment for cancer are excluded. Studies of this population that were reviewed for the Hospital IQR Program readmission measure showed them to have a different trajectory of illness and mortality than other patient populations.¹⁶ The measure also excludes patients who died during the IRF stay, IRF patients under the age of 18, or IRF patients discharged against medical advice (AMA).

Readmissions that are not included in the measure are:

- Transfers from an IRF to another IRF or acute care facility.
- Readmissions within the 30-day window that are usually considered planned due to the nature of the procedures and principal diagnoses of the readmission.
- IRF stays with data that are problematic. (The Medicare data files occasionally have anomalous records that indicate a person is in two facilities or stays that overlap in dates, or are otherwise potentially erroneous or contradictory.)

The planned readmission list includes the planned procedures specified in the Hospital-Wide All-Cause Unplanned Readmission (HWR) Measure (NQF #1789) used in the Hospital IQR Program, plus other procedures that we determined in consultation with technical expert panels. In addition to the list of planned procedures is a list of diagnoses (provided at the link below in the planned readmission criteria), which, if found as the principal diagnosis on the readmission claim, would indicate that the procedure occurred during an unplanned readmission. The planned readmissions criteria may be found at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/Downloads/DRAFT-Specifications-for-the-Proposed-All-Cause-Unplanned-30-day-Post-IRF-Discharge-Readmission-Measure.pdf> with a link to the latest planned readmissions criteria used in the HWR at the end of Table 1.

A discharged patient is tracked until one of the following occurs: (1) The 30-day period ends; (2) the patient dies; or (3) the patient is readmitted to an acute level of care (short or long term). If multiple readmissions occur, only the first is considered for this measure. If the readmission is unplanned, it is counted as a readmission in the measure

rate. If the readmission is planned, the readmission is not counted in the measure rate. The occurrence of a planned readmission ends further tracking for readmissions in the 30-day window following discharge from the IRF.

Readmission rates are risk-adjusted for patient case-mix characteristics, independent of quality. The risk adjustment modeling estimates the effects of patient characteristics on the probability of readmission so they can be adjusted out when reporting the readmission rates. The risk-adjustment model for IRFs accounts for demographic characteristics, principal diagnosis, comorbidities, case-mix group in the IRF, length of stay in the prior acute care facility, critical care days in the prior acute care facility, number of acute care facility stays in the prior year, and the occurrence of various surgery types in the prior acute care facility stay. In modeling IRF readmissions, all patients are included in a single model. We did not divide patients into groups clinically, modeling separate patient types separately as was done in the IPPS HWR measure. In the HWR there are five patient cohorts, each modeled separately, and a combined score for the facility. All IRF patients are modeled as one group, both because IRFs have a substantially smaller patient population, restricting the ability to create reasonably large subgroups, and the technical expert panel did not recommend any such stratification.

While the HWR measure used 1 year of data, the smaller IRF patient population led us to merge 2 years of data for the IRF QRP. This approach is similar to that used by the Hospital IQR Program condition-specific readmission measures, such as that for heart attack and heart failure patients, which use 3 years of claims data. Increasing sample size by merging multiple years produces more precise estimates of the effects of all the risk adjusters and increases the sample size associated with each facility. Larger patient samples are generally better for meaningfully distinguishing facility performance. We proposed this measure under the exception authority in section 1886(m)(5)(D)(ii) of the Act for the IRF QRP. This section provides that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been

endorsed or adopted by a consensus organization identified by the Secretary.

We noted in the proposed rule we had not been able to identify an NQF-endorsed readmission measure that was appropriate for the IRF setting. In 2012, NQF endorsed hospital-wide readmission measures, the National Committee for Quality Assurance (NCQA) measure intended for health plans, Plan All-Cause Readmissions (NQF #1768), and CMS' Hospital-Wide All-Cause Unplanned Readmission Measure (HWR) (NQF #1789), of which the latter is the model for the All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from Inpatient Rehabilitation Facilities measure, proposed in the FY 2014 IRF PPS proposed rule. This measure was present on CMS's List of Measures Under Consideration, and the most recent MAP Pre-Rulemaking Report noted that "readmission measures are also examples of measures that MAP recommends be standardized across settings, yet customized to address the unique needs of the heterogeneous PAC/LTC population" (http://www.qualityforum.org/Publications/2013/02/MAP_Pre-Rulemaking_Report_-_February_2013.aspx (pp. 177-180)). Although the MAP supported the direction of this measure, they cautioned that the readmission measure required further development. The MAP has also continually noted the need for "care transition measures in PAC/LTC performance measurement programs" and stated that "setting-specific admission and readmission measures under consideration would address this need."¹⁷

In the May 8, 2013 proposed rule, we stated our intention to seek NQF endorsement of the All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from Inpatient Rehabilitation Facilities measure. We noted that because this is a claims-based measure not requiring reporting of new data by IRFs, this measure will not be used to determine IRF reporting compliance for the IRF QRP. We also stated that we expected to begin reporting feedback to IRFs on performance of this measure in CY 2016 and that initial provider feedback will be based on CY 2013 and CY 2014 Medicare FFS claims data related to IRF readmissions and that the readmission measure will be part of the IRF public reporting program once public reporting

¹⁶ National Quality Forum, "Patient Outcomes: All-Cause Readmissions Expedited Review 2011". July 2012. pp12.

¹⁷ National Quality Forum, *Measure Applications Partnership Pre-Rulemaking Report: 2013 Recommendations of Measures Under Consideration by HHS: February 2013*. Available at <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdIdentifier=id&ItemID=72738>.

is implemented. We noted that details pertaining to this measure can be found on the IRF Quality Reporting Program Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/index.html>. We invited stakeholders to submit public comments in response to our proposal to adopt the All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from Inpatient Rehabilitation Facilities. A summary of the public comments received and our responses to comments are discussed below.

Comment: Many commenters have expressed concern that CMS has not yet sought and obtained NQF endorsement for the IRF readmission measure.

Response: We are aware this measure is not yet NQF-endorsed for the IRF setting and are working to submit the measure for NQF review and endorsement. Currently, we are working with contractors to submit the measure for NQF endorsement in October 2013. For the time being, we have chosen to adopt this measure by exercising our authority to finalize a non-NQF endorsed measure when NQF endorsed measures are not available or appropriate for a setting and the Secretary has given due consideration to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We were not able to find a measure that was appropriate for the IRF setting.

Comment: Several commenters requested that additional risk adjusters be added to the risk adjustment model for the IRF readmission measure, including patient data such as function and social support, on the IRF-PAI.

Response: The proposed readmission measure is a risk-standardized readmission measure that adjusts for case-mix differences based on the clinical status of the patient at the time of admission to the IRF. That is, the measure is risk-adjusted for certain key variables that are clinically relevant or have been found to have strong relationships with the outcome, including age group, sex, comorbid diseases, history of repeat admissions. We also include as adjusters the IRF case-mix groups (CMGs). The 92 CMGs are patient classes based on information on the IRF-PAI and are reported on claims. The CMG assigned to a patient contain information on the reason for IRF treatment (impairment group), functional status, and sometimes cognitive status and age group. These data elements from claims further enhance risk adjustment which, along with information from the IRF-PAI, are sufficient without requiring linking the

IRF-PAI assessments themselves. We will investigate in the future if including data elements, such as function and social support, directly from the IRF-PAI would produce substantive improvement of the model.

Comment: Several commenters suggested that socioeconomic status and social factors be added to the risk adjustment model for the IRF readmission measure.

Response: The inclusion of factors related to socioeconomic status (SES) has been raised in the context of the IPPS Hospital IQR measures and our policy in that program omits them as explicit risk adjusters. Medicaid dual eligibility, which is related to income, is a socioeconomic factor, and is also not accounted for explicitly in IQR measures. The IRF measure harmonizes with the other readmission measures in that respect (the IQR and the final long-term care hospital readmission measure). The effect of SES is similar in the case of IRFs to the effects in the IPPS setting and the reasoning for not explicitly accounting for SES is similar. The effect of levels of SES is captured to a great extent by other variables included in the model. The readmission measure is a risk-standardized readmission measure that adjusts for case-mix differences based on the clinical status of the patient at the time of admission to the hospital. That is, they are risk-adjusted for certain key variables (for example, age, sex, comorbid diseases, and a history of repeat admissions) that are clinically relevant and/or have been found to have strong relationships with the outcome. To the extent that race or SES results in certain patient groups having a worse medical condition profile, those factors are accounted for in the measure.

These measures are not otherwise adjusted for other factors such as race or English language proficiency. We believe such additional adjustments are not appropriate because the association between such patient factors and health outcomes can be due, in part, to differences in the quality of health care received by groups of patients with varying race/language/SES. Differences in the quality of health care received by certain racial and ethnic groups may be obscured if the measures risk-adjust for race and ethnicity. In addition, risk-adjusting for patient race, for instance, may suggest that hospitals with a high proportion of minority patients are held to different standards of quality than hospitals treating fewer minority patients. We appreciate the concerns of hospitals that care for disproportionately large numbers of disadvantaged populations. Our

analysis indicates that better quality of care is achievable regardless of the demographics of the hospital's patients.

Comment: Many commenters, including MedPAC, suggested the IRF readmission measure should focus on avoidable or related hospitalizations.

Response: The issue of all-cause readmissions as opposed to a more focused set of readmission types has been raised in other contexts such as the HWR IQR measure. Discussions with technical experts have led us to prefer using an all-cause measure rather than a condition-specific readmissions measure. A measure of avoidable or related readmissions is possible when the population being measured is narrowly defined and certain complications are being targeted. For broader measures, a narrow set of readmission types is not practical. In addition, readmissions may be clinically related even if they are not diagnostically related. A patient may have comorbid conditions that are unrelated to the reason for rehabilitation. If not properly dealt with in discharge planning a readmission for such a condition may become more likely. One of the primary purposes of a readmission measure is to encourage improved transitions at discharge, a choice among discharge destinations and care coordination. A readmission can occur that is less related to the primary condition being treated in the IRF than to the coordination of care post-discharge. That said, we have chosen to reduce the all-cause readmission set by excluding readmissions that are normally for planned or expected diagnosis and procedures. We augmented the research for the Hospital IQR set of planned readmissions for the IRF setting with recommendations and input from a TEP in the field of post-acute care (including IRFs). Nearly 9 percent of readmissions are considered planned. In the case where the readmission is due to a random event, such as a car accident, we expect these events to be randomly distributed across hospitals.

Comment: Several commenters indicated that the readmission measure may have the unintended consequence of reducing access to IRF care.

Response: We recognize that in some cases, hospital readmission will occur. Hospital readmission is not considered as a "never event" that hospitals are expected to reduce to zero. The measure of hospital readmission is risk-adjusted to account for the factors that increase this readmission risk, so that hospitals with a disproportionately larger share of patients who are at high risk for readmission do not perform worse on

the quality measure due to factors out of their control. We appreciate the commenters' concerns but the risk adjustment is intended to adjust for more complex patients so that access to care will not be reduced. Nonetheless, as with all quality measures that we have implemented, we will examine IRF data to monitor for potential unintended consequences.

Comment: Some commenters suggested that more than 2 years of data be included in the readmissions measure to increase sample size.

Response: The 2 years of data for each reporting period is a compromise between sample size and timeliness. In this case the total number of IRF stays in 1 year of national data is much smaller than the number of IPPS stays. However, 2 years of data generally yield good sample sizes at the facility level. Ninety-five percent of facilities have more than 100 patients averaged in their measure. We do not think that 3 years of data is needed at this time. However, we will continue to monitor this data over time and if there is a significant change in number of IRF discharges in total or in individual facilities we will reconsider the data requirement.

Final Decision: Having carefully considered the comments we received on the All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from Inpatient Rehabilitation Facilities, we are finalizing the adoption of this measure for use in the IRF QRP. We will also continue to seek NQF endorsement of the All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from Inpatient Rehabilitation Facilities measure.

b. IRF QRP Quality Measure #2: Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680)

In the May 8, 2013 proposed rule (78 FR 26909 through 26924), we proposed to add the NQF #0680 Percent of Residents or Patients who were assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) measure to the IRF QRP, and we proposed to collect the data for this measure through the addition of data items to the Quality Indicator section of the IRF-PAI. We noted that this measure was on CMS's list of measures under consideration that were reviewed by the MAP and was included in the MAP input that was transmitted to CMS, as required by the pre-rulemaking process in section 1890A(a)(3) of the Act. The MAP panel supported the use of this measure in the IRF setting, noting that it promotes alignment across

settings and addresses a core measure concept.

Although influenza is prevalent among all population groups, the rates of death and serious complications related to influenza are highest among those ages 65 and older and those with medical complications that put them at higher risk. The CDC reports that an average of 36,000 Americans die annually from influenza and its complications, and most of these deaths are among people 65 years of age and over.¹⁸ In 2004, approximately 70,000 deaths were caused by influenza and pneumonia, and more than 85 percent of these deaths were among the elderly.¹⁹ Given that many individuals receiving health care services in IRFs are elderly and/or have several medical conditions, many IRF patients are within the target population for influenza immunization.^{20 21}

We have also proposed to add the data elements needed for this measure, as an influenza data item set, to the Quality Indicator section of the IRF-PAI and that data for this measure will be collected using a revised version of the IRF-PAI. Our proposed revision of the IRF-PAI includes a new data item set designed to assess patients' influenza vaccination status. The revised IRF-PAI would become effective on October 1, 2014. We noted that these proposed data set items are harmonized with data elements (O0250: Influenza Vaccination Status) from the Minimum Data Set (MDS) 3.0 and LTCH CARE Data Set item sets^{22 23} and that the specifications

¹⁸ Centers for Medicare & Medicaid Services (2011, May). Adult Immunization: Overview. Retrieved from <https://www.cms.gov/Immunizations/>.

¹⁹ Gorina Y, Kelly T, Lubitz J, et al. (2008, February). Trends in influenza and pneumonia among older persons in the United States. *Aging Trends* no. 8. Retrieved from <http://www.cdc.gov/nchs/data/ahcd/agingtrends/08influenza.pdf>.

²⁰ Centers for Disease Control and Prevention. (2008, September). Influenza e-brief: 2008–2009 flu facts for policymakers. Retrieved from http://www.cdc.gov/washington/pdf/flu_newsletter.pdf.

²¹ Zorowitz, RD. Stroke Rehabilitation Quality Indicators: Raising the Bar in the Inpatient Rehabilitation Facility. *Topics in Stroke Rehabilitation* 2010; 17 (4):294–304.

²² Centers for Medicare & Medicaid Services. MDS 3.0 Item Subsets V1.10.4 for the April 1, 2012 Release. Retrieved from https://www.cms.gov/NursingHomeQualityInits/30_NHQIMDS30TechnicalInformation.asp.

²³ The LTCH CARE Data Set Version 2.00, the data collection instrument for the submission of the Percent of Residents or Patients with Pressure Ulcers That are New or Worsened (Short-Stay) measure and the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) measure, is currently under review by the Office of Management and Budget (OMB) in accordance with the Paperwork Reduction Act (PRA) <http://www.gpo.gov/fdsys/pkg/FR-2013-02-01/pdf/2013-02155.pdf>. The LTCH CARE Data Set Version 1.01

and data elements for this proposed measure are available in the MDS 3.0 QM User's Manual available on our Web site at <https://www.cms.gov/NursingHomeQualityInits/Downloads/MDS30QM-Manual.pdf>.

For purposes of this measure, the influenza vaccination season consists of October 1st (or when the vaccine becomes available) through March 31st each year. We proposed that while an IRF's compliance with reporting quality data for this measure will be based on the calendar year, the measure calculation and public reporting of this measure (once public reporting is implemented) will be based on the influenza vaccination season starting on October 1 (or when vaccine becomes available) and ending on March 31 of the subsequent year.

The IRF-PAI Training Manual will indicate how providers should complete these items during the time period outside of the vaccination season (that is, prior to October 1st or when vaccine becomes available and after March 31 of the following year). The measure specifications for this measure, Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680), can be found on the CMS Web site: <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/NHQIQualityMeasures.html>. Measure specifications are located in the download titled: MDS 3.0 QM User's Manual V6.0. Additional information on this measure can also be found at <http://www.qualityforum.org/QPS/0680>.

In the May 8, 2013 proposed rule, we invited public comment on our proposal to use 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 IRF PPS annual increase factor and subsequent years. A summary of the public comments received and our responses to comments are discussed below.

Comment: Several commenters indicated that they did not support the patient immunization measure because it is not a core focus of care in IRFs.

Response: While we appreciate the commenters' point of view, influenza is a serious illness, especially for patients who are elderly, immuno-compromised, or who have recently undergone surgery—characteristics that describe

was approved on April 24, 2012 by OMB in accordance with the PRA. The OMB Control Number is 0938–1163. Expiration Date April 30, 2013.

many of the patients in IRFs. CDC reports that pneumonia and influenza were the 5th leading cause of death amongst individuals 65 and older and that between 1997 and 2007, deaths among people aged 65 and older accounted for 87.9 percent of deaths related to pneumonia and influenza. Providing appropriate influenza vaccination is an important preventative measure that is the responsibility of healthcare providers in all settings. Although many patients may have already been offered and/or received the influenza vaccine in the acute care setting, the ultimate goal is that 100 percent of patients are assessed for appropriate receipt of the influenza vaccine, and achieving this goal requires the participation of all healthcare providers.

Comment: Several commenters expressed concern that the NQF #0680 Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine is redundant because patients are offered many opportunities to receive the influenza vaccination prior to admission into the IRF and are highly likely to have already received the influenza vaccine in the acute care hospital. Several commenters also noted that the patient influenza measure may lead to over-vaccination of patients.

Response: We appreciate the comments and acknowledge the commenters' concern for redundancy and over-vaccination. The specifications for the Percent of Patients or Residents Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (short stay) measure are written so that clinicians can document if patients have already received the influenza vaccine for the current influenza season. The numerator statement of the measure includes patients who received the influenza vaccine, either inside or outside the IRF, for the current influenza season. An IRF can report that a patient received the vaccine prior to admission to the IRF and that it should not re-vaccinate the patient for purposes of being able to report the patient receiving a vaccination in the IRF. We acknowledge that facilities will need to adhere to the principles of proper care coordination and documentation to avoid over-immunization and under-immunization. However, the specifications for the measure are designed to encourage facilities to only vaccinate when the patient has not already received the vaccination.

Comment: Several commenters requested guidance on how to track down the influenza vaccination history of patients.

Response: We refer commenters to the measure description and specifications of the NQF-endorsed measure at the NQF Web site <http://www.qualityforum.org/QPS/0680>. Further, to the extent that the commenters are asking us to issue guidance on proper vaccine documentation for purposes of ensuring that the receiving facility has an accurate immunization history, we agree that care coordination is essential to avoid over- as well as under-immunization. The influenza vaccination measure, however, was not designed to offer guidance to providers on how to vaccinate. The measure is specified to assess if the patient was vaccinated, where the patient was vaccinated (if they were vaccinated), or why the vaccination was not given (if the patient was not vaccinated). Patients who were not vaccinated due to a contraindication and patients who refused the vaccination are both counted in the numerator and accounted separately in the numerator of the measure. In a situation where vaccination status is unknown, we would expect that the IRF provider would make a clinical judgment on whether or not to vaccinate a patient, taking into account the patient's medical history and current health status, as well as the existing policy of their IRF on vaccination. The IRF must only report the decision it made; that is, whether the vaccination was or was not given. The measure does not require an IRF to provide a vaccination that was not appropriate due to a contraindication or a patient refusal, or to provide a vaccination to a patient who was already given a vaccination outside of the IRF. We encourage all IRFs to vaccinate according to their facilities' policies and the best clinical judgment of the medical providers treating each individual patient and to document the reason for the vaccination decision in the patient's medical record.

Comment: Many commenters requested clarification about the data collection period for the patient influenza vaccine.

Response: Starting with 2014–2015 Influenza season data collection will be required for all patients in the IRF for 1 or more days between October 1 and March 31. Clinicians can report that the reason a given patient did not receive the vaccine was that the patient was not in the facility during the current influenza vaccination season. Consistent with NQF #0431, the vaccination measure for healthcare personnel, it is the vaccinations received for patients in the IRF during the influenza season (October 1st to March 31st) that will be

included in measure calculations and for the purpose of public reporting.

Final Decision: After careful consideration of the public comments received, we are finalizing our proposal to adopt 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 IRF PPS annual increase factor and subsequent years. We are additionally clarifying that data collection will begin starting with the 2014–2015 Influenza season. Data collection for this and all subsequent influenza seasons will be from October 1 through March 31 of the following year. All data collection and submission guidelines will be addressed in the IRF Quality Reporting Manual.

c. IRF QRP Quality Measure #3: Percent of Residents or Patients With Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678)—Adoption of the NQF-Endorsed Version of This Measure

In the May 8, 2013 proposed rule (78 FR 26909 through 26924), we have proposed to adopt the NQF-endorsed version of the NQF #0678 pressure ulcer measure, with data collection beginning October 1, 2014 using the revised version of IRF-PAI, for quality reporting affecting the FY 2017 and subsequent years IRF PPS annual increase factors. We also proposed to remove the current non-risk adjusted application of this measure when the revised IRF-PAI is implemented on October 1, 2014. We noted in the proposed rule that, until September 30, 2014, IRFs should continue to submit pressure ulcer data using the IRF-PAI released on October 1, 2012 for the purposes of data submission requirements for the FY 2015 and FY 2016 IRF PPS increase factors. Details about our proposed changes to the IRF-PAI and additional information regarding data submission are discussed in the proposed rule (78 FR 26909 through 26924).

We invited public comment in response to our proposed removal of the currently adopted non-risk adjusted application of the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (short-stay) (NQF #0678) and the adoption of the NQF-endorsed version of the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (NQF #0678). A summary of the public comments received and our responses to comments are discussed below in this final rule.

Comment: Several commenters expressed support for our proposal to remove the currently adopted non-risk

adjusted application of the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (short-stay) (NQF #0678) and adopt the NQF endorsed version of the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) for the FY 2017 annual increase factor. These commenters also expressed general

support for the addition of the risk adjustment factors associated with this measure to the IRF-PAI.

Response: We appreciate the commenters for their supportive comments and their feedback for the measure to the IRF-PAI.

Final Decision: After careful consideration of the comments received, we are finalizing our proposal to adopt

the NQF-endorsed version of the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (short-stay) (NQF #0678) measure beginning on October 1, 2014, using the revised version of the IRF-PAI. We are also finalizing our proposal to remove the existing non-risk adjusted application of NQF #0678 from the IRF QRP effective October 1, 2014.

TABLE 12—SUMMARY OF MEASURES AFFECTING THE FY 2017 IRF PPS ANNUAL INCREASE FACTOR AND SUBSEQUENT YEAR INCREASE FACTORS

Continued Measure Affecting the FY 2015 Annual Increase Factor:

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

New IRF QRP Measure Affecting the FY 2016 IRF PPS Annual Increase Factor:

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

New IRF QRP Measures Affecting the FY 2017 IRF PPS Annual Increase Factor:

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

+ Using CDC/NHSN.

* Using the IRF-PAI released October 1, 2014.

^ Medicare Fee-For-Service claims data.

D. Changes to the IRF-PAI That Are Related to the IRF Quality Reporting Program

1. General Background

A version of the IRF-PAI has been in use in the IRF setting since January 1, 2002, when IRFs first began receiving payment under the IRF PPS. IRFs must submit a completed IRF-PAI for each Medicare Part A, B, and C patient that is admitted and discharged from the IRF.

The IRF PPS utilizes information from the IRF-PAI to classify patients into distinct groups based on clinical characteristics and expected resource needs. Separate payments are calculated for each group, including the application of case and facility level adjustments available at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/index.html>.

In the FY 2014 proposed rule, we proposed to release an updated version of the IRF-PAI on October 1, 2014 (78 FR 26909-26924). Proposed revisions included data elements that will (1) allow for risk adjustment of the NQF #0678 Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay), (2) allow for voluntary submission of more detailed data collection related to NQF #0678 Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay), and (3) allow for data collection for NQF #0680 Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay).

We also proposed to adopt a new numbering schema for the IRF-PAI.

What we have proposed includes both mandatory and voluntary additions to the IRF-PAI. Collection of voluntary data elements by IRFs will have no impact on measure calculations or on our determination of whether the IRF has met the reporting requirements under the IRF QRP. In contrast, failure to complete mandatory data elements may result in non-compliance with the IRF QRP requirements and subject the facility to a 2 percentage point reduction in its annual increase factor. We have provided more details about these items below at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/Spotlights-Announcements.html> under “CMS-10036”.

The October 1, 2014 release of the IRF-PAI that we proposed, inclusive of all the changes that we intend to finalize here, and information about the IRF-PAI submission process can be found at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Downloads/508c-IRF-PAI-2014.pdf>. A PRA package for the revised IRF-PAI discussed here has been submitted for the Office of Management and Budget's (OMB) review and approval. The PRA package documents are available for viewing on the CMS PRA Listings Web page at: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS1216518.html?DLPage=1&DLFilter=IRF-PAI&DLSort=1&DLSortDir=>

descending. The PRA package form number is cms-10036, and the OMB control number for this PRA package is 0938-0842.

a. Background Related to Collection of Pressure Ulcer Data Elements Using the IRF-PAI

In the FY 2012 IRF PPS final rule, we finalized a proposal to adopt an application of the NQF #0678 “Percent of Residents with Pressure Ulcers That Are New or Worsened (Short-Stay)” measure for use in the IRF QRP, beginning with the IRF PPS annual increase factor for FY 2014. We also finalized our proposal to collect the data for this pressure ulcer measure using the IRF-PAI. In order to comply with section 3004 of the Affordable Care Act requirements, we deleted the set of outdated pressure ulcer assessment items that were voluntary quality questions and had been located in the “Quality Indicator” section of the IRF-PAI and replaced them with a new set of pressure ulcer quality measure data items that were designed to capture the data necessary for the finalized application of NQF #0687. These items were modeled after the MDS 3.0 items, numbered 48A to 50D, and changed the status of the pressure ulcer data items from “voluntary” to “mandatory.” These revisions to the IRF-PAI went into effect on October 1, 2012.

Since the publication of the FY 2012 final rule (76 FR 47836) we have received numerous comments about the current version of the IRF-PAI from IRF providers, provider organizations, and

advocacy groups. In the CY 2013 OPPS/ASC final rule, we discussed a number of specific public comments related to pressure ulcer data that we received in response to the CY 2013 OPPS/ASC IRF proposed rule (77 FR 68506). In that CY 2013 proposed rule, we proposed to update the application of NQF #0678 that we had previously incorporated into the IRF QRP by instead incorporating the actual NQF-endorsed version of this measure (77 FR 45196). NQF #0678 is a risk adjusted measure. Commenters expressed specific concerns regarding the ability of the data elements in the IRF-PAI to sufficiently risk-adjust the measure. We agreed that there were limitations related to the risk adjustment data items that are on the IRF-PAI that went into effect on October 1, 2012, impacting the ability to calculate the measure using all of the risk adjustment related covariates. As a result, the CY 2013 OPPS/ASC final rule adopted an application of #0680 without risk-adjustment for FY 2015 and subsequent years (77 FR 68507).

In the proposed rule, we noted that in response to the comments and feedback received in previous rules discussed above, we intended to propose modifications to the data items in both the admission and discharge IRF-PAI assessments as discussed below.

2. Revisions to the IRF-PAI To Add Mandatory Risk Adjustment Data Items for NQF #0678 Percent of Residents or Patients With Pressure Ulcers That Are New or Worsened (Short-Stay)

In the FY 2014 IRF PPS proposed rule (78 FR 26909–26924), we proposed to update the current IRF-PAI to include data elements that are necessary to risk adjust the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678). These updates to the IRF-PAI include the addition of the following indicator boxes to the IRF-PAI admission assessment: (1) Peripheral Vascular Disease, (2) Peripheral Arterial Disease, and (3) Diabetes. The additions would be placed in the Quality Indicators section of the revised IRF-PAI.

We further determined that risk adjustment factors related to height and weight had inadvertently been left off of the revised version of the IRF-PAI that became effective on October 1, 2012. We proposed to add height and weight to the IRF-PAI to correct this oversight into the “Medical Information” section of the IRF-PAI. As a general rule, we would place all data items related to quality reporting and quality measures within the Quality Indicator section of

the IRF-PAI. However, the height and weight items have a dual purpose because they can be used for the calculation of Body Mass Index (BMI), which is used as one part of the analysis for compliance with the 60 percent rule. Even though the height and weight items are placed in the “Medical Information” section of the IRF-PAI, they are also being added to the IRF-PAI for calculating risk adjustment for the pressure ulcer measure. Failure to provide height and weight information could result in a finding of non-compliance with the reporting requirements.

We invited public comment on our proposal to include data elements required for risk-adjustment of NQF #0678 Percent of Patients with Pressure Ulcers That Are New or Worsened measure as mandatory data collection elements in the revised IRF-PAI. Below is a summary of public comments received for the additional elements required for risk-adjustment of the pressure ulcer measure, and our responses to these comments.

Comment: One commenter questioned the use of peripheral artery disease (PAD), peripheral vascular disease (PVD), and diabetes mellitus (DM) as risk adjusters for the pressure ulcer quality measure.

Response: Peripheral Arterial Disease, Peripheral Vascular Disease, and Diabetes are all conditions affecting perfusion and oxygenation, which are considered to impact risk of pressure ulcer development. Conditions causing issues of sensory perception (for example, peripheral neuropathy) or an alteration to intact skin (dry skin, erythema and other skin alterations) also are considered to impact risk of pressure ulcer development (Pressure Ulcer Prevention Clinical Practice Guideline, NPUAP). Additionally, statistical analyses showed that these factors were found to be significantly associated with the development of pressure ulcers when risk adjustment models were tested in a large sample of IRF patients.

Comment: Several commenters requested that CMS consider adding impairment group as a risk adjuster for the pressure ulcer measure.

Response: When developing the pressure ulcer quality measure, we reviewed the literature and obtained input from clinicians on which factors should be tested as potential risk adjusters. Various measurements of functional status/functional impairment were tested on a large sample of IRF patients, and were not found to be statistically significant in the population as a whole. We will continue to analyze

this measure as more data is collected and will consider testing additional risk adjusters for future iterations of the measure.

Comment: A commenter expressed concern that the adoption of the NQF-endorsed version of the pressure ulcer measure “may be too premature.” This commenter noted that CMS recently held a technical expert panel to discuss the potential development of a standardized set of pressure ulcer measurement items to be used across multiple healthcare settings (referred to as “cross-setting”), and therefore, this commenter suggested that CMS delay implementing the revised pressure ulcer items.

Response: It was necessary for us to finalize development of the proposed updates to the pressure ulcer data items for the October 1, 2014 IRF-PAI release prior to work on the cross-setting pressure ulcer measures because of the significant amount of time required to implement such a data item set. However, we will continue to work on improving the data collection efforts to ensure that the most relevant patient information is obtained.

Final Decision: After careful consideration of the public comments we received, we are finalizing our proposal to include the additional risk adjustment elements discussed above to the IRF-PAI for the purpose of risk-adjustment for NQF #0678 Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay).

3. Revisions to the IRF-PAI To Add Voluntary Data Items Related to NQF #0678 Percent of Residents or Patients With Pressure Ulcers That Are New or Worsened (Short-Stay)

The pressure ulcer measure numerator for the NQF #0678 endorsed version of the “Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay)” measure looks at the number of patients with a target assessment during the selected time window who have one or more Stage 2 through 4 pressure ulcer(s) that are new or that have worsened compared with the previous assessment. According to the NQF Web site, in its description of NQF #0678, “Stage 1 pressure ulcers are excluded from this measure because recent studies have identified difficulties in objectively measuring them across different populations.” The measure numerator also does not include what is referred to as “unstageable” pressure ulcers, which we describe below. The data that has been mandatory for IRFs to report under the IRF QRP are those that met

the requirements of the application of NQF #0678 that we finalized in the CY 2013 OPPTS/ASC final rule (as incorporated into the 2012 version of the IRF PAI), which reflected the same staging for pressure ulcers as the NQF-endorsed version of the measure. We have proposed to include in the 2014 version of the IRF-PAI additional mandatory data items to accommodate the risk adjustment requirements of the NQF-endorsed version of this measure.

We have received feedback from providers through a variety of sources (including a May 2, 2012 in-person training and special open door forums that occurred on November 29, 2011; April 19, 2012; July 26, 2012; August 16, 2012; September 20, 2012; and October 18, 2012) in regard to the pressure ulcer items on the IRF-PAI. Additionally, we have received feedback in the form of questions from IRF providers submitted to the IRF Quality Reporting Program Helpdesk.

We learned from provider feedback that a majority of IRF providers want the ability and flexibility to document information about all stages of pressure ulcers (numerical stages 1 through 4 and pressure ulcers that are not numerically stageable due to suspected deep tissue injury, slough and/or eschar, or non-removable devices, known as unstageable pressure ulcers), in addition to data on the stages of pressure ulcers required for the quality measure, and that they felt this extended documentation would allow them to track the evolution of pressure ulcers. We further learned that many providers felt that it is important to have a way to document information about healed pressure ulcers because they wanted us to know about these positive outcomes.

In response to the feedback we received from providers, we proposed to add voluntary data items to the IRF-PAI Quality Indicators section, designed to address providers' concerns about the adequacy of current pressure ulcer data items. As modified, our proposed admission assessment consists of 2 main topics: (1) Unhealed Pressure Ulcers; and (2) Pressure Ulcer Risk Conditions. Also, the discharge assessment consists of 2 main topics: (1) Unhealed Pressure Ulcers; and (2) Healed Pressure Ulcers. Within each main topic there are sub-topics that contain a set of questions. The provider is asked to document how many pressure ulcers, if any, the patient has at each stage upon admission. We have added new questions that extend beyond stages 2 through 4 pressure ulcers, covering the presence of stage 1 pressure ulcers, as well as unstageable pressure ulcers that are due to a non-removable device or dressing, to slough

or eschar, or deep tissue injury. We note that the discharge assessment differs somewhat from the admission assessment with regard to the pressure ulcer questions. A copy of the 2014 IRF-PAI can be found at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/IRFPAL.html>.

We have added this greater specificity to the pressure ulcer items to allow providers to document pressure ulcers in more detail. In describing the inadequacy they perceived in the present pressure ulcer items, providers described such situations as those in which a patient is admitted into an IRF with an unstageable pressure ulcer that is a suspected deep tissue injury (DTI). During the course of the IRF stay the DTI evolves into a stage 3 and, after several days, worsens to a stage 4. On the current version of the IRF-PAI, providers have no ability to document the presence of an unstageable pressure ulcer that existed when the patient was admitted. Whether or not the IRF believes there is an unstageable pressure ulcer, the IRF must document that the patient had no pressure ulcers on the admission assessment. However later, after the DTI worsens to a stage 3, if the IRF judges from the nature of the pressure ulcer that it was extremely likely to have been present at admission, the IRF would have to go back and change their documentation on the admission assessment to reflect that the patient actually had a stage 3 pressure ulcer upon admission. Upon discharge, the IRF would document that the patient has a stage 4 pressure ulcer. With the new pressure ulcer data items for 2014, the IRF will be able to document the presence of the unstageable pressure ulcer or suspected DTI on the admission assessment. The revisions to the IRF-PAI for 2014 will allow the IRF to give a more complete and accurate picture of the progression of this pressure ulcer when the patient is discharged.

While Stage 1 and unstageable pressure ulcers are not part of the NQF #0678 endorsed version of the "Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay)," and are not mandatory, we nonetheless believe that it is appropriate and important for us to collect this information. As the measure steward for this measure, CMS would like to gather and analyze data regarding Stage 1 and unstageable pressure ulcers to help determine if any modification to the existing measure should be made. This data could also help us determine if any additional pressure ulcer measures should be developed. For

example, collecting data about Stage 1 pressure ulcers could provide us with information that would allow us to assess whether these pressure ulcers can now be objectively measured across different populations.

Additionally, as we have noted above, some pressure ulcers that are present on admission can become stageable and then worsen to a higher stage during the IRF stay. Access to data on these kinds of situations would assist us in determining whether including unstageable and Stage 1 measures in the measure results may be appropriate in the future. We might accomplish this by expanding the current measure or developing an entirely new pressure ulcer measure.

We invited public comment on our proposed revisions to the IRF-PAI of voluntary items related to the staging of pressure ulcers. We received the following public comments in response to our proposals for the addition of these voluntary pressure ulcer items to the IRF-PAI.

Comment: Several commenters suggested that stage 1 pressure ulcers should not be collected on the IRF-PAI.

Response: We obtained feedback from providers on the pressure ulcer items on the IRF-PAI released in October 2012 during Provider Trainings, Open Door Forums, and via the Quality Reporting Program Helpdesk. Based on the feedback we received, we learned that many IRF providers want the ability to document as much information as possible about all types of pressure ulcers and feel that this will help them to better track the evolution of pressure ulcers. Because it would be useful to us, as well as providers, to obtain complete, accurate information about the quality of care being provided in IRFs, we included fields for the documentation of all stages of pressure ulcers, including Stage 1 and Unstageable pressure ulcers. However, NQF #0678 covers only Stages 2-4 pressure ulcers. Stage 1 pressure ulcers are not included in the quality measure. If a facility does not wish to report data on these pressure ulcers, they are under no obligation to do so.

Comment: Several commenters requested that each IRF-PAI quality indicator pressure ulcer item be labeled as to whether it is mandatory or voluntary. Another commenter recommended that the voluntary IRF-PAI quality indicator pressure ulcer items be segregated from the mandatory items, or that CMS in some way on the IRF-PAI indicate which of the items are voluntary.

Response: We have posted on our Web site a detailed matrix that identifies which data elements will be required,

and which will be voluntary (available at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/Spotlights-Announcements.html>) and this matrix will also be incorporated into the final IRF PAI Training Manual which will be posted on CMS IRF PPS Web site. We do not directly indicate on the IRF-PAI which items are mandatory versus which items are voluntary. These designations are subject to change, and although we can address such changes in rulemaking, the IRF-PAI is only released biannually. Thus, our ability to change these designations on the IRF-PAI itself is limited and could lead to provider confusion should these designations not align with current policy because they have changed during the interim year when we do not have a new release of the IRF-PAI.

Comment: One commenter suggested that if a pressure ulcer is discovered after the removal of a “non-removable device or other dressing” during the IRF stay, and there was no documentation of this wound from the discharging hospital, this should not be counted on the IRF-PAI due to issues of attribution.

Response: Assessment items collecting data on unstageable pressure ulcers are voluntary. However, if a numerically staged pressure ulcer is observed when a non-removable device/dressing is removed, and the pressure ulcer is still present at the time of discharge, that pressure ulcer will be reported on the IRF-PAI at discharge. If there were documentation that the pressure ulcer was present at admission at the same stage, and it did not worsen to a higher stage during the stay, then the pressure ulcer would not be considered new or worsened. The item in the proposed October 1, 2014 IRF-PAI “Unstageable due to Non-Removable Device or Dressing” should be used on admission when there is documentation of a known pressure ulcer that cannot be fully visualized and staged due to a non-removable device.

Comment: Several commenters indicated that the IRF-PAI is now too long and causes undue burden.

Response: We obtained feedback from providers in October of 2012 on the IRF PAI during Provider Trainings, Open Door Forums, and via the Quality Reporting Program Helpdesk. Based on the feedback we received, providers wanted the ability to provide as much information as possible to truly track the evolution of pressure ulcers, so in order to accommodate these providers, we are adding voluntary items. However, only those pressure ulcer items required to calculate the quality measure NQF #0678, Percent of Patients or Residents

with Pressure Ulcers That Are New or Worsened (Short Stay), are required in order for providers to avoid a 2 percentage point reduction of the applicable IRF PPS annual increase factor. Therefore, if a facility finds completing the additional data items burdensome, it is under no obligation to do so. Please refer to the 2014 IRF-PAI training manual for the voluntary/mandatory status of each item.

Comment: One commenter requested that CMS consider capturing the degree to which a pressure ulcer has healed by discharge.

Response: Pressure ulcer healing and treatment is a complex clinical issue that is difficult to capture in standardized assessment items. The IRF-PAI does not record incremental improvement, but instead captures only condition on admission and discharge, based on staging pressure ulcers, to avoid undue burden of data collection on facilities. Possible indicators of healing are numerous and not always accurate. These include surface area reduction, a common indicator for tracking the healing of pressure ulcers; however, we do not believe it is an appropriate data element to include in the IRF-PAI because it is not the sole determinant of healing. Development of granulation tissue, decrease in erythema, decrease in exudate, re-epithelialization, etc., are also other ways to document pressure ulcer healing. We cannot add data elements for all possible indicators. Also, many IRF stays are short, averaging 13 days, and we have no expectation that severe pressure ulcers will heal completely during this timeframe. If the patient is admitted with a full thickness pressure ulcer which will likely not be healed in approximately 13 days, it would simply be noted in the patient’s record as full thickness on discharge. The IRF would not experience any negative impact from a quality reporting standpoint in a situation such as this, because this information is not required for purposes of NQF #0678. Also, from a more general perspective, quality measures are not designed to track a full set of details about the progress of any individual patient, but rather to include just enough information to register a patient’s decline or improvement while in the care of a facility. This kind of assessment can assist us in monitoring the overall quality of facilities to ensure patients are receiving high-quality care and to identify facilities whose practices can be improved.

Final Decision: After giving careful consideration to the public comments received in response to our proposal to add new voluntary pressure ulcer items

to the IRF-PAI, we are finalizing the proposal to add the new pressure ulcer items that were posted on the IRF PPS Web page and as part of the IRF-PAI PRA package.

4. Revisions to the IRF-PAI To Add Mandatory Data Items Related to NQF #0680 Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay)

We have proposed to make changes to the IRF-PAI discharge assessment to include the addition of elements necessary to report data for the proposed measure, Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680). These items will be based on the items from the MDS 3.0 and LTCH CARE Data Set items.^{24 25} There are 3 data elements that will be collected in relation to this measure: Two are used to calculate the measure, and a third is used to ensure internal consistency and data accuracy. The items are as follows:

- Did the patient receive the influenza vaccine in this facility for this year’s influenza vaccination season?
- Date influenza vaccine was received, and
- If influenza vaccine not received, state reason.

These items and questions allow the IRF to report if and when an influenza vaccine was given at the facility. They also allow the IRF to indicate why a vaccine was not given if that is the case. Further details on the specifications and data elements for this measure are available in the MDS 3.0 QM User’s Manual available on our Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/NHQIQualityMeasures.html>. Measure specifications are located in the download titled: MDS 3.0 QM User’s Manual V6.0. Measure information is

²⁴ Centers for Medicare & Medicaid Services. MDS 3.0 Item Subsets V1.10.4 for the April 1, 2012 Release. Retrieved from https://www.cms.gov/NursingHomeQualityInits/30_NHQIMDS30TechnicalInformation.asp.

²⁵ The LTCH CARE Data Set Version 2.00, the data collection instrument for the submission of the Percent of Residents or Patients with Pressure Ulcers That are New or Worsened (Short-Stay) measure and the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) measure, is currently under review by the Office of Management and Budget (OMB) in accordance with the Paperwork Reduction Act (PRA) <http://www.gpo.gov/fdsys/pkg/FR-2013-02-01/pdf/2013-02155.pdf>. The LTCH CARE Data Set Version 1.01 was approved on April 24, 2012 by OMB in accordance with the PRA. The OMB Control Number is 0938-1163. Expiration Date April 30, 2013.

also available at <http://www.qualityforum.org/QPS/0680>.

In the proposed rule, we invited public comment on our proposed revisions to the IRF-PAI related to NQF #0680 Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay). The comments we received were related to our proposal to adopt the measure itself, and not on how we were proposing to modify the IRF-PAI. For a summary of comments and responses on this issue, please see section XIV.3.b. of this final rule.

Final Decision: After careful consideration of the public comments we received, we are finalizing our proposal to modify the IRF-PAI discharge item set to add the 3 data elements for collecting data for NQF #0680.

5. Revisions to the IRF-PAI Related to Numbering of Quality Indicator Items

In the revised IRF-PAI, we include changes in the numbering scheme used in the Quality Indicator section of the IRF-PAI from a "consecutive numbering scheme" for numbering assessment items to a numbering scheme that allows greater flexibility for item removal and insertion. Problems arise with a consecutive numbering scheme when items are removed or new ones are inserted because this changes the numbers of some or all of the items around them. Other CMS post-acute care data collection vehicles, such as the MDS 3.0 and the LTCH CARE Data Set, have adopted a more flexible numbering schema that allows insertion or removal of items without requiring renumbering of the remaining items. We proposed to adopt a similar numbering schema in the revised IRF-PAI. A less flexible numbering system that necessitates renumbering items on the IRF-PAI in the event of such changes will result in a given item number having very different meanings on different versions of the IRF-PAI item set.

For more details about our plans for changes to the IRF-PAI, see <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/IRFPAI.html>.

In the May 8, 2013 proposed rule, we invited public comments about our proposal to change the numbering scheme used in the quality indicator section of the IRF-PAI. A summary of the public comments received and our responses to comments are discussed below.

Comment: We did not receive any comments in response to our proposal to change the type of numbering used on the quality indicator section of the

IRF-PAI from a consecutive scheme to a numbering scheme similar to that used in the MDS 3.0. We did, however, receive comments requesting that page numbers be added to the IRF-PAI. The commenters suggested that because this document was being increased from 3 to 9 pages in length as a result of the proposed changes to the Quality Indicator section of the IRF-PAI then the page numbering should be added. Another commenter requested that page numbers be added to the IRF-PAI because "numbering the IRF-PAI pages will help keep it in correct order, since it is filed in the medical record."

Response: We agree with the commenters that adding page numbering to the IRF-PAI can assist IRFs in keeping the document in correct order. We also acknowledge that the proposed changes to the Quality Indicator section of the IRF-PAI will significantly increase the length of this document.

Final Decision: After careful consideration of the public comments we received, we are finalizing our proposal to adopt a flexible numbering scheme (similar to that used in MDS 3.0) into the Quality Indicator section of the IRF-PAI. In addition, we will add general page numbering to the IRF-PAI document.

E. Change in Data Collection and Submission Periods for Future Program Years

The FY 2012 final rule (76 FR 47836) included an initial framework for the IRF QRP. In that rule we also finalized the initial quality measures to be used in the IRF QRP, stated how data for these measures would be collected, and selected the time periods for the data collection and reporting of the quality data.

The FY 2012 final rule (76 FR 47836) also finalized the initial IRF QRP data reporting cycle, affecting the FY 2014 annual increase factor, as beginning on October 1, 2012 and ending on December 31, 2012. Beginning in 2013 for the FY 2015 annual increase factor, and for subsequent year annual increase factors, we finalized that quality reporting cycles would be based on a full calendar year (CY) cycle (76 FR 47879).

When there are new measures added to the quality reporting program that will be collected on the IRF-PAI, that data collection instrument must be updated accordingly. The next update to the IRF-PAI will take place on October 1, 2014. Under current policy, the IRF QRP data collection cycle for the FY 2016 annual increase factor will not begin until January 1, 2014.

In the FY 2014 proposed rule, we proposed to change the IRF-PAI data collection periods for the FY 2016 and FY 2017 annual increase factors in order to align with the release of the new version of the IRF-PAI on October 1, 2014. We have also proposed to shorten the data collection period impacting the FY 2016 IRF PPS annual increase factor to 9 months, so that the FY 2017 reporting periods can begin on October 1, 2014 using the new version of the IRF-PAI. Under this proposal, the next data collection period would run from January 1, 2014 to September 30, 2014 and affect the IRF PPS annual increase factor for FY 2016.

We further proposed to start fiscal year data collection periods beginning on October 1, 2014, and data collected for discharges during October 1, 2014 to September 30, 2015 will affect the FY 2017 IRF PPS annual increase factor. In addition, we proposed that data collection will continue on FY cycles unless there is an event that requires that this cycle be amended. We noted that, in the event the established cycles must be changed, we will make this apparent to the public and follow all necessary processes to make the change. Finalizing these proposals will result in having 2 separate data collection and submission schedules for IRF-PAI and NHSN based measures. We provide more details on this distinction below.

We invited public comment on our proposal to alter the IRF-PAI data collection periods impacting the FY 2016 and FY 2017 increase factors in a way that aligns with the release of the next version of the IRF-PAI instrument. A summary of the public comments received and our responses to comments are discussed below.

Comment: Several commenters expressed support for this proposal. We did not receive any comments that included objections to our proposal to change the data collection and submission timeframe for data collected using the IRF-PAI from a calendar year basis to a fiscal year basis, beginning on October 1, 2014. Likewise, no commenters objected to our continuing collection of NHSN data on a calendar year basis.

Response: We thank those commenters for their support of the proposed changes to the data collection and submission cycle for data collected using the IRF-PAI from a calendar to a fiscal year basis.

Comment: Several commenters expressed their support for our proposal to continue data collection and submission of NHSN measures data on a calendar year basis beginning on October 1, 2014 with the exception of

the Influenza Vaccination Among Healthcare Personnel Measure (NQF #0431). These commenters expressed an opinion that IRF units within acute care hospitals should be permitted to attest that their health care personnel flu vaccination measure data is reported through the acute care hospital's reporting, thereby automatically receiving credit for reporting in the IRF QRP.

Response: We thank those commenters for their support of our proposal to continue to report data to NHSN on a calendar year. We do not agree, however, that IRF units located within IPPS hospitals should be permitted to attest to the submission of (NQF #0431) Influenza Vaccination among Healthcare Personnel measure data as part of the IPPS data. We will require all IRFs to report data for this measure. For a full discussion of this specific issue, as well as details about this measure, see section XIV.3.C.2 above "*IRF QRP Measure #1: Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431)*".

Final Decision: After careful consideration of the public comments received, we are finalizing our proposal to change the data collection timeframe for data submitted via the IRF-PAI to a fiscal year basis beginning on October 1, 2014, and to continue data collection of data that is reported via NHSN on a calendar year basis.

1. Implementation of Data Submission Deadlines for the IRF QRP

In the FY 2012 IRF PPS final rule we stated that details regarding data submission and reporting requirements would be posted on the CMS Web site at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/index.html> no later than January 31, 2012 (76 FR 47879). Further data submission details for the IRF QRP were posted on the CMS IRF QRP Web site on January 31, 2012, as promised. In addition, data submission details were disseminated to IRFs at various times from January 31, 2012 to December 31, 2012, through an in-person training held on May 2, 2012, Open Door Forums, list-serve announcements, IRF QRP Web page postings and responses to IRF QRP Helpdesk inquiries. In these communications, we announced that the final data submission deadline for the IRF QRP would be May 15th for all measures finalized for the FY 2014 annual increase factor and each subsequent years annual increase factor.

We realize the value in providing clear submission deadlines for the IRF QRP and we believe that we should provide deadlines that clearly distinguish between data submitted using the NHSN and data submitted using the IRF-PAI. Further, it is important to have distinct deadlines at which point data submitted afterward, including data modifications and corrections, could not be used for reporting or IRF PPS annual increase factor determinations. For purposes of

the FY 2016 and subsequent year IRF PPS annual increase factors, and for the purposes of applying quarterly deadlines for public reporting purposes, we proposed the inclusion of quarterly data submission deadlines in addition to the previously finalized deadlines. We believe that clear submission deadlines this will ensure timely submission of data.

2. Quarterly Timelines for Submitting Data Using the IRF-PAI

For the purposes of submitting quality data using the IRF-PAI for the IRF QRP, we have proposed new quarterly timeframes described below that we believe will provide sufficient time for IRFs to meet quality reporting requirements and allow us to harmonize IRF QRP data submission deadlines with the LTCHQR Program and Hospital IQR. Beginning with data collection and reporting impacting the FY 2016 annual increase factor, we proposed that IRFs follow the deadlines presented in the tables below to complete submission of data for each quarter. For each quarter outlined in the tables below during which IRFs are required to collect data, we proposed a final deadline occurring approximately 135 days (or approximately 4 and 1/2 months) after the end of each quarter by which all data collected during that quarter must be submitted. We believe that this is a reasonable amount of time to allow IRFs to submit data and make any necessary corrections. We have summarized these deadlines in the tables below.

TABLE 13—TIMELINES FOR SUBMISSION OF IRF QRP PROGRAM QUALITY DATA USING IRF-PAI* FOR FY 2016 IRF PPS ANNUAL INCREASE FACTOR+: APPLICATION OF NQF #0678 PERCENT OF RESIDENTS OR PATIENTS WITH PRESSURE ULCERS THAT ARE NEW OR WORSENERD (SHORT-STAY)

| Quarter | IRF-PAI Data collection period | IRF-PAI Data submission deadline for corrections of the IRF QRP |
|---------------------------------------|---------------------------------------|---|
| FY 2016 Annual Increase Factor | | |
| Quarter 1 | January 1, 2014–March 31, 2014 | August 15, 2014. |
| Quarter 2 | April 1, 2014–June 30, 2014 | November 15, 2014. |
| Quarter 3 | July 1, 2014–September 30, 2014 | February 15, 2015. |

* Using October 1, 2012 release of IRF-PAI.

+ FY 2016 APU determination is based on 3 quarters of data submission for the pressure ulcer measure.

TABLE 14—TIMELINES FOR SUBMISSION OF IRF QRP PROGRAM QUALITY DATA USING IRF-PAI* FOR FY 2017 IRF PPS ANNUAL INCREASE FACTOR: NQF #0678 PERCENT OF RESIDENTS OR PATIENTS WITH PRESSURE ULCERS THAT ARE NEW OR WORSENERD (SHORT-STAY), AND NQF #0680 PERCENT OF RESIDENTS OR PATIENTS WHO WERE ASSESSED AND APPROPRIATELY GIVEN THE SEASONAL INFLUENZA VACCINE (SHORT-STAY)

| Quarter | IRF-PAI Data collection period | IRF-PAI Data submission deadline for corrections of the IRF QRP |
|---------------------------------------|---|---|
| FY 2017 Annual Increase Factor | | |
| Quarter 1 | October 1, 2014–December 31, 2014 | May 15, 2015. |

TABLE 14—TIMELINES FOR SUBMISSION OF IRF QRP PROGRAM QUALITY DATA USING IRF–PAI * FOR FY 2017 IRF PPS ANNUAL INCREASE FACTOR: NQF #0678 PERCENT OF RESIDENTS OR PATIENTS WITH PRESSURE ULCERS THAT ARE NEW OR WORSENER (SHORT-STAY), AND NQF #0680 PERCENT OF RESIDENTS OR PATIENTS WHO WERE ASSESSED AND APPROPRIATELY GIVEN THE SEASONAL INFLUENZA VACCINE (SHORT-STAY)—Continued

| Quarter | IRF–PAI Data collection period | IRF–PAI Data submission deadline for corrections of the IRF QRP |
|-----------------|---------------------------------------|---|
| Quarter 2 | January 1, 2015–March 31, 2015 | August 15, 2015. |
| Quarter 3 | April 1, 2015–June 30, 2015 | November 15, 2015. |
| Quarter 4 | July 1, 2015–September 30, 2015 | February 15, 2016. |

* Using October 1, 2014 release of IRF–PAI.

3. Quarterly Submission Timelines of Data Reported Using NHSN

In the FY 2014 proposed rule (78 FR 26909 through 26924), we proposed that the IRF QRP align its deadlines for submitting of quality data via the NHSN with the established deadlines set forth in the Hospital IQR and LTCHQR Programs. We noted that the CDC

recommends that a facility report Healthcare Acquired Infection (HAI) events such as CAUTI as close to the time of the event as possible, and certainly within 30 days after the event. We agree with the CDC’s recommendations and therefore are requiring that IRFs report CAUTI events, even null events (months without

CAUTIs) within 30 days (on a monthly level) after each event using the NHSN.

We are finalizing our proposal to continue the calendar year basis of reporting CAUTI, using quarterly deadlines as established by the Hospital IQR program for all events that occur during each quarter. Final submission deadlines for data collected through the NHSN are shown in the tables below.

TABLE 15—TIMELINES FOR SUBMISSION OF IRF QRP PROGRAM QUALITY DATA USING CDC/NHSN FOR FY 2016 AND FY 2017 IRF PPS ANNUAL INCREASE FACTOR: NATIONAL HEALTH SAFETY NETWORK (NHSN) CATHETER-ASSOCIATED URINARY TRACT INFECTION (CAUTI) OUTCOME MEASURE

| Quarter | CDC/NHSN Data collection period | CDC/NHSN Data submission deadline |
|---------------------------------------|---|-----------------------------------|
| FY 2016 Annual Increase Factor | | |
| Quarter 1 | January 1, 2014–March 31, 2014 | August 15, 2014. |
| Quarter 2 | April 1, 2014–June 30, 2014 | November 15, 2014. |
| Quarter 3 | July 1, 2014–September 30, 2014 | February 15, 2015. |
| Quarter 4 | October 1, 2014–December 31, 2014 | May 15, 2015. |
| FY 2017 Annual Increase Factor | | |
| Quarter 1 | January 1, 2015–March 31, 2015 | August 15, 2015. |
| Quarter 2 | April 1, 2015–June 30, 2015 | November 15, 2015. |
| Quarter 3 | July 1, 2015–September 30, 2015 | February 15, 2016. |
| Quarter 4 | October 1, 2015–December 31, 2015 | May 15, 2016. |

Further, we proposed to apply to IRF QRP the same deadlines established for the reporting of the Influenza

Vaccination Coverage Among Health Personnel (NQF #0431) measure in the

Hospital IQR Program and proposed in the LTCH QRP.

TABLE 16—TIMELINES FOR SUBMISSION OF IRF QRP PROGRAM QUALITY DATA USING CDC/NSHN FOR FY 2016 AND FY 2017 IRF PPS ANNUAL INCREASE FACTOR: NQF #0431 INFLUENZA VACCINATION COVERAGE AMONG HEALTHCARE PERSONNEL

| Data collection timeframe | CDC/NHSN Data submission deadline |
|--|-----------------------------------|
| FY 2016 Annual Increase Factor | |
| October 1, 2014 (or when the influenza vaccine becomes available)–March 31, 2015 | May 15, 2015. |
| FY 2017 Annual Increase Factor | |
| October 1, 2015 (or when the influenza vaccine becomes available)–March 31, 2016 | May 15, 2016. |

We invited public comment on the proposals made in the proposed rule regarding data submission quarterly and

final deadlines for the purposes of reporting data using the IRF–PAI and for the purposes of reporting data using the

NHSN. The following are comments received in response to these proposals and our response to these comments.

Comment: A few comments expressed support for our proposal to apply quarterly reporting deadlines to both the measures reported using the IRF-PAI on a fiscal year basis and to the measures reported to the CDC via NHSN on a calendar year basis.

Response: We thank the commenters for their supportive comments on the IRF-PAI measure on a fiscal year basis.

Final Decision: After careful consideration of the public comments we received, we are finalizing our proposal to apply quarterly deadlines to both the measures reported using the IRF-PAI on a fiscal year basis and to the measures reported to the CDC via NHSN on a calendar year basis.

F. Reconsideration and Appeals Process

In the proposed rule (78 FR 26909 through 26921) we provided details pertaining to a reconsideration process, and the mechanisms related to provider requests for reconsideration of their annual increase factor, such as filing requests, required content, supporting documentation, and mechanisms of notification and final determinations on the IRF QRP Web site this spring at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/index.html>. We also invited public comment on the proposed procedures for reconsideration and appeals. We received the following public comments related to our discussion of the reconsideration process in the proposed rule:

Comment: Many commenters expressed support of CMS' proposed IRF QRP reconsideration and appeals process. Further, one commenter encouraged CMS to mirror the processes used in the Hospital IQR Program and the Hospital Outpatient Quality Reporting (OQR) Program when developing reconsideration and appeals and for the IRF QRP.

Response: We thank the commenters for their support for the inclusion of reconsideration and appeals processes in the IRF QRP. It is our goal to align our reconsideration and appeals process and policies with those of existing quality reporting programs, such as Hospital IQR Program and the Hospital Outpatient Quality Reporting Program, to the extent appropriate for the IRF QRP. We greatly appreciate the commenters' views on the reconsideration process, and will consider all of these comments for future rulemaking and program development.

Comment: One commenter expressed concern that CMS did not provide procedural details of the reconsideration

process through rulemaking and encouraged CMS to ensure that sufficient outreach and education is conducted in a timely manner regarding these processes.

Response: We thank the commenter for the comments. We established a Web site that provides procedural details for the FY 2014 IRF QRP reconsideration process. This information is available at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/Reconsideration-and-Disaster-Waiver-Requests.html>. We noted in the FY 2014 proposed rule (78 FR 26909 through 26921) that we developed this Web site as a resource to inform providers on how to seek reconsideration of any decision of non-compliance for the FY 2014 annual increase factor, and the necessary steps to do so. We provided a process for reconsideration should IRFs choose to avail themselves of it. In the FY 2014 proposed rule (78 FR 26909 through 26921), we stated that IRFs must first apply for reconsideration through CMS prior to appealing our initial finding of non-compliance to the PRRB. In light of a commenter's concern that CMS did not provide procedural details of the reconsideration process through rulemaking and concern that CMS ensure that sufficient outreach and education are available, we have decided to continue with an IRF QRP reconsideration process that is voluntary for the time being in order to fully address these concerns. We are therefore only recommending that IRFs use the reconsideration process prior to appealing to the PRRB. We note that the agency has had good success under the Hospital IQR program with a process that is very similar to the one we proposed for the IRF QR. From the provider perspective, it allows for the opportunity to resolve issues early in the process when we have dedicated resources to considering all reconsideration requests before payment changes are applied to an IRF's annual payment update. From CMS' perspective, it decreases the number of appeals presented to the PRRB, which reviews cases for all quality reporting programs, allowing for more efficient operations at the appeals level.

Because we have been aware that providers should be able to request a reconsideration of their annual increase factor if their circumstances warrant it as soon as possible, we provided details pertaining to the voluntary reconsideration process, and the mechanisms related to provider requests for reconsiderations of their annual increase factor, such as filing requests, required content, supporting

documentation, and mechanisms of notification and final determinations on the IRF QRP Web site in spring 2013 prior to any IRF's need for information on the CMS reconsideration process for the FY 2014 annual increase factor and subsequent years annual increase factors at: <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting>. CMS' subregulatory approach to the FY 2014 reconsideration process was necessary, as any other form of the reconsideration process that we might propose and finalize in this rule would not be final and in effect until October 1, 2013. This would have the effect of proposing and finalizing a FY 2014 process for reconsiderations that should already be completed. We note that we are finalizing the policy that this subregulatory approach to the reconsideration process will remain in effect until we can propose and finalize a regulatory version of the reconsideration process in future rulemaking.

As part of the voluntary process, IRFs that are non-compliant with the reporting requirements during a given reporting cycle will be notified of that finding. The purpose of this notification is to put the IRF on notice of the following: (1) That the IRF has been identified as being non-compliant with the IRF QRP's reporting requirements for the reporting cycle in question; (2) that the IRF will be scheduled to receive a reduction in the amount of two percentage points to the annual payment update for the upcoming fiscal year; (3) that the IRF may file a request for reconsideration if they believe that the finding of non-compliance is erroneous, or that if they were non-compliant, they have a valid and justifiable excuse for this non-compliance; and (4) that the IRF must follow a defined process on how to file a request for reconsideration, which will be described in the notification.

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

G. Policy for Granting a Waiver of the IRF QRP Data Submission Requirements in Case of Disaster or Extraordinary Circumstances

Our experience with other quality reporting programs has shown that there are times when providers are unable to submit quality data due to the occurrence of extraordinary circumstances beyond their control (for example, natural or man-made disasters). We define a “disaster” as any natural or man-made catastrophe which causes damages of sufficient severity and magnitude to partially or completely destroy or delay access to medical records and associated documentation. Natural disasters could include events such as hurricanes, tornadoes, earthquakes, volcanic eruptions, fires, mudslides, snowstorms, and tsunamis. Man-made disasters could include such events as terrorist attacks, bombings, floods caused by man-made actions, civil disorders, and explosions. A disaster may be widespread or impact multiple structures or be isolated and impact a single site only.

In certain instances of either natural or man-made disasters, an IRF may have the ability to conduct a full patient assessment, and record and save the associated data either during or before the occurrence of an extraordinary event. In this case, the extraordinary event has not caused the facility’s data files to be destroyed, but it could hinder the IRF’s ability to meet the quality reporting program’s data submission deadlines. In this scenario, the IRF would potentially have the ability to report the data at a later date, after the emergency circumstances have subsided. In such cases, a temporary waiver of the IRF duty to report quality measure data may be appropriate.

In other circumstances of natural or man-made disaster, an IRF may not have had the ability to conduct a full patient assessment, and record and save the associated data before the occurrence of an extraordinary event. In such a scenario, the facility does not have data to submit to CMS as a result of the extraordinary event. We believe that it is appropriate, in these situations, to grant a full waiver of the reporting requirements.

It is our goal not to penalize IRF providers in these circumstances or to unduly increase their burden during these times. Therefore, we proposed a process, for payment year 2015 and subsequent years, for IRF providers to request and for us to grant waivers with respect to the reporting of quality data when there are extraordinary

circumstances beyond the control of the provider. When a waiver is granted, an IRF will not incur payment reduction penalties for failure to comply with the requirements of the IRF QRP.

In the FY 2014 proposed rule (78 FR 26909 through 26921), we proposed to establish a disaster waiver process, in which IRFs that have experienced a disaster can request a waiver of their quality reporting responsibilities for purposes of payment year 2015 and subsequent payment years. We proposed that the IRF may request a waiver for one or more quarters by submitting a written request to CMS. We also proposed that should IRFs compose a letter to CMS that documents the waiver request, with the information described below, and submit the letter to CMS via email to the IRF Help Desk at IRFQRPReconsiderations@cms.hhs.gov. IRFs that have filed a request for an IRF QRP disaster waiver with an IRF-PAI waiver request using the procedure that is described under our regulations at 42 CFR § 412.614 can indicate this in their letter to CMS for their request for a waiver for quality reporting purposes.²⁶

Note that the subject of the email must read “Disaster Waiver Request” and the letter must contain the following information:

- IRF CCN;
- IRF name;
- CEO or CEO-designated personnel contact information including name, telephone number, email address, and mailing address (the address must be a physical address, not a post office box);
- IRF’s reason for requesting a waiver;
- Evidence of the impact of extraordinary circumstances, including but not limited to photographs, newspaper and other media articles; and
- A date when the IRF believes that it will again be able to submit IRF QRP data and a justification for the proposed date.

We proposed that the letter documenting the disaster waiver request be signed by the IRF’s CEO, and must be submitted within 30 days of the date that the extraordinary circumstances occurred. Following receipt of the letter, we would: (1) Provide a written acknowledgement, using the contact information provided in the letter, to the CEO or designated contact person, notifying them that the request has been received, and (2) after CMS has made a decision as to whether to grant the waiver request, provide a formal response to the CEO, or designated

contact person notifying them of our decision.

This policy does not preclude us from granting waivers to IRFs that have not requested them when we determine that an extraordinary circumstance, such as an act of nature, affects an entire region or locale. If we make the determination to grant a waiver to IRFs in a region or locale, we propose to communicate this decision through routine communication channels to IRFs and vendors, including but not limited to issuing memos, emails, and notices on <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/index.html>.

In the proposed rule, we invited public comment on our proposed disaster waiver process. A summary of the public comments received and our responses to comments are discussed below.

Comment: Several commenters stated that they support the IRF QRP disaster waiver policy and “applaud the agency for recognizing the impact of natural disasters and other extenuating circumstances on the ability of IRFs to collect and report quality data.”

Response: We appreciate the commenters’ support and recognition of our efforts to plan for various types of emergency situations that can impact an IRF’s ability to report quality data.

Final Decision: After careful consideration of the public comments received, we are finalizing the IRF QRP disaster/extraordinary circumstances waiver and appeals processes as proposed.

H. Public Display of Data Quality Measures for the IRF QRP Program

Under section 1886(j)(7)(E) of the Act, the Secretary is required to establish procedures for making data submitted under the IRF QRP available to the public. Section 1886(j)(7)(E) of the Act also requires procedures to ensure that each IRF provider has the opportunity to review the data that is to be made public with respect to its facility, prior to such data being made public. Section 1886(j)(7)(E) of the Act requires CMS to report quality measures that relate to services furnished in IRFs on CMS’ Web site.

Currently, the Agency is developing plans regarding the implementation of these provisions. We appreciate the need for transparency in the processes and procedures that will be implemented to allow for the public reporting of the IRF QRP data and to afford providers the opportunity to preview that data before it is made public. At this time, we have not

²⁶ <http://www.gpo.gov/fdsys/pkg/CFR-2011-title42-vol2/pdf/CFR-2011-title42-vol2-sec412-614.pdf>.

established procedures or timelines for public reporting of data, but we intend to include related proposals in future rule making.

Comment: Several commenters urged CMS to convene stakeholders to inform this process prior to rulemaking. One commenter strongly encouraged CMS to display the most current performance data for public reporting of IRF QRP data.

Response: We appreciate the commenters for their feedback. We appreciate the need to ensure that the data made publicly available is easily understood by all stakeholders, including providers and consumers. At this time, we are working to establish procedures for public reporting, including procedures that provide the opportunity for IRFs to review their data before it is made public, and will propose such procedures through future rulemaking after allowing stakeholders the opportunity to submit input.

We thank the commenters for the input and suggestions, and we will consider them as we develop proposals for public reporting of quality measures in future rulemaking.

I. Method for Applying the Reduction to the FY 2014 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 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. FY 2014 is to be the first year that the mandated reduction will be applied for IRFs that failed to comply with the data submission requirements during the data collection period October 1, 2012 through December 31, 2012. Thus, in compliance with 1886(j)(7)(A)(i) of the Act, we will apply a 2 percentage point

reduction to the applicable FY 2014 market basket increase factor (1.8 percent) in calculating an adjusted FY 2014 standard payment conversion factor to apply to payments for only those IRFs that failed to comply with the data submission requirements. As noted previously, application of the 2 percentage point reduction may result in an update that is less than 0.0 for a fiscal year and in payment rates for a fiscal year being less than such payment rates for the preceding fiscal year. Also, reporting-based reductions to the market basket increase factor will not be cumulative; they will only apply for the FY involved. Table 17 shows the calculation of the adjusted FY 2014 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 period from October 1, 2012 through December 31, 2012.

TABLE 17—CALCULATIONS TO DETERMINE THE ADJUSTED FY 2014 STANDARD PAYMENT CONVERSION FACTOR FOR IRFS THAT FAILED TO MEET THE QUALITY REPORTING REQUIREMENT

| Explanation for Adjustment | Calculations |
|---|--------------|
| Standard Payment Conversion Factor for FY 2013 | \$14,343 |
| Adjusted Market Basket Increase Factor for FY 2014 (2.6 percent), reduced by 0.3 percentage point in accordance with sections 1886(j)(3)(C) and (D) of the Act and a 0.5 percentage point reduction for the productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act, further reduced by 2 percentage points for IRFs that failed to meet the quality reporting requirement | × 0.99800 |
| Budget Neutrality Factor for the Wage Index and Labor-Related Share | × 1.0010 |
| Budget Neutrality Factor for the Revisions to the CMG Relative Weights | × 1.0000 |
| Budget Neutrality Factor for the Update to the Rural Adjustment Factor | × 1.0025 |
| Budget Neutrality Factor for the Update to the LIP Adjustment Factor | × 1.0171 |
| Budget Neutrality Factor for the Update to the Teaching Status Adjustment Factor | × 0.9962 |
| Adjusted FY 2014 Standard Payment Conversion Factor | = \$14,555 |

XV. Miscellaneous Comments

Comment: Several commenters requested that CMS use the most recent three years of data and the first year of data collected under ICD–10 to review and update the list of comorbidities used to determine the tier payments to ensure that the tier list reflects all conditions that contribute significantly to IRF costs of care. One commenter also suggested that CMS re-examine the omission from this list of certain comorbidities that are considered preventable and might lead to perverse incentives for the IRF to undertreat these conditions.

Response: We appreciate the commenters' suggestions, and will consider these suggestions for future analyses.

Comment: One commenter suggested that CMS revise the IRF coverage requirements that are described in chapter 1, section 110 of the Medicare Benefit Policy Manual (Pub. L. 100–02)

to allow recreational therapy services to count, on a limited basis, towards the intensive rehabilitation therapy requirement in IRFs when the medical necessity is well-documented by the rehabilitation physician in the medical record and is ordered by the rehabilitation physician as part of the overall plan of care for the patient.

Response: As we did not propose any changes to the IRF coverage requirements in § 412.622(a)(3), (4), and (5) that would affect any of the requirements described in chapter 1, section 110 of the Medicare Benefit Policy Manual (Pub. L. 100–02), this comment is outside the scope of the proposed rule. However, as we have indicated previously in the FY 2012 IRF PPS final rule (76 FR 47836 at 47883), we do not believe that recreational therapy services should replace the provision of the 4 core skilled therapy services (physical therapy, occupational therapy, speech-language therapy, and prosthetics/orthotics). Thus, we believe

it should be left to each individual IRF to determine whether offering recreational therapy is the best way to achieve the desired patient care outcomes. As we have stated previously, recreational therapy is a covered service in IRFs when the medical necessity is well-documented by the rehabilitation physician in the medical record and is ordered by the rehabilitation physician as part of the overall plan of care for the patient. Recreational therapy may be offered as an additional service above and beyond the core skilled therapy services used to demonstrate the provision of an intensive rehabilitation therapy program, but may not replace one of these therapies.

Comment: One commenter requested that we consider a new model of payment for post-acute care services, such as the Continuing Care Hospital (CCH) model, that would pay based on the needs of the patient rather than the setting in which the care is provided.

This commenter urged us to pilot test the CCH idea.

Response: As we did not propose any new payment models for post-acute care services in the FY 2014 IRF PPS proposed rule (78 FR 26880), this comment is outside the scope of this rule. However, we appreciate the commenter's suggestions, and we note that on May 15, 2013, CMS announced a second round of Health Care Innovation Awards. Under this announcement, we will spend up to \$1 billion for awards and evaluation of projects from across the country that test new payment and service delivery models that will deliver better care and lower costs for Medicare, Medicaid, and Children's Health Insurance Program (CHIP) enrollees. In addition, we commenced the Bundled Payments for Care Improvement Initiative, whereby organizations will enter into payment arrangements that include financial and performance accountability for episodes of care. These models may lead to higher quality, more coordinated care at a lower cost to Medicare. In one of the model designs being tested (referred to as "Model 3" at <http://innovation.cms.gov/initiatives/BPCI-Model-3>), the episode of care will be triggered by an acute care hospital stay and will begin at initiation of post-acute care services with a participating skilled nursing facility, inpatient rehabilitation facility, long-term care hospital or home health agency.

Comment: Several commenters requested that we use the electronic signature guidelines provided in the Medicare Program Integrity Manual to allow the use of electronic signatures for all required documentation, including for the rehabilitation physician's review and concurrence with the preadmission screening requirements under the IRF coverage requirements in 412.622(a)(3)(i).

Response: As we did not propose any changes to the regulations in § 412.622(a)(3)(i) in the May 8, 2013 proposed rule (78 FR 26880), this comment is outside the scope of this final rule. However, we have provided specific guidance on the use of electronic signatures for documentation of the rehabilitation physician's review and concurrence with the IRF preadmission screening requirements, which can be downloaded from the IRF PPS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Downloads/ElecSysClar.pdf>.

XVI. Provisions of the Final Regulations

In this final rule, we are adopting the provisions set forth in the FY 2014 IRF

PPS proposed rule (78 FR 26880), except as noted elsewhere in the preamble. Specifically:

A. Payment Provision Changes

- We will update the FY 2014 IRF PPS relative weights and average length of stay values using the most current and complete Medicare claims and cost report data in a budget-neutral manner, as discussed in section IV of this final rule.

- We will update the FY 2014 IRF PPS facility-level adjustment factors, using the most current and complete Medicare claims and cost report data with an enhanced estimation methodology, in a budget-neutral manner, as discussed in section V of this final rule.

- We will update the FY 2014 IRF PPS payment rates by the market basket increase factor, based upon the most current data available, with a 0.3 percentage point reduction as required by sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(iii) of the Act and a productivity adjustment required by section 1886(j)(3)(C)(ii)(I) of the Act, as described in section VI of this final rule.

- We will indicate the Secretary's Final Recommendation for updating IRF PPS payments for FY 2014, in accordance with the statutory requirements, as described in section VI of this final rule.

- We will update the FY 2014 IRF PPS payment rates by the FY 2014 wage index and the labor-related share in a budget-neutral manner, as discussed in section VI of this final rule.

- We will calculate the final IRF Standard Payment Conversion Factor for FY 2014, as discussed in section VI of this final rule.

- We will update the outlier threshold amount for FY 2014, 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 2014, as discussed in section VII of this final rule.

- We will adopt revisions to the list of eligible ICD-9-CM diagnosis codes that meet the presumptive compliance criteria, with a one-year delayed implementation date, as discussed in section VIII of this final rule.

- We will adopt non-quality-related revisions to IRF-PAI sections effective October 1, 2014, as discussed in section IX 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, effective October 1, 2014, as

discussed in section XIV of this final rule.

B. Revisions to Existing Regulation Text

In this final rule, we will make the following revisions to the existing regulations:

- We will revise § 412.25(a)(1)(iii) to specify a minimum required number of beds that are not excluded from the inpatient prospective payment system (IPPS) for a hospital that has an IRF unit, with a one-year delayed implementation date to give providers an opportunity to comply with the requirements, as described in section XI of this final rule.

- We will make technical corrections to § 412.130, to reflect prior changes to the regulations at § 412.29 and § 412.30 that we made in the FY 2012 IRF PPS final rule (76 FR 47836), as described in section X of this final rule.

- We will make clarifications to § 412.630, to reflect the scope of section 1886(j)(8) of the Act, as described in section XII of this final rule.

- We will revise § 412.29(d), to clarify that Medicare requires the rehabilitation physician's review and concurrence on the preadmission screening for Medicare Part A Fee-for-Service patients only, as described in section XIII of this final rule.

XVII. Collection of Information Requirements

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

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.

- The accuracy of our estimate of the information collection burden.

- The quality, utility, and clarity of the information to be collected.

- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

This final rule does not impose any new information collection requirements as outlined in the regulation text. However, this final rule does make reference to associated information collections that are not discussed in the regulation text contained in this document. The

following is a discussion of these information collections, some of which have already received OMB approval.

A. ICRs Regarding IRF QRP

As stated in section XIV. of this final rule, we are adopting one new measure for use in the IRF QRP which will affect the increase factor for FY 2016. This quality measure is: Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431). We are also adopting 2 new measures that will affect the increase factor for FY 2017. The first is an All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from Inpatient Rehabilitation Facilities. This measure is a claims-based measure that does not require submission of data by IRF providers. In addition, we are adopting the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680) measure. Finally, we are replacing a non-risk adjusted application of an NQF-endorsed pressure ulcer measure, in which only numerator and denominator data is collected, to use the NQF-endorsed version of this measure "Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay)" (NQF #0678), which is a risk-adjusted measure. Each of these measures will be collected in the manner described below:

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

In section XIV. of this final rule, we are adopting the new measure, Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) to the IRF QRP. IRFs will be required to collect data related to the number of healthcare personnel working at a facility who have been vaccinated against the influenza virus during a given influenza vaccination season. The CDC has determined that the influenza vaccination season begins on October 1st (or when the vaccine becomes available) and ends on the following March 31st each year. This measure requires that the provider submit only one report to NHSN by the data submission deadline of May 15 following the close of the data collection period each year.

It has become a common practice for healthcare facilities, including IRFs, to promote vaccination of employees for the influenza virus and to keep records of which of their staff members received this vaccination each year. Therefore, we do not believe that IRFs will incur

any additional burden related to the collection of the data for this measure.

We anticipate that it will take approximately 15 minutes to prepare and transmit the required data for this measure to the CDC each year. The reporting of the data for this measure can be done while the provider is logged onto NHSN for the purpose of entering their CAUTI measure data. We believe that this task can be completed by an administrative person such as a Medical Secretary/Medical Data Entry Clerk. The average hourly wage for Medical Records or Health Information Technicians is \$15.55.²⁷ We estimate that the annual cost to each IRF for the reporting of the staff influenza measure will be \$3.89.²⁸ The annual cost across the 1161 IRFs in the U.S. that are reporting data to CMS is estimated to be \$4,516.²⁹

2. All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from Inpatient Rehabilitation Facilities

As stated in section XIV. of this final rule, data for this measure will be collected from Medicare claims and therefore will not add any additional reporting burden for IRFs.

3. Percent of Residents or Patients with Pressure Ulcers that are New or Have Worsened (Short-Stay) (NQF #0678)

In section XIV of this final rule, we are adopting the NQF-endorsed version of the measure titled "Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay)" (NQF #0678), affecting the FY 2017 annual increase factor. To support the standardized collection and calculation of this quality measure, we are modifying the current Inpatient Rehabilitation Facility-Patient Assessment Instrument (IRF-PAI) by replacing the current pressure ulcer items with data elements similar or identical to those collected through the Minimum Data Set 3.0 (MDS 3.0) used in nursing homes. By building upon preexisting resources, we intend to reduce administrative burden related to data collection and submission. We anticipate that the initial setup and acclimation to pressure ulcer data collection will have already occurred

²⁷ According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a Medical Records & Health Information Technician is \$15.55. See: <http://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm>.

²⁸ 15 minutes Administrative staff time to collect and report staff influenza measure @ \$15.55 per hour = \$3.9889 per IRF per year.

²⁹ At the time of the writing of this rule, there were 1161 IRFs reporting quality data to CMS. (\$3.9889 per IRF per year × 1161 IRFs in U.S. = \$4,621516).

with the adoption of the pressure ulcer measure for the IRF QRP for the FY 2014 annual increase factor. Therefore, we believe the transition to reporting similar as well as additional data elements for this measure will be less burdensome.

We expect that the admission and discharge pressure ulcer data will be collected by a clinician such as an RN because the assessment and staging of pressure ulcers requires a high degree of clinical judgment and experience. We estimate that it will take approximately 10 minutes of time by the RN to perform the admission pressure ulcer assessment. We further estimate that it will take an additional 15 minutes of time to complete the discharge pressure ulcer assessment. We expect that during these time periods, the RN would be engaged in the collection of data for the purpose of the IRF QRP and would not be engaged in the performance of routine patient care.

We estimate that there are 359,000 IRF-PAI submissions per year³⁰ and that there are 1161 IRFs in the U.S. reporting quality data to CMS. Based on these figures, we estimate that each IRF will submit approximately 309 IRF-PAIs per year or 26 IRF-PAIs per month.³¹ Assuming that each IRF-PAI submission requires 25 minutes of time by an RN at an average hourly wage of \$33.23,³² the yearly cost to each IRF would be \$4,278.36³³ and the annualized cost across all IRFs would be \$4,967,176.³⁴

We also expect that most IRFs will use administrative personnel, such as a medical secretary or medical data entry clerk, to perform the task of entering the IRF-PAI pressure ulcer assessment data into their electronic health record (EHR) system and/or the CMS JIRVEN program. We estimate that this data entry task will take no more than 3 minutes for each IRF-PAI record or 15.45 hours for each IRF annually or

³⁰ MedPAC, A Data Book: Health Care Spending and the Medicare Program (June 2012), <http://www.medpac.gov/chapters/Jun12DataBookSec8.pdf>.

³¹ 359,000 IRF-PAIs per all IRFs per year/1161 IRFs in U.S. = 309 IRF-PAIs per each IRF per year. 309 IRF-PAI reports per IRF per year/12 months per year = 26 IRF-PAI reports per each IRF per year.

³² According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a Registered Nurse is \$33.23. (See <http://www.bls.gov/oes/2011/may/oes291111.htm>).

³³ 25 minutes × 309 IRF-PAI assessments per each IRF per year = 7,725 minutes per each IRF per year.

7,725 minutes per each IRF per year/60 minutes per hour = 128.75 hours per each IRF per year. 128.75 hours per year × \$33.23 per hour = \$4,278.36 nursing wages per each IRF per year.

³⁴ \$4,278.36 × 1161 IRF providers = \$4,967,176 per all IRFs per year.

17,937 hours across all IRFs. As noted above, the average hourly wage for a Medical Records & Health Information Technician is \$15.55. As we noted above, there are approximately 359,000 IRF-PAI submissions per year and 1161 IRFs reporting quality data to CMS. Given this wage information, the estimated total annual cost across all reporting IRFs for the time required for entry of pressure ulcer data into the IRF-PAI record is \$278,930. We further estimate the average yearly cost to each individual IRF to be \$240.25.

We estimate that the combined annualized time burden related to the pressure ulcer data item set for work performed, by the both clinical and administrative staff will be 144.20 hours for each individual IRF and 167,416 hours across all IRFs. The total estimated annualized cost for collection and submission of pressure ulcer data is \$4,518.61 for each IRF and \$5,246,106 across all IRFs. We estimate the cost for each pressure ulcer submission to be \$14.61.

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

In section XIV. of this final rule, we are adding the measure, Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680) to the IRF QRP. We further are adding a new set of standardized data elements now used in the MDS 3.0 to the IRF-PAI to collect the data required for this measure.

IRFs are already required to complete and transmit certain IRF-PAI data on all Medicare Part A Fee-for-Service and Medicare Part C (Medicare Advantage) patients to receive payment from Medicare. By building upon preexisting resources, we intend to reduce administrative burden related to data collection and submission. We anticipate that the initial setup and acclimation to data collection through the IRF-PAI for purposes of reporting IRF quality measure data will have already occurred with the adoption of the Pressure Ulcer measure for the IRF QRP for the FY 2014 increase factor. Therefore, we believe the transition to reporting an additional measure via the IRF-PAI may be less burdensome.

We estimate that completion of the patient influenza measure item set will take approximately 5 minutes to complete. The patient influenza item set consists of three items (questions). Each item is straightforward and does not require physical assessment for completion. We estimate that it will take

approximately 0.7 minutes to complete each item, or 2.1 minutes to complete the entire item set. However, in some cases, the person completing this item set may need to consult the patient's medical record to obtain data about the patient's influenza vaccination. Therefore, we have allotted 1.6 minutes per item or a total of 5 minutes to complete the item set.

The IRF staff will be required to perform a full influenza assessment only during the influenza vaccination season. The CDC defines that influenza vaccination season as the time period from October 1st (or when the vaccine becomes available) through March 31 each year. From April 1st through September 30th, IRFs are not required to perform full influenza screening and may skip to the next item set after checking the selection which indicates that the patient's IRF stay occurred outside of the influenza vaccination season. Our time estimate reflects the averaged amount of time necessary to complete the influenza item set both during and outside the influenza vaccination season.

We anticipate that the patient influenza item set will be completed by a clinician such an RN, while completing the Quality Indicator section of the IRF-PAI. It is most appropriate for an RN to complete the influenza item set because it involves performing a skilled assessment to determine, from a patient's records, whether the patient has received a vaccination and, if not, to discuss with the patient any medications or other related topics such as medication allergies, other vaccinations that the patient may have had, and any contraindications that might exist for receiving the influenza vaccination. The nurse has knowledge and experience to determine the relevance of this information to the patient influenza items and also to determine if the patient should be given the influenza vaccination.

As noted above, we estimate that it will take approximately 5 minutes to complete the patient influenza measure item set. We have also noted above that there are approximately 359,000 IRF-PAIs completed annually across all 1161 IRFs that report IRF quality data to CMS. This breaks down to approximately 309 IRF-PAIs completed by each IRF yearly.³⁵ We estimate that the annual time burden for reporting the patient influenza vaccination measure data is 29,896 hours across all IRFs in the U.S. and 26 hours for each

individual IRF. According to the U.S. Bureau of Labor, the hourly wage for a Registered Nurse is \$33.23. Taking all of the above information into consideration, we estimate the annual cost across all IRFs for the submission of the patient influenza measure data to be \$993,433. We further estimate the cost for each individual IRF to be \$855.67. A summary of the public comments received on our burden estimate for this measure and our responses to those comments are discussed below.

Comment: The additional burden of data collection (that is, seeking information directly from the patient or by searching through the paper medical record) must not take away from limited resources in these facilities which are needed to provide direct care.

Response: We agree that there will be some additional burden added because IRFs will be required to check to see if the patient received the influenza vaccination prior to admission to the IRF. However, we believe that the burden will be minimal.

Most patients are transferred to IRFs from an acute care facility. If the patient received the influenza vaccination while in the acute care facility, there should be several places where the information about the administration of this vaccination can be quickly and easily located. The influenza vaccination is a medication, so the Medication Administration Record would be one place that this information could be located. Also, if this vaccination was ordered by a physician or the acute care facility had standing orders for the administration of the vaccination, then the Physicians Order section of the chart is another place that is likely to contain the influenza vaccination information.

Comment: One commenter suggested that CMS' estimates on the burden caused by the implementation of the two vaccination measures (Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) and Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF#0680) are inaccurate because they do not encompass changes that must be made to its billing software, electronic medical records, or administrative processes.

Response: When making a burden estimate, we estimate only those activities and costs that are common to a majority of providers and which can be fairly and accurately estimated across all IRFs. Unfortunately, costs related to changes to billing and electronic medical record software, or

³⁵ 359,000 IRF-PAI reports per all IRFs per year/ 1161 IRFs in U.S. = 309 IRF-PAI reports per each IRF per year.

administrative processes are costs that are so variable among different IRFs we are not able to make an accurate estimate of these costs that can be applied across all providers.

Costs for updates to electronic medical records are extremely variable and will depend on many factors such as the manufacturer of the electronic medical records software; whether there is a warranty that covers updates; whether the IRF has a service contract which covers updates; who the IRF hires to perform upgrades to its system; where the IRF is geographically located; or whether the cost is incurred by a large corporation that owns many IRFs or the IRF is a solely owned and operated facility. In regard to costs for changes to administrative processes, these costs are also difficult to define or quantify as they are equally variable, if not more so than costs related to changes to electronic record systems.

Even though it was not reflected in the burden estimate, CMS does recognize that many IRFs will incur costs for changes that will be required to billing software, electronic medical records, or administrative processes. Some of these changes are required as a result of the IRF QRP proposals that we are finalizing in this final rule. However, we believe that some of these costs are also attributable to non-quality related proposals that are being finalized in this rule.

B. ICRs Regarding Non-Quality Related Changes to the IRF-PAI

We will revise several items on the IRF-PAI to provide greater clarity for providers. The changes include updating several items regarding the response options available to providers. Additionally, we are removing several items that we believe are unnecessary for providers to continue documenting on the IRF-PAI since those items are already being documented in the patients' medical record. We are also adding several items, such as a signature page, to fulfill providers' request to have an organized way to document who has assessed the patient and when that assessment took place. We do not estimate any additional burden for IRFs to complete the IRF-PAI as a result of these changes. We estimate the time that will be needed to complete the new non-quality related proposed items, equals the time that was needed to complete the previous non-quality related items. When the original burden estimates were completed for the IRF-PAI, we estimated that the proposed deletion of the non-quality related items would take approximately 3 minutes to complete. Thus, removing these items

the IRF-PAI would decrease the total estimated burden of completing the non-quality related portions of the IRF-PAI by 3 minutes. However, we estimate that it will take about 3 minutes to complete the new non-quality related items that we are proposing to add. Therefore, we estimate no net change in the amount of time associated with completing the non-quality related portions of the IRF-PAI and that the burden for completing these portions of the IRF-PAI will not change.

We did not receive any comments specifically on the information collection requirements regarding the non-quality related changes to the IRF-PAI.

We will be submitting a revision to the current IRF-PAI collection of information approval under (OMB control number 0938-0842) for OMB review and approval.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of the proposed rule; or
2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, *Attention: CMS Desk Officer, CMS-1448-P, Fax: (202) 395-6974; or, Email: OIRA_submission@omb.eop.gov.*

VIII. Regulatory Impact Analysis

A. Statement of Need

This final rule updates the IRF prospective payment rates for FY 2014 as required under section 1886(j)(3)(C) of the Act. It responds to section 1886(j)(5) of the Act, which requires the Secretary to publish in the **Federal Register** on or before the August 1 that precedes the start of each fiscal year, the classification and weighting factors for the IRF PPS's case-mix groups and a description of the methodology and data used in computing the prospective payment rates for that fiscal year.

This rule implements sections 1886(j)(3)(C) and (D) of the Act. Section 1886(j)(3)(C)(ii)(I) of the Act requires the Secretary to apply a multi-factor productivity adjustment to the market basket increase factor, and to apply other adjustments as defined by the Act. The productivity adjustment applies to FYs from 2012 forward. The other adjustments apply to FYs 2010 through 2019.

This rule also adopts some policy changes within the statutory discretion afforded to the Secretary under section 1886(j) of the Act. We will revise the list

of diagnosis codes that are eligible under the presumptive compliance method of calculating an IRF's compliance percentage under the "60 percent rule" effective for compliance review periods beginning on or after October 1, 2014 (a one-year delay), update the IRF facility-level adjustment factors, revise sections of the Inpatient Rehabilitation Facility-Patient Assessment Instrument, revise requirements for acute care hospitals that have IRF units beginning on or after October 1, 2014 (a one-year delay), clarify the IRF regulation text regarding limitation of review, and revise and update quality measures under the IRF quality reporting program. We believe that the policy changes will enhance the clarity, accuracy, and fairness of the IRF PPS.

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 one year). We estimate the total impact of the policy updates described in this final rule by comparing the estimated payments in FY 2014 with those in FY 2013. This analysis results in an estimated \$170 million increase for FY 2014 IRF PPS payments. As a result, this final rule is designated as economically "significant" under section 3(f)(1) of Executive Order 12866, and hence a major rule under the Congressional Review Act. Also, the rule has been reviewed by OMB.

The Regulatory Flexibility Act (RFA) requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most IRFs and most other providers and suppliers are small entities, either by having revenues of \$7 million to \$34.5 million or less in any 1 year depending on industry classification, or by being nonprofit organizations that are not dominant in their markets. (For details, see the Small Business Administration's final rule that set forth size standards for health care industries, at 65 FR 69432 at http://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf, effective March 26, 2012.) Because we lack data on individual hospital receipts, we cannot determine the number of small proprietary IRFs or the proportion of IRFs' revenue that is derived from Medicare payments. Therefore, we assume that all IRFs (an approximate total of 1,100 IRFs, of which approximately 60 percent are nonprofit facilities) are considered small entities and that Medicare payment constitutes the majority of their revenues. The Department of Health and Human Services generally uses a revenue impact of 3 to 5 percent as a significance threshold under the RFA. As shown in Table 18, we estimate that the net revenue impact of this final rule on all IRFs is to increase estimated payments by approximately 2.3 percent. However, we find that certain categories of IRF providers would be expected to experience revenue impacts in the 3 to 5 percent range. We estimate a 5.0 percent overall impact for teaching IRFs with resident to average daily census ratios of 10 to 19 percent, a 10.1 percent overall impact for teaching IRFs with a resident to average daily census ratio greater than 19 percent, and a 4.1 percent overall impact for IRFs with a DSH patient percentage of 0 percent. As a result, we anticipate this final rule adopts a net positive impact on a substantial number of small entities. Medicare fiscal intermediaries, Medicare Administrative Contractors, and carriers 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 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. As discussed in detail below, the rates and policies set forth in this final rule will not have a significant impact (not greater than 3 percent) on rural hospitals based on the data of the 167 rural units and 18 rural hospitals in our database of 1,134 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 one year of \$100 million in 1995 dollars, updated annually for inflation. In 2013, that threshold level is approximately \$141 million. This final rule will not impose spending costs on State, local, or tribal governments, in the aggregate, or by the private sector, of greater than \$141 million.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. As stated above, this final rule will not have a substantial effect on State and local governments, preempt state law, or otherwise have a federalism implication.

C. Detailed Economic Analysis

1. Basis and Methodology of Estimates

This final rule sets forth policy changes and updates to the IRF PPS rates contained in the FY 2013 notice (77 FR 44618). Specifically, this final rule updates the CMG relative weights and average length of stay values, the facility-level adjustment factors, the wage index, and the outlier threshold for high-cost cases. This final rule also applies a MFP adjustment to the FY 2014 RPL market basket increase factor in accordance with section 1886(j)(3)(C)(ii)(I) of the Act, and a 0.3 percentage point reduction to the FY 2014 RPL market basket increase factor in accordance with sections 1886(j)(3)(C)(ii)(II) and (D)(iii) of the Act. Further, this final rule contains changes to the list of ICD-9-CM codes that are used in the 60 percent rule presumptive methodology. Since these changes are being made with a one-year delayed implementation date, for compliance review periods beginning on or after October 1, 2014, no financial

impacts will accrue until FY 2015 from these changes. In addition, section XIV of this rule discusses the first implementation (in FY 2014) 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 \$170 million in payments to IRF providers. This estimate does not include the estimated impacts of the changes to the list of ICD-9-CM codes that are used in the 60 percent rule presumptive compliance (as discussed below), which are effective for compliance review periods on or after October 1, 2014, or the estimated impacts of the implementation (in FY 2014) 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 below). The impact analysis in Table 18 of this final rule represents the projected effects of the updates to IRF PPS payments for FY 2014 compared with the estimated IRF PPS payments in FY 2013. 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 2014, 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 2014 RPL market basket increase factor in accordance with section 1886(j)(3)(C)(ii)(I) of the Act, and

a 0.3 percentage point reduction to the FY 2014 RPL market basket increase factor in accordance with sections 1886(j)(3)(C)(ii)(II) and (D)(iii) of the Act. We estimate the total increase in payments to IRFs in FY 2014, relative to FY 2013, will be approximately \$170 million.

This estimate is derived from the application of the FY 2014 RPL market basket increase factor, as reduced by a productivity adjustment in accordance with section 1886(j)(3)(C)(ii)(I) of the Act, and a 0.3 percentage point reduction in accordance with sections 1886(j)(3)(C)(ii)(II) and (D)(iii) of the Act, which yields an estimated increase in aggregate payments to IRFs of \$135 million. Furthermore, there is an additional estimated \$35 million increase in aggregate payments to IRFs due to the update to the outlier threshold amount. Outlier payments are estimated to increase from approximately 2.5 percent in FY 2013 to 3.0 percent in FY 2014. Therefore, summed together, we estimate that these updates will result in a net increase in estimated payments of \$170 million from FY 2013 to FY 2014.

The effects of the updates that impact IRF PPS payment rates are shown in Table 18. 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 2.5 percent to 3.0 percent of total estimated payments for FY 2014, consistent with section 1886(j)(4) of the Act.
- The effects of the annual market basket update (using the RPL market basket) to IRF PPS payment rates, as required by section 1886(j)(3)(A)(i) and sections 1886(j)(3)(C) and (D) of the Act, including a productivity adjustment in accordance with section 1886(j)(3)(C)(i)(I) of the Act, and a 0.3 percentage point reduction in accordance with sections 1886(j)(3)(C) and (D) of the Act.
- The effects of applying the budget-neutral labor-related share and wage index adjustment, as required under section 1886(j)(6) of the Act.
- The effects of the budget-neutral changes to the CMG relative weights and average length of stay values, under the authority of section 1886(j)(2)(C)(i) of the Act.
- The effects of the updates to the Rural, LIP, and Teaching Status adjustment factors, using an updated methodology.
- The total change in estimated payments based on the FY 2014 payment changes relative to the estimated FY 2013 payments.

2. Description of Table 18

Table 18 categorizes IRFs by geographic location, including urban or rural location, and location with respect to 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 18 shows the overall impact on the 1,134 IRFs included in the analysis.

The next 12 rows of Table 18 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 949 IRFs located in urban areas included in our analysis. Among these, there are 733 IRF units of hospitals located in urban areas and 216 freestanding IRF hospitals located in urban areas. There are 185 IRFs located in rural areas included in our analysis. Among these, there are 167 IRF units of hospitals located in rural areas and 18 freestanding IRF hospitals located in rural areas. There are 302 for-profit IRFs. Among these, there are 263 IRFs in urban areas and 39 IRFs in rural areas. There are 688 non-profit IRFs. Among these, there are 571 urban IRFs and 117 rural IRFs. There are 144 government-owned IRFs. Among these, there are 115 urban IRFs and 29 rural IRFs.

The remaining four parts of Table 18 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 with respect to their location within a particular one of the nine Census geographic regions. Second, IRFs located in rural areas are categorized with respect to their location within a particular one of the nine Census geographic regions. In some cases, especially for rural IRFs located in the New England, Mountain, and Pacific regions, the number of IRFs represented is small. IRFs are then grouped by teaching status, including non-teaching IRFs, IRFs with an intern and resident

to average daily census (ADC) ratio less than 10 percent, IRFs with an intern and resident to ADC ratio greater than or equal to 10 percent and less than or equal to 19 percent, and IRFs with an intern and resident to ADC ratio greater than 19 percent. Finally, IRFs are grouped by DSH PP, including IRFs with zero DSH PP, IRFs with a DSH PP less than 5 percent, IRFs with a DSH PP between 5 and less than 10 percent, IRFs with a DSH PP between 10 and 20 percent, and IRFs with a DSH PP greater than 20 percent.

The estimated impacts of each policy described in this final rule to the facility categories listed above are shown in the columns of Table 18. The description of each column is as follows:

- Column (1) shows the facility classification categories described above.
 - Column (2) shows the number of IRFs in each category in our FY 2012 analysis file.
 - Column (3) shows the number of cases in each category in our FY 2012 analysis file.
 - Column (4) shows the estimated effect of the adjustment to the outlier threshold amount.
 - Column (5) shows the estimated effect of the update to the IRF PPS payment rates, which includes a productivity adjustment in accordance with section 1886(j)(3)(C)(ii)(I) of the Act, and a 0.3 percentage point reduction in accordance with sections 1886(j)(3)(C)(ii)(II) and (D)(iii) of the Act.
 - Column (6) shows the estimated effect of the update to the IRF labor-related share and wage index, in a budget-neutral manner.
 - Column (7) shows the estimated effect of the update to the CMG relative weights and average length of stay values, in a budget-neutral manner.
 - Column (8) shows the estimated effect of the update to the facility adjustment factors using an updated methodology, in a budget-neutral manner.
 - Column (9) compares our estimates of the payments per discharge, incorporating all of the proposed policies reflected in this final rule for FY 2014 to our estimates of payments per discharge in FY 2013.
- The average estimated increase for all IRFs is approximately 2.3 percent. This estimated net increase includes the effects of the RPL market basket increase factor for FY 2014 of 2.6 percent, reduced by a productivity adjustment of 0.5 percentage point in accordance with section 1886(j)(3)(C)(ii)(I) of the Act, and further reduced by 0.3 percentage point in accordance with sections

1886(j)(3)(C)(ii)(II) and (D)(iii) of the Act. It also includes the approximate 0.5 percent overall estimated 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, the facility-level adjustments, 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 18—IRF IMPACT TABLE FOR FY 2014
[Columns 4–9 in %]

| Facility classification | Number of IRFs | Number of cases | Outlier | Adjusted market basket increase factor for FY 2014 ¹ | FY 2014 CBSA wage index and labor-share | CMG | Facility adjust. | Total percent change |
|---|----------------|-----------------|---------|---|---|------|------------------|----------------------|
| (1) | (2) | (3) | (4) | (5) | (6) | (7) | (8) | (9) |
| Total | 1,134 | 382,756 | 0.5 | 1.8 | 0.0 | 0.0 | 0.0 | 2.3 |
| Urban unit | 733 | 181,133 | 0.7 | 1.8 | 0.0 | 0.0 | 0.2 | 2.8 |
| Rural unit | 167 | 27,098 | 0.6 | 1.8 | 0.1 | 0.0 | -2.4 | 0.0 |
| Urban hospital | 216 | 168,609 | 0.2 | 1.8 | -0.1 | 0.0 | 0.3 | 2.1 |
| Rural hospital | 18 | 5,916 | 0.1 | 1.8 | -0.1 | -0.1 | -3.0 | -1.3 |
| Urban For-Profit | 263 | 143,162 | 0.2 | 1.8 | -0.2 | 0.0 | 0.2 | 2.0 |
| Rural For-Profit | 39 | 7,728 | 0.3 | 1.8 | 0.1 | 0.0 | -2.9 | -0.7 |
| Urban Non-Profit | 571 | 178,424 | 0.6 | 1.8 | 0.2 | 0.0 | 0.2 | 2.8 |
| Rural Non-Profit | 117 | 20,578 | 0.5 | 1.8 | 0.0 | 0.0 | -2.4 | -0.1 |
| Urban Government | 115 | 28,156 | 0.7 | 1.8 | -0.2 | 0.0 | 0.3 | 2.7 |
| Rural Government | 29 | 4,708 | 0.7 | 1.8 | 0.2 | 0.0 | -2.6 | 0.1 |
| Urban | 949 | 349,742 | 0.5 | 1.8 | 0.0 | 0.0 | 0.2 | 2.5 |
| Rural | 185 | 33,014 | 0.5 | 1.8 | 0.0 | 0.0 | -2.5 | -0.2 |
| Urban by Region | | | | | | | | |
| Urban New England | 32 | 16,779 | 0.3 | 1.8 | 0.7 | 0.0 | 0.0 | 2.8 |
| Urban Middle Atlantic | 140 | 59,466 | 0.4 | 1.8 | 0.0 | 0.0 | 0.7 | 2.9 |
| Urban South Atlantic | 130 | 62,557 | 0.3 | 1.8 | -0.3 | 0.0 | 0.0 | 1.9 |
| Urban East North Central | 182 | 52,632 | 0.6 | 1.8 | 0.2 | 0.0 | 0.6 | 3.2 |
| Urban East South Central | 49 | 24,489 | 0.2 | 1.8 | -0.8 | 0.0 | 0.4 | 1.7 |
| Urban West North Central | 73 | 18,097 | 0.6 | 1.8 | 0.5 | 0.0 | -0.1 | 2.8 |
| Urban West South Central | 171 | 67,575 | 0.4 | 1.8 | -0.1 | 0.0 | 0.3 | 2.4 |
| Urban Mountain | 73 | 23,459 | 0.6 | 1.8 | -0.5 | 0.0 | 0.1 | 2.0 |
| Urban Pacific | 99 | 24,688 | 0.9 | 1.8 | 0.7 | 0.0 | -0.9 | 2.5 |
| Rural by Region | | | | | | | | |
| Rural New England | 6 | 1,400 | 0.8 | 1.8 | -0.5 | -0.1 | -1.8 | 0.1 |
| Rural Middle Atlantic | 15 | 2,711 | 0.3 | 1.8 | -0.2 | 0.0 | -2.2 | -0.3 |
| Rural South Atlantic | 24 | 5,624 | 0.3 | 1.8 | 0.1 | 0.0 | -2.5 | -0.3 |
| Rural East North Central | 32 | 5,595 | 0.5 | 1.8 | 0.3 | 0.0 | -2.4 | 0.1 |
| Rural East South Central | 22 | 3,852 | 0.4 | 1.8 | 0.0 | 0.1 | -2.7 | -0.4 |
| Rural West North Central | 27 | 3,660 | 0.7 | 1.8 | -0.7 | 0.0 | -2.2 | -0.4 |
| Rural West South Central | 48 | 9,130 | 0.4 | 1.8 | 0.4 | 0.0 | -3.1 | -0.6 |
| Rural Mountain | 7 | 664 | 1.2 | 1.8 | 0.2 | 0.1 | -1.5 | 1.9 |
| Rural Pacific | 4 | 378 | 1.9 | 1.8 | 0.1 | -0.1 | -1.1 | 2.6 |
| Teaching Status | | | | | | | | |
| Non-teaching | 1,018 | 334,415 | 0.4 | 1.8 | 0.0 | 0.0 | -0.2 | 2.0 |
| Resident to ADC less than 10% | 65 | 32,238 | 0.5 | 1.8 | 0.1 | 0.0 | 0.6 | 3.0 |
| Resident to ADC 10%–19% | 39 | 14,504 | 0.8 | 1.8 | 0.1 | 0.0 | 2.3 | 5.0 |
| Resident to ADC greater than 19% | 12 | 1,599 | 0.6 | 1.8 | 0.3 | 0.0 | 7.1 | 10.1 |
| Disproportionate Share Patient Percentage (DSH PP) | | | | | | | | |
| DSH PP = 0% | 38 | 7,859 | 1.1 | 1.8 | 0.2 | 0.0 | 1.0 | 4.1 |
| DSH PP less than 5% | 195 | 64,484 | 0.4 | 1.8 | -0.1 | 0.0 | 0.8 | 2.9 |
| DSH PP 5%–10% | 323 | 123,384 | 0.3 | 1.8 | -0.1 | 0.0 | 0.3 | 2.4 |
| DSH PP 10%–20% | 347 | 124,564 | 0.4 | 1.8 | 0.1 | 0.0 | -0.1 | 2.2 |
| DSH PP greater than 20% | 231 | 62,465 | 0.7 | 1.8 | 0.0 | 0.0 | -1.1 | 1.3 |

¹ This column reflects the impact of the RPL market basket increase factor for FY 2014 of 1.8 percent, which includes a market basket update of 2.6 percent, a 0.3 percentage point reduction in accordance with sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(iii) of the Act and a 0.5 percentage point reduction for the productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) 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 18. In the July 30, 2012 FY 2013 IRF PPS notice (77 FR 44618), we used FY 2011 IRF claims data (the best, most complete data available at that time) to set the outlier threshold amount for FY 2013 so that estimated outlier payments would equal 3 percent of total estimated payments for FY 2013.

For this final rule, we are updating our analysis using FY 2012 IRF claims data and, based on this updated analysis, we estimate that IRF outlier payments as a percentage of total estimated IRF payments are 2.5 percent in FY 2013. We attribute this underpayment in IRF outliers for FY 2013 to the effects of the recently-implemented IRF outlier reconciliation policy (as outlined in Chapter 3, Section 140.2.8 of the Medicare Claims Processing Manual (Pub. 100–04) that we believe is causing a downward trend in IRF cost-to-charge ratios (CCR). We are seeing this downward trend in CCRs in all of the settings for which we implemented the outlier reconciliation policy. 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 2014. The estimated change in total IRF payments for FY 2014, therefore, includes an approximate 0.5 percent increase in payments because the estimated outlier portion of total payments is estimated to increase from approximately 2.5 percent to 3 percent.

The impact of this outlier adjustment update (as shown in column 4 of Table 18) is to increase estimated overall payments to IRFs by about 0.5 percent. We estimate the largest increase in payments from the update to the outlier threshold amount to be 1.9 percent for rural IRFs in the Pacific region. We do not estimate that any group of IRFs will experience a decrease in payments from this update.

4. Impact of the Market Basket Update to the IRF PPS Payment Rates

The estimated effects of the market basket update to the IRF PPS payment rates are presented in column 5 of Table 18. In the aggregate the update will result in a net 1.8 percent increase in overall estimated payments to IRFs. This net increase reflects the estimated RPL market basket increase factor for FY 2014 of 2.6 percent, reduced by the 0.3 percentage point in accordance with sections 1886(j)(3)(C)(ii)(I) and

1886(j)(3)(D)(iii) of the Act, and further reduced by a 0.5 percentage point productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act.

5. Impact of the CBSA Wage Index and Labor-Related Share

In column 6 of Table 18, we present the effects of the budget-neutral update of the wage index and labor-related share. The proposed 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 69.981 percent in FY 2013 to 69.494 percent in FY 2014.

In the aggregate, since these updates to the wage index and the labor-related share are applied in a budget-neutral manner as required under section 1886(j)(6) of the Act, we do not estimate that these proposed updates will affect overall estimated payments to IRFs. However, we estimate that these updates will have small distributional effects. For example, we estimate the largest increase in payments from the update to the CBSA wage index and labor-related share of 0.7 percent for urban IRFs in the New England and Pacific regions. We estimate the largest decrease in payments from the update to the CBSA wage index and labor-related share to be a 0.8 percent decrease for urban IRFs in the East South Central region.

6. Impact of the Update to the CMG Relative Weights and Average Length of Stay Values

In column 7 of Table 18, 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 to IRFs. However, we do expect these updates to have small distributional effects. Freestanding rural hospitals will see a 0.1 decrease in payments as a result of these updates. The rural areas affected are New England and Pacific. The largest estimated increase in payments as a result of these updates is a 0.1 increase in the rural Mountain and East South Central regions.

7. Impact of the Updates to the Facility-Level Adjustments

In column 8 of Table 18, we present the effects of the budget-neutral updates to the IRF facility-level adjustment factors (the rural, LIP, and teaching status adjustment factors) for FY 2014.

In the aggregate, we do not estimate that these updates will affect overall estimated payments to IRFs. However, we estimate that these updates will have distributional effects, as shown in Table 18. The largest estimated decrease in payments as a result of these updates is a 3.1 percent decrease to rural IRFs in the West South Central region. The largest estimated increase in payments as a result of these updates is a 10.1 percent increase for teaching IRFs with a resident to average daily census ratio greater than 19 percent.

8. Impact of the Refinements to the Presumptive Compliance Criteria Methodology

As discussed in section VIII of this final rule, we are changing the list of ICD–9–CM codes available to meet the presumptive compliance criteria. We believe that these changes will improve the accuracy and integrity of the IRF PPS by ensuring that the cases that qualify as meeting the 60 percent rule truly meet the requirements in 42 CFR 412.29(b). These changes will affect all 1,134 IRFs, as these facilities will need to change their coding practices to continue to meet the 60 percent compliance percentage using the presumptive methodology. However, we are implementing these changes with a one-year delayed effective date, so that these changes will be effective for compliance review periods beginning on or after October 1, 2014. Thus, any potential financial impacts of these policy changes will not accrue until FY 2015.

We estimate that the financial impact, in the absence of any behavioral responses to these changes on the part of providers, would be a decrease of 6.9 percent (or \$520 million) in overall estimated payments to IRFs for FY 2015. We note that these estimates are unchanged from the ones we had noted in the proposed rule, even though we have decided to add some ICD–9–CM codes that we had proposed for deletion back onto the list of ICD–9–CM codes that would qualify a patient as meeting the 60 percent rule criteria. This is because we inadvertently used the wrong list of ICD–9–CM codes in our analysis for the proposed rule. Had we used the correct list of ICD–9–CM codes for the proposed rule analysis, our estimates of the financial impact of the proposals would have been \$20 million (or 0.2%) higher than those presented in the proposed rule, and our estimates would therefore have reduced to \$520 million (6.9 percent) for this final rule.

However, as we noted in the proposed rule, we believe that IRFs will be able to improve the specificity of their

coding practices, alter their admitting practices, meet the 60 percent compliance threshold under medical review, and make other modifications to their operations to continue to meet the 60 percent compliance threshold.

For example, we estimate that about 90 percent of the IRF cases that will potentially be affected by the final revisions to the presumptive methodology codes are affected by the removal of the non-specific codes. However, we have been careful to remove only those non-specific codes for which more specific codes for the same conditions will remain on the list of codes that meet the presumptive methodology. Thus, in all of these cases, we believe that the IRF will be able to switch to a more specific code for the same condition, leaving the IRF's admission practices and classification status unaffected.

About 1 percent of the cases that we estimate would be affected by the final revisions are affected by the Unilateral Upper Extremity Amputation codes, the Congenital Anomaly codes, and the Miscellaneous codes combined. Thus, we do not estimate that the removal of these code groups will have a significant effect on IRF admission or coding practices, or classification status.

Finally, approximately 9 percent of the cases that we estimate will be affected by the final revisions involve arthritis diagnoses. We estimate that the revisions in this category will have the largest potential effects on providers because, by the very nature of these revisions, IRFs would not have another arthritis code on the list to code instead. We estimate that about 14 percent of all IRF cases are coded with the arthritis codes that we are removing from the list, and in 11 percent of these cases, the arthritis code is the only code that would qualify the patient as meeting the 60 percent rule requirements. However, for the arthritis category of codes, we estimate that most of these cases will still be found to meet the 60 percent rule requirements under medical review, so we estimate that these revisions will lead to few if any IRF declassifications.

Historically, we have seen that IRFs adapt quickly to changes in the 60 percent rule, as evidenced by the rapid response to changes over time in the compliance threshold. Thus, we have every reason to believe that they will adapt quickly to the changes to the presumptive methodology list. In addition, the changes will not affect how many patients would ultimately be shown to meet the 60 percent rule criteria on medical review. For these reasons, we believe that our best

estimate of the impact on IRFs of these changes is no net change in Medicare reimbursement payments. Instead, IRFs will quickly change their coding practices, admission practices, meet the 60 percent compliance threshold under medical review, and make other changes to their business practice to ensure that they continue to meet the 60 percent rule requirements; although we lack data to more precisely characterize the rule-induced costs, benefits and transfers that would be experienced by IRFs, their patients and other relevant entities, we note that the \$520 million estimate appearing earlier in this section represents an upper bound (probably an extreme upper bound) on the costs that would be borne by IRFs.

We intend to closely monitor provider coding practices to these changes to the 60 percent rule in order to identify whether those patients that we envisioned would be served under the IRF PPS are counting toward the presumptive compliance percentage. We will also monitor whether these changes are having any unintended consequences in terms of limiting access to care.

Comment: One commenter requested that CMS make its impact analysis of the changes to the presumptive methodology public.

Response: We used the same methodology in the FY 2014 proposed and final rules to estimate the impacts of changes to the ICD-9-CM codes used in the presumptive methodology that we used in the May 7, 2004 to estimate the impacts of the modifications to the 60 percent rule, with one exception. A description of that methodology is included in the May 7, 2004 final rule (69 FR 25752 at 25770 through 25774). We deviated from this methodology in one respect. In this final rule, we report the estimated financial impact on IRF providers of the changes to the presumptive compliance method. In the May 7, 2004 final rule, however, we reported the estimated financial impact on Medicare's baseline (that is, the amount of savings that would be projected to accrue to the Medicare program from the policies that were finalized in the May 7, 2004 final rule). Thus, in the May 7, 2004 final rule, we estimated a net decrease in IRF admission, and then estimated that patients that were no longer treated in IRFs would be treated instead in another Medicare setting (such as a skilled nursing facility or home health care setting). We estimated the decrease in Medicare payments to IRFs, but added to that estimate the total estimated Medicare payments to the alternative Medicare settings in which the patients

would have received care. Those estimates, therefore, represent the net savings to the Medicare program. In this final rule, we are only estimating the financial impacts on IRFs, so we do not add back in the payments for the patients treated in alternative settings.

9. Effects of Updates to the IRF QRP

This final rule sets forth a number of updates and several policy changes to the IRF Quality Reporting Program. Specifically, we are taking the following actions: (A) finalizing the use of the following measures for the IRF QRP: (1) Percent of Patients/Residents with Pressure Ulcers that are New or Worsened (NQF #0678); (2) Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680); (3) Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431); (4) All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from Inpatient Rehabilitation Facilities Measure; (B) Adding new data items to the IRF-PAI to collect data for the patient influenza vaccination and pressure ulcer measures; (C) Re-numbering of Quality Indicator section of the IRF-PAI items, using a flexible numbering system; (D) finalizing our proposal to change data collection for all IRF-PAI based measures to a fiscal year basis; (E) Finalizing our proposal to impose quarterly data submission deadlines for all but one measure; (F) providing a discussion of the voluntary reconsideration process for IRFs that CMS finds to be out of compliance with the reporting requirements; (G) and a disaster waiver process.

We have based our assessment of the effects of this final rule on all of the actions described in the previous paragraph. One of the changes we have finalized is the adoption of a new pressure ulcer measure. Currently, the IRF QRP contains a pressure ulcer measure that is an application of an NQF-endorsed measure (Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay)" (NQF #0678)) that we adopted in the FY 2012 IRF PPS final rule (76 FR 47836). That measure affects an IRF's annual increase factors up through the FY 2016 annual increase factor. We have now adopted the actual NQF-endorsed version of this measure, which will affect the IRF PPS increase factor for FY 2017 and subsequent years increase factors. We also made revisions to the pressure ulcer items on the IRF-PAI that providers will use to collect data for this measure.

IRFs will incur some financial impact from the use of the pressure ulcer

measure item set that will be incorporated into the IRF-PAI. We expect that the admission and discharge pressure ulcer data will be collected by a clinician such as a RN because the assessment and staging of pressure ulcers requires a high degree of clinical judgment and experience. We estimate that it will take approximately 10 minutes of time by the RN to perform the admission pressure ulcer assessment. We further estimate that it will take 15 minutes of time to complete the discharge pressure ulcer assessment. During these time periods, the RN would be engaged in the collection of data for the purpose of the IRF QRP and would not be performing patient care. An RN or clinician with a similar level of training and expertise should perform the pressure ulcer assessment and record this data on the IRF-PAI.

We believe use of the NQF-endorsed pressure ulcer measure will cause IRFs to incur additional annual financial burden in the amount of \$4,518.61 and across all IRFs, \$5,246,106. This burden is comprised of the clinical and administrative wages. The clinical wages are based on an average hourly wage rate of \$33.23 for a RN.³⁶ We estimate that there are 359,000 IRF-PAI submissions per year³⁷ and that there are 1161 IRFs in the U.S. that will report quality data to CMS. Based on these figures, we estimate that each IRF will submit approximately 309 IRF-PAIs per year or 25.75 IRF-PAIs per month.³⁸ Assuming that each IRF-PAI submission requires 25 minutes of time by an RN at an average hourly wage of \$33.23, the yearly cost to each IRF would be \$4,278.36³⁹ and the annualized cost across all IRFs would be \$4,967,176.⁴⁰ To calculate the total amount of administrative staff wages incurred, we estimate that this data entry task will take no more than 3 minutes per each IRF-PAI record or 15.45 hours per each IRF annually or

17,937 hours across all IRFs. According to the U.S. Bureau of Labor, the average hourly wage for Administrative Assistants is \$15.55. We have estimated that there are approximately 359,000 IRF-PAI submissions per year and 1161 IRFs in the U.S. that are reporting quality data to CMS. Given this wage information, the estimated total annual cost across all IRFs for the time required for entry of pressure ulcer data into the IRF-PAI record is \$278,930. We further estimate the average yearly cost to each IRF to be \$240.25.

In addition to updating the pressure ulcer measure, we have added 3 new quality measures to the IRF QRP. These measures include: (1) Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680), which will affect the FY 2017 increase factor and subsequent years increase factors; (2) Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431), which will affect the FY 2016 increase factor and subsequent years increase factors; and (3) an All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from Inpatient Rehabilitation Facilities, which will affect the FY 2017 increase factor and subsequent years increase factors. We discuss the impact of each measure upon IRFs below.

IRFs will now submit their data for the patient influenza measure (NQF #0680) on the IRF-PAI. We have added a new data item set consisting of 3 items to the IRF-PAI to collect the data for this measure. IRF staff will be required to perform a full influenza assessment only during the influenza vaccination season, which has been defined by the CDC as the time period from October 1st (or when the vaccine becomes available) through March 31 each year. From April 1st through September 30th, IRFs are not required to perform a full influenza screening. Our time estimate reflects the averaged amount of time necessary to complete the influenza item set both during and outside the influenza vaccination season.

We believe that it will be most appropriate for a clinician, such as an RN, to complete the influenza items because this assessment requires clinical judgment and knowledge of vaccinations. An administrative employee, such as a medical data entry clerk or administrative assistant would not have this level of knowledge. We do not believe that IRFs will require additional time by administrative staff to encode and transmit this data to CMS, because submission of an IRF-PAI for each patient is already required as a condition for payment.

As noted above, we estimate that it will take approximately 5 minutes to complete the patient influenza measure item set. We have also noted above that there are approximately 359,000 IRF-PAIs completed annually across all 1161 IRFs that report IRF quality data to CMS. This breaks down to approximately 309 IRF-PAIs completed by each IRF yearly. We estimate that the annual time burden for reporting the patient influenza vaccination measure data is 29,896 hours across all IRFs in the U.S. and 25.75 hours for each individual IRF. According to the U.S. Bureau of Labor, the hourly wage for a Registered Nurse is \$33.23. The estimated annual cost across all IRFs in the U.S. for the submission of the patient influenza measure data is \$993,433 and \$855.67 for each individual IRF.

IRFs will submit their data for the staff immunization measure (NQF #0431) to the CDC's healthcare acquired (HAI) surveillance Web site known as NHSN. Data collection for this measure is only required from October 1st (or when the vaccine becomes available) through March 31st each year, during which time IRFs will be required to keep records of which staff members receive the influenza vaccination. IRFs are only required to make one report to NHSN after the close of the reporting period on March 31st. All data must be submitted by May 15th of each year. We do not believe that IRFs will incur any new burden associated with the collection of data during the influenza vaccination season. We believe that most IRFs already keep records related to the influenza vaccination of their staff because this impacts many aspects of their business, including but not limited to, staff absences and transmission of illness to other staff and patients.

We estimate that it will take each IRF approximately 15 minutes of time once per year to gather the data that was collected during the influenza vaccinations season, and prepare to make their report to NHSN. We do not estimate that it will take IRFs additional time to input their data into NHSN, once they have logged onto the system for the purpose of submitting their monthly CAUTI report. We believe that this task can be completed by an administrative person such as a Medical Secretary Medical Data Entry Clerk. As noted above, the average hourly wage for Medical Records or Health Information Technicians is \$15.55.⁴¹ We

³⁶ According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a Registered Nurse is \$33.23. (See <http://www.bls.gov/oes/2011/may/oes291111.htm>).

³⁷ MedPAC, A Data Book: Health Care Spending and the Medicare Program (June 2012), <http://www.medpac.gov/chapters/Jun12DataBookSec8.pdf>.

³⁸ 359,000 IRF-PAI reports per all IRFs per year/1161 IRFs in U.S. = 309 IRF-PAI reports per each IRF per year 309 IRF-PAI reports per IRF per year/12 months per year = 26 IRF-PAI reports per each IRF per year.

³⁹ 25 minutes × 309 IRF-PAI assessments per each IRF per year = 7,725 minutes per each IRF per year 7,725 minutes per each IRF per year/60 minutes per hour = 128.75 hours per each IRF per year 128.75 hours per year × \$33.23 per hour = \$4,278.36 nursing wages per each IRF per year.

⁴⁰ \$4,278.36 × 1161 IRF providers = \$4,967,176 per all IRFs per year.

⁴¹ According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a Medical Records & Health Information Technician is \$15.55.

estimate that the average yearly cost to each IRF for the reporting of this measure will be \$3.89⁴² and the cost across all IRFs will be \$4,516.⁴³

The readmission measure (All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from Inpatient Rehabilitation Facilities) is a claims-based measure and, therefore, IRFs are not required to submit any data for this measure. We do not anticipate that IRFs will be impacted by any financial or time burdens as a result of the use of this measure for the IRF QRP.

Taking all of the above-stated information into consideration, we estimate that the total cost to IRFs in FY 2015, including staff wages and 48 percent for fringe benefits and overhead, is \$9.2 million as related to (1) Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431); (2) Percent of Patients with Pressure Ulcers That Are New or Worsened (NQF #0678); and (3) Percent of Patients that Were Appropriately Assessed and Given the Influenza Vaccination (NQF #0680).

Over the past 18 months, we have received a great deal of positive feedback from IRFs about the IRF QRP, and overall, IRFs have been very receptive to the introduction of the IRF QRP into the IRF setting. The IRF provider community has shared many suggestions and ideas related to the IRF QRP. Outreach activities, such as a one-day in-person training, and 6 open door forums were well attended. Given the amount of positive feedback and willingness to participate in the IRF QRP that has been demonstrated by IRFs, we anticipate that there will be a relatively small number of IRFs that fail to report the type and amount of quality data that IRFs are required to collect and submit. Our proposed reconsideration process allows IRFs that receive an initial finding of non-compliance an opportunity to file a request for reconsideration of this finding. Access to this process may have the effect of lowering even further the number of IRFs who have not ultimately succeeded in meeting the IRF QRP reporting requirements.

10. Impact of the Implementation of the 2 Percentage Point Reduction in the Increase Factor for Failure To Meet the IRF Quality Reporting Requirements

As discussed in section XIV. of this final rule and in accordance with

section 1886(j)(7) of the Act, we will implement a 2 percentage point reduction in the FY 2014 increase factor for IRFs that have failed to report the required quality reporting data to us during the first IRF quality reporting period (from October 1, 2012 through December 31, 2012). In section XIV of this final rule, we discuss how the 2 percentage point reduction will be applied. Currently, we cannot estimate the overall financial impacts of the application of this reduction on aggregate IRF PPS payments or on the distribution of IRF PPS payments among providers because we cannot predict the number of or types of IRFs that will fail to report the required quality reporting data. IRFs are currently required to complete the non-quality portions of the IRF-PAI to receive payment for all Medicare fee-for-service admissions. Therefore, we estimate that the number of IRFs that would fail to submit the additional quality reporting data on the IRF-PAI form is very low.

The official reporting period end date for the first IRF quality reporting period was May 15, 2013. While we made a preliminary determination of compliance related to IRFs in June 2013, we feel that it would not be prudent to release those numbers at this time. We believe that these numbers could change substantially during the reconsideration process (described in section XIII. of the May 8, 2013 (78 FR 26880) proposed rule that will occur between July and September 2013, and that we will not have a true picture of IRF performance until after this final rule is displayed. We intend to closely monitor the effects of this new quality reporting program on IRF providers as we cannot predict the number of, or types of IRFs that would fail to report the required quality reporting data for the first quality reporting period.

D. Alternatives Considered

As stated in section XVIII (B) of this final rule, we estimate that the changes discussed in the rule would result in a significant economic impact on IRFs. The overall impact on all IRFs is an estimated increase in FY 2014 payments of \$170 million (2.3 percent), relative to FY 2013. The following is a discussion of the alternatives considered for the IRF PPS updates contained in this final rule.

Section 1886(j)(3)(C) of the Act requires the Secretary to update the IRF PPS payment rates by an increase factor that reflects changes over time in the prices of an appropriate mix of goods and services included in the covered IRF services. Thus, we did not consider alternatives to updating payments using

the estimated RPL market basket increase factor for FY 2014. 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 2014 and sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(iii) of the Act require the Secretary to apply a 0.3 percentage point reduction to the market basket increase factor for FY 2014. Thus, in accordance with section 1886(j)(3)(C) of the Act, we are updating IRF federal prospective payments in this final rule by 1.8 percent (which equals the 2.6 percent estimated RPL market basket increase factor for FY 2014 reduced by 0.3 percentage points, and further reduced by a 0.5 percentage point productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act).

We considered maintaining the existing CMG relative weights and average length of stay values for FY 2014. 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 maintaining the current facility-level adjustment factors (that is, the rural factor at 18.4 percent, the LIP factor at 0.4613, and teaching status adjustment factor at 0.6876). However, as discussed in more detail in section V (B) of this final rule, our recent research efforts have shown significant differences in cost structures between freestanding IRFs and IRF units of acute care hospitals (and CAHs). We have found that these cost structure differences substantially influence the estimates of the adjustment factors. For this reason, our regression analysis found that the proposed inclusion of the control variable for a facility's status as either a freestanding IRF hospital or an IRF unit of an acute care hospital (or a CAH) would greatly enhance the accuracy of the adjustment factors for FY 2014, as we incorporate updated data. Further, as noted previously, we received comments on the FY 2012 IRF PPS proposed rule suggesting this enhancement to the methodology. Thus, we believe that the best approach at this time is to update the facility-level adjustment factors for FY 2014 using this enhancement to the methodology.

We considered maintaining the existing outlier threshold amount for FY

See: <http://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm>.

⁴² 15 minutes Administrative staff time to collect and report staff influenza measure @ \$15.55 per hour = \$3.9889 per IRF per year.

⁴³ \$3.89 per IRF per year × 1161 IRFs in U.S. = \$4,621,516.

2014. However, analysis of updated FY 2012 data indicates that estimated outlier payments would be lower than 3 percent of total estimated payments for FY 2013, by approximately 0.5 percent, unless we updated the outlier threshold amount. Consequently, we are adjusting the outlier threshold amount in this final rule to reflect a 0.5 percent increase thereby setting the total outlier payments equal to 3 percent, instead of 2.5 percent, of aggregate estimated payments in FY 2014.

Finally, we considered maintaining the current list of ICD-9-CM codes used to determine an IRF's compliance with the 60 percent rule under the presumptive methodology, or maintaining some of the categories of codes that we proposed removing from the list in the proposed rule. However, we believe that the specific ICD-9-CM codes removed in section VIII of this final rule results in a list that better reflects the 60 percent rule regulations. For example, the removal of the non-specific diagnosis codes (as discussed in

section VIII of this final rule) is in accordance with the trend toward requiring more specific coding in other Medicare payment settings, such as the IPPS. We believe that the incentives to use more specific codes, whenever possible, will also lead to improvements in the quality of care for patients by providing more detailed information that medical personnel can use to enhance the specificity of patients' care plans. In addition, the removal of the arthritis diagnosis codes (as discussed in section VIII of this final rule) will enable CMS to ensure that we only count patients as meeting the 60 percent rule requirements if they have met the necessary severity and prior treatment requirements, information which is not discernible from the ICD-9-CM codes themselves. With respect to the other code categories that we are removing from the presumptive methodology list, we do not believe that patients who are coded with these codes would typically require treatment in an IRF, as described in more detail in section VIII of this

final rule. However, to give providers more time to adjust to the changes, we are delaying the effective date of these changes by one year, so that the changes will be effective for compliance review periods beginning on or after October 1, 2014.

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 19, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final rule. Table 19 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 1,134 IRFs in our database. In addition, the table below presents the costs associated with the new IRF quality reporting program requirements for FY 2015.

TABLE 19—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES

| Category | Transfers |
|--|--|
| Change in Estimated Transfers from FY 2013 IRF PPS to FY 2014 IRF PPS: | |
| Annualized Monetized Transfers | \$170 million. |
| From Whom to Whom? | Federal Government to IRF Medicare Providers. |
| Estimated Impacts in FY 2015 | |
| Refinements to the presumptive compliance criteria methodology under the '60 percent rule': | |
| Annualized Monetized Transfers | The estimated FY 2015 impact of the refinements to the presumptive compliance criteria methodology reflects a decrease of payments between \$0 to \$520 million, depending on the IRFs behavioral responses to the changes, with \$520 million representing the upper bound. |
| From Whom to Whom? | Federal Government to IRF Medicare Providers. |
| Cost to updating the Quality Reporting Program for IRFs: | |
| Annualized Monetized Costs for IRFs to Submit Data (Quality Reporting Program). | \$9.2 million. |

F. Conclusion

Overall, the estimated payments per discharge for IRFs in FY 2014 are projected to increase by 2.3 percent, compared with the estimated payments in FY 2013, as reflected in column 9 of Table 18. IRF payments per discharge are estimated to increase 2.5 percent in urban areas and decrease 0.2 percent in rural areas, compared with estimated FY 2013 payments. Payments per discharge to rehabilitation units are estimated to increase 2.8 percent in urban areas, whereas we estimate no change in payments per discharge to rehabilitation units in rural areas. Payments per

discharge to freestanding rehabilitation hospitals are estimated to increase 2.1 percent in urban areas and decrease 1.3 percent in rural areas.

Overall, IRFs are estimated to experience a net increase in payments as a result of the policies in this final rule. The largest payment increase is estimated to be a 3.2 percent increase for urban IRFs located in the East North Central region. This is due to the large positive effect of the facility adjustment updates for urban IRFs in this region. Finally, the total cost to IRFs in FY 2015 is \$9.2 million as related to (1) Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431); (2) Percent of

Patients with Pressure Ulcers That Are New or Worsened (NQF #0678); and (3) Percent of Patients that Were Appropriately Assessed and Given the Influenza Vaccination (NQF #0680).

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 follows:

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

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

Authority: Sections 1102, 1862, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395y, and 1395hh).

■ 2. Section 412.25 is amended by revising paragraph (a)(1)(iii) to read as follows:

§ 412.25 Excluded hospital units: Common requirements.

- (a) * * *
- (1) * * *

(iii) Unless it is a unit in a critical access hospital, the hospital of which an IRF is a unit must have at least 10 staffed and maintained hospital beds that are not excluded from the inpatient prospective payment system, or at least 1 staffed and maintained hospital bed for every 10 certified inpatient rehabilitation facility beds, whichever number is greater. Otherwise, the IRF will be classified as an IRF hospital, rather than an IRF unit. In the case of an inpatient psychiatric facility unit, the hospital must have enough beds that are not excluded from the inpatient prospective payment system to permit the provision of adequate cost information, as required by § 413.24(c) of this chapter.

* * * * *

■ 3. Section 412.29 is amended by revising paragraph (d) to read as follows:

§ 412.29 Classification criteria for payment under the inpatient rehabilitation facility prospective payment system.

* * * * *

(d) Have in effect a preadmission screening procedure under which each

prospective patient's condition and medical history are reviewed to determine whether the patient is likely to benefit significantly from an intensive inpatient hospital program. This procedure must ensure that the preadmission screening for each Medicare Part A Fee-for-Service patient is reviewed and approved by a rehabilitation physician prior to the patient's admission to the IRF.

* * * * *

■ 4. Section 412.130 is amended by revising paragraphs (a)(1), (a)(2) and (a)(3) to read as follows:

§ 412.130 Retroactive adjustments for incorrectly excluded hospitals and units.

- (a) * * *

(1) A hospital that was excluded from the prospective payment systems specified in § 412.1(a)(1) or paid under the prospective payment system specified in § 412.1(a)(3), as a new rehabilitation hospital for a cost reporting period beginning on or after October 1, 1991 based on a certification under § 412.29(c) regarding the inpatient population the hospital planned to treat during that cost reporting period, if the inpatient population actually treated in the hospital during that cost reporting period did not meet the requirements of § 412.29(b).

(2) A hospital that has a unit excluded from the prospective payment systems specified in § 412.1(a)(1) or paid under the prospective payment system specified in § 412.1(a)(3), as a new rehabilitation unit for a cost reporting period beginning on or after October 1, 1991, based on a certification under § 412.29(c) regarding the inpatient population the hospital planned to treat in that unit during the period, if the

inpatient population actually treated in the unit during that cost reporting period did not meet the requirements of § 412.29(b).

(3) A hospital that added new beds to its existing rehabilitation unit for a cost reporting period beginning on or after October 1, 1991 based on a certification under § 412.29(c) regarding the inpatient population the hospital planned to treat in these new beds during that cost reporting period, if the inpatient population actually treated in the new beds during that cost reporting period did not meet the requirements of § 412.29(b).

* * * * *

■ 5. Section 412.630 is revised to read as follows:

§ 412.630 Limitation on review.

Administrative or judicial review under sections 1869 or 1878 of the Act, or otherwise, is prohibited with regard to the establishment of the methodology to classify a patient into the case-mix groups and the associated weighting factors, the Federal per discharge payment rates, additional payments for outliers and special payments, and the area wage index.

Authority: (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program).

Dated: July 23, 2013.

Marilyn Tavenner,
Administrator, Centers for Medicare & Medicaid Services.

Approved: July 29, 2013.

Kathleen Sebelius,
Secretary.

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