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Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities (SNFs) for FY 2016, SNF Value-Based Purchasing Program, SNF Quality Reporting Program, and Staffing Data Collection; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 483

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Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities (SNFs) for FY 2016, SNF Value-Based Purchasing Program, SNF Quality Reporting Program, and Staffing Data Collection

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

ACTION: Final rule.

SUMMARY: This final rule updates the payment rates used under the prospective payment system (PPS) for skilled nursing facilities (SNFs) for fiscal year (FY) 2016. In addition, it specifies a SNF all-cause all-condition hospital readmission measure, as well as adopts that measure for a new SNF Value-Based Purchasing (VBP) Program, and includes a discussion of SNF VBP Program policies we are considering for future rulemaking to promote higher quality and more efficient health care for Medicare beneficiaries. Additionally, this final rule will implement a new quality reporting program for SNFs as specified in the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act). It also amends the requirements that a long-term care (LTC) facility must meet to qualify to participate as a skilled nursing facility (SNF) in the Medicare program, or a nursing facility (NF) in the Medicaid program, by establishing requirements that implement the provision in the Affordable Care Act regarding the submission of staffing information based on payroll data.

DATES: *Effective date:* The provisions of this final rule are effective on October 1, 2015 with the exception of provisions in § 483.75(u) which are effective on July 1, 2016.

FOR FURTHER INFORMATION CONTACT:

Penny Gershman, (410) 786-6643, for information related to SNF PPS clinical issues (excluding any issues raised in section III.D. of this final rule).

John Kane, (410) 786-0557, for information related to the development of the payment rates and case-mix indexes.

Kia Sidbury, (410) 786-7816, for information related to the wage index.

Bill Ullman, (410) 786-5667, for information related to level of care determinations, consolidated billing, and general information.

Shannon Kerr, (410) 786-0666, for information related to skilled nursing facility value-based purchasing.

Charlayne Van, (410) 786-8659, for information related to skilled nursing facility quality reporting.

Lorelei Chapman, (410) 786-9254, for information related to staffing data collection.

SUPPLEMENTARY INFORMATION:

Availability of Certain Tables Exclusively Through the Internet on the CMS Web Site

As discussed in the FY 2016 SNF PPS proposed rule (80 FR 22044), tables setting forth the Wage Index for Urban Areas Based on CBSA Labor Market Areas and the Wage Index Based on CBSA Labor Market Areas for Rural Areas are no longer published in the **Federal Register**. Instead, these tables are available exclusively through the Internet on the CMS Web site. The wage index tables for this final rule can be accessed on the SNF PPS Wage Index homepage, at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPSP/WageIndex.html>.

Readers who experience any problems accessing any of these online SNF PPS wage index tables should contact Kia Sidbury at (410) 786-7816.

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Acronyms

In addition, because of the many terms to which we refer by acronym in this final rule, we are listing these abbreviations and their corresponding terms in alphabetical order below:

- AIDS Acquired Immune Deficiency Syndrome
- ARD Assessment reference date
- BBA Balanced Budget Act of 1997, Pub. L. 105–33
- BBRA Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, Public Law 106–113
- BIPA Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Public Law 106–554
- CAH Critical access hospital
- CASPER Certification and Survey Provider Enhanced Reports
- CBSA Core-based statistical area
- CCN CMS Certification Number
- CFR Code of Federal Regulations
- CMI Case-mix index
- CMS Centers for Medicare & Medicaid Services
- COT Change of therapy
- ECI Employment Cost Index
- EHR Electronic health record
- EOT End of therapy
- EOT–R End of therapy—resumption
- ESRDQIP End-Stage Renal Disease Quality Incentive Program
- FAQ Frequently Asked Questions
- FFS Fee-for-service
- FR Federal Register
- FY Fiscal year
- GAO Government Accountability Office
- HAC Hospital-Acquired Conditions
- HACRP Hospital-Acquired Condition Reduction Program
- HCPCS Healthcare Common Procedure Coding System
- HIQR Hospital Inpatient Quality Reporting
- HOQR Hospital Outpatient Quality Reporting
- HRRP Hospital Readmissions Reduction Program
- HVBP Hospital Value-Based Purchasing
- ICR Information Collection Requirements
- IGI IHS (Information Handling Services) Global Insight, Inc.
- IMPACT Improving Medicare Post-Acute Care Transformation Act of 2014, Public Law 113–185
- IPPS Inpatient prospective payment system
- IRF Inpatient Rehabilitation Facility
- LTC Long-term care
- LTCH Long-term care hospital
- MAP Measures Application Partnership
- MDS Minimum data set
- MFP Multifactor productivity
- MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173
- MSA Metropolitan statistical area
- NAICS North American Industrial Classification System
- NF Nursing facility
- NH Nursing Home
- NQF National Quality Forum
- OBRA Omnibus Budget Reconciliation Act of 1987, Public Law 100–203
- OMB Office of Management and Budget
- OMRA Other Medicare-Required Assessment
- PAC Post-acute care
- PAMA Protecting Access to Medicare Act of 2014, Public Law 113–93
- PBJ Payroll-Based Journal
- PPS Prospective Payment System
- PQRS Physician Quality Reporting System
- QIES Quality Improvement Evaluation System
- QIES ASAP Quality Improvement and Evaluation System Assessment Submission and Processing
- QRP Quality Reporting Program
- RAI Resident assessment instrument
- RAVEN Resident assessment validation entry
- RFA Regulatory Flexibility Act, Public Law 96–354
- RIA Regulatory impact analysis
- RUG–III Resource Utilization Groups, Version 3
- RUG–IV Resource Utilization Groups, Version 4
- RUG–53 Refined 53-Group RUG–III Case-Mix Classification System
- SCHIP State Children’s Health Insurance Program
- sDTI Suspected deep tissue injuries
- SNF Skilled nursing facility
- SNFRM Skilled Nursing Facility 30-Day All-Cause Readmission Measure
- STM Staff time measurement
- STRIVE Staff time and resource intensity verification
- TEP Technical expert panel
- UMRA Unfunded Mandates Reform Act, Public Law 104–4
- VBP Value-based purchasing

I. Executive Summary

A. Purpose

This final rule updates the SNF prospective payment rates for FY 2016 as required under section 1888(e)(4)(E) of the Social Security Act (the Act). It also responds to section 1888(e)(4)(H) of the Act, which requires the Secretary to provide for publication in the **Federal Register** before the August 1 that precedes the start of each fiscal year (FY), certain specified information relating to the payment update (see section II.C.). In addition, it implements a new quality reporting program (QRP) for SNFs required under section 1888(e)(6) of the Act. The final rule also specifies a SNF all-cause all-condition hospital readmission measure required under section 1888(g)(1) of the Act, and adopts that measure for a new SNF value-based purchasing (VBP) program as required under section 1888(h) of the Act. Further, this final rule establishes new regulatory reporting requirements for SNFs and NFs to implement the statutory obligation to submit staffing information based on payroll data under section 1128I(g) of the Act.

B. Summary of Major Provisions

In accordance with sections 1888(e)(4)(E)(ii)(IV) and 1888(e)(5) of the Act, the federal rates in this final rule reflect an update to the rates that we published in the SNF PPS final rule for FY 2015 (79 FR 45628), which reflects the SNF market basket index as adjusted by the applicable forecast error correction and by the multifactor productivity adjustment for FY 2016. We are also finalizing a SNF all-cause all-condition hospital readmission measure under section 1888(g)(1) of the

Act, as well as adopting that measure for a new SNF VBP Program as required under section 1888(h) of the Act. We are also implementing a new QRP for SNFs under section 1888(e)(6) of the Act, which was added by section 2(c)(4) of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act, Pub. L. 113–185).

For payment determinations beginning with FY 2018, we are adopting measures meeting three quality domains specified in section 1899B(c)(1) of the Act: Functional status, skin integrity, and incidence of major falls.

In addition, we are adding new language at 42 CFR, part 483 to implement section 1128I(g) of the Act. Specifically, beginning on July 1, 2016, long-term care (LTC) facilities that participate in Medicare or Medicaid will be required to submit electronically direct care staffing information (including information for agency and contract staff) based on payroll and other verifiable and auditable data in a uniform format.

C. Summary of Cost and Benefits

Provision description	Total transfers
FY 2016 SNF PPS payment rate update.	The overall economic impact of this final rule will be an estimated increase of \$430 million in aggregate payments to SNFs during FY 2016.

II. Background on SNF PPS

A. Statutory Basis and Scope

As amended by section 4432 of the Balanced Budget Act of 1997 (BBA, Pub. L. 105–33), section 1888(e) of the Act provides for the implementation of a PPS for SNFs. This methodology uses prospective, case-mix adjusted per diem payment rates applicable to all covered SNF services defined in section 1888(e)(2)(A) of the Act. The SNF PPS is effective for cost reporting periods beginning on or after July 1, 1998, and covers all costs of furnishing covered SNF services (routine, ancillary, and capital-related costs) other than costs associated with approved educational activities and bad debts. Under section 1888(e)(2)(A)(i) of the Act, covered SNF services include post-hospital extended care services for which benefits are provided under Part A, as well as those items and services (other than a small number of excluded services, such as physician services) for which payment may otherwise be made under Part B and which are furnished to Medicare beneficiaries who are residents in a SNF

during a covered Part A stay. A comprehensive discussion of these provisions appears in the May 12, 1998 interim final rule (63 FR 26252). In addition, a detailed discussion of the legislative history of the SNF PPS is available online at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/Downloads/Legislative_History_07302013.pdf.

Section 215(a) of the Protecting Access to Medicare Act of 2014 (PAMA, Pub. L. 113–93, enacted on April 1, 2014), added section 1888(g) to the Act, requiring the Secretary to specify certain quality measures for the SNF setting. Additionally, section 215(b) of PAMA added section 1888(h) to the Act, requiring the Secretary to implement a VBP program for SNFs. Finally, section 2(a) of the IMPACT Act added section 1899B to the Act that, among other things, requires SNFs to report standardized data for measures in specified quality and resource use domains. In addition, the IMPACT Act added section 1888(e)(6) to the Act, which requires the Secretary to implement a QRP for SNFs, under which SNFs that do not report certain data will receive a reduction in their payments under the SNF PPS of 2 percentage points for FYs beginning with FY 2018.

B. Initial Transition for the SNF PPS

Under sections 1888(e)(1)(A) and 1888(e)(11) of the Act, the SNF PPS included an initial, three-phase transition that blended a facility-specific rate (reflecting the individual facility’s historical cost experience) with the federal case-mix adjusted rate. The transition extended through the facility’s first three cost reporting periods under the PPS, up to and including the one that began in FY 2001. Thus, the SNF PPS is no longer operating under the transition, as all facilities have been paid at the full federal rate effective with cost reporting periods beginning in FY 2002. As we now base payments for SNFs entirely on the adjusted federal per diem rates, we no longer include adjustment factors under the transition related to facility-specific rates for the upcoming FY.

C. Required Annual Rate Updates

Section 1888(e)(4)(E) of the Act requires the SNF PPS payment rates to be updated annually. The most recent annual update occurred in a final rule that set forth updates to the SNF PPS payment rates for FY 2015 (79 FR 45628, August 5, 2014).

Section 1888(e)(4)(H) of the Act specifies that we provide for publication

annually in the **Federal Register** of the following:

- The unadjusted federal per diem rates to be applied to days of covered SNF services furnished during the upcoming FY.
- The case-mix classification system to be applied for these services during the upcoming FY.
- The factors to be applied in making the area wage adjustment for these services.

Along with other revisions discussed later in this preamble, this final rule provides the required annual updates to the per diem payment rates for SNFs for FY 2016.

III. Analysis of and Responses to Public Comments on the FY 2016 SNF PPS Proposed Rule

In response to the publication of the FY 2016 SNF PPS proposed rule, we received 53 timely public comments from individuals, providers, corporations, government agencies, private citizens, trade associations, and major organizations. The following are brief summaries of each proposed provision, a summary of the public comments that we received related to that proposal, and our responses to the comments.

A. General Comments on the FY 2016 SNF PPS Proposed Rule

In addition to the comments we received on specific proposals contained within the proposed rule (which we address later in this final rule), commenters also submitted the following, more general observations on the SNF PPS and SNF care generally. A discussion of these comments, along with our responses, appears below.

Comment: One commenter expressed concern regarding the recent evolution of SNF care, stating that, in the commenter’s opinion, while resident acuity is increasing, facilities worry more about money than about actual resident care. The commenter further stated that fewer staff hours should be focused on determining a resident’s particular Resource Utilization Group (RUG) level for the purpose of managing facility budgets, and instead should be focused on resident care. Additionally, the commenter asked that we establish standards of practice to eliminate unwarranted variability in care, such as residents sharing various health characteristics but receiving very different amounts of care.

Response: We appreciate the commenter raising these points and are mindful of the commenter’s concern regarding the apparent tension between profit and resident care. We also agree

that SNF care appropriately should focus on the resident's unique characteristics and goals, and note that RUG determinations should be based on the type and amount of nursing and therapy care required by the resident, rather than on facility budget considerations. We will consider the concerns the commenter raised as we identify future areas for analysis and program monitoring.

Comment: One commenter recommended that we address the need for CMS to broaden the categories of healthcare professionals who may order patient diets. The commenter stated that such a change would improve patient health and allow SNFs to respond more quickly to resident nutritional needs.

Response: We appreciate this comment, but would note as we did in the FY 2015 SNF PPS final rule (79 FR 45630) that the specific issues the commenter raised about who may prescribe diets for SNF residents do not relate to payment policy, but rather to certification standards for long-term care facilities more generally. Therefore, while we once again note that such comments lie outside of the scope of this final rule, we will share them with the relevant CMS staff that works on survey and certification issues.

Comment: Several commenters made comments related to potential refinements or revisions of the existing SNF PPS. Some commenters expressed concern regarding compensation for non-therapy ancillary services, with one commenter stating specifically that the SNF PPS emphasizes therapy services and deemphasizes the care needs for medically complex residents, particularly in hospital-based SNFs. A second commenter stated that the current RUG system does not appropriately capture the intensity or cost of services for residents in certain non-therapy RUG groups, most notably those resident living with Alzheimer's disease and dementia. Both commenters urged CMS to revise the SNF PPS to account for the potentially increased intensity or cost of services for medically complex residents, some of which may result from the provision of non-therapy ancillary services. One commenter expressed a "growing impatience" with CMS's lack of progress in implementing a revised SNF PPS and urged CMS to move forward with a revised PPS design or provide a timeline for when such revisions will be ready given that the flaws with the current system are already well known. A different commenter expressed support for CMS's current efforts to revise the SNF PPS, while at the same time cautioning CMS to proceed

gradually by considering an approach that would transition to a revised PPS design over time.

Response: We appreciate the commenters raising these points and share the commenters' interest in exploring ways to revise the SNF PPS that may improve payment policy as well as promote appropriate resident care. We believe that our SNF payment model research (<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html>) will help us establish a strong basis for examining potential improvements and refinements to the overall SNF PPS, most notably given that we recently expanded the scope of this research to focus not only on therapy payment but nursing and non-therapy ancillary payments as well. With regard to comments on the overall approach CMS is taking in developing a revised PPS design, and specifically, the two comments that presented contrasting views on the pace of our progress, we would agree with the commenter who urged a certain degree of caution in moving to a revised SNF PPS. While we also agree that many of the issues with the current system are well known at this point, we believe that arriving at appropriate solutions to issues of this complexity will, of necessity, entail an investment of time and effort that goes considerably beyond simply identifying the issues themselves. That said, we do believe that we should continue to move as quickly as possible to address the issues with the existing SNF PPS design, though without compromising the overall integrity of our research and analysis for the sake of time. We also welcome additional comments and feedback on this research, which may be submitted to: SNFTherapyPayments@cms.hhs.gov.

Comment: One commenter raised a concern regarding the potential impact of current Minimum Data Set (MDS) 3.0 assessment rules and policies during facility audits of completed MDS assessments. Specifically, the commenter stated that during an audit of assessments completed by a given facility, it might be discovered that correcting a given error (for example, an error in the number of therapy minutes coded on a given assessment) also means that a Change-of-Therapy (COT) Other Medicare-Required Assessment (OMRA) may have been missed during that timeframe when the original error occurred. Due to the missed assessment policy outlined in Chapters 2 and 6 of the MDS 3.0 manual, this could mean that the days associated with that missed assessment could be considered

provider liable, which could have a significant financial impact on the facility. The commenter recommended that CMS re-evaluate the potentially punitive impact of not being able to complete an MDS after the resident's Medicare-covered SNF stay has ended.

Response: The consequences associated with coding errors and the use of audits to identify these errors are necessary to ensure that SNFs take seriously the responsibility of ensuring that accurate information is coded on the MDS. While we appreciate that errors are always possible, we do not believe that this is sufficient to warrant a change in policy at this time. We will continue to consider this issue as part of our ongoing evaluation of potential refinements and improvements to the overall SNF PPS.

B. SNF PPS Rate Setting Methodology and FY 2016 Update

1. Federal Base Rates

Under section 1888(e)(4) of the Act, the SNF PPS uses per diem federal payment rates based on mean SNF costs in a base year (FY 1995) updated for inflation to the first effective period of the PPS. We developed the federal payment rates using allowable costs from hospital-based and freestanding SNF cost reports for reporting periods beginning in FY 1995. The data used in developing the federal rates also incorporated a Part B add-on, which is an estimate of the amounts that, prior to the SNF PPS, would have been payable under Part B for covered SNF services furnished to individuals during the course of a covered Part A stay in a SNF.

In developing the rates for the initial period, we updated costs to the first effective year of the PPS (the 15-month period beginning July 1, 1998) using a SNF market basket index, and then standardized for geographic variations in wages and for the costs of facility differences in case mix. In compiling the database used to compute the federal payment rates, we excluded those providers that received new provider exemptions from the routine cost limits, as well as costs related to payments for exceptions to the routine cost limits. Using the formula that the BBA prescribed, we set the federal rates at a level equal to the weighted mean of freestanding costs plus 50 percent of the difference between the freestanding mean and weighted mean of all SNF costs (hospital-based and freestanding) combined. We computed and applied separately the payment rates for facilities located in urban and rural areas, and adjusted the portion of the federal rate attributable to wage-related

costs by a wage index to reflect geographic variations in wages.

2. SNF Market Basket Update

a. SNF Market Basket Index

Section 1888(e)(5)(A) of the Act requires us to establish a SNF market basket index that reflects changes over time in the prices of an appropriate mix of goods and services included in covered SNF services. Accordingly, we have developed a SNF market basket index that encompasses the most commonly used cost categories for SNF routine services, ancillary services, and capital-related expenses. We use the SNF market basket index, adjusted in the manner described below, to update the federal rates on an annual basis. In the SNF PPS final rule for FY 2014 (78 FR 47939 through 47946), we revised and rebased the market basket, which included updating the base year from FY 2004 to FY 2010.

For the FY 2016 proposed rule, the FY 2010-based SNF market basket growth rate was estimated to be 2.6 percent, which was based on the IHS Global Insight, Inc. (IGI) first quarter 2015 forecast with historical data through fourth quarter 2014. However, as discussed in the FY 2016 SNF PPS proposed rule (80 FR 22049), we proposed that if more recent data become available (for example, a more recent estimate of the FY 2010-based SNF market basket and/or MFP adjustment), we would use such data, if appropriate, to determine the FY 2016 SNF market basket percentage change, labor-related share relative importance, forecast error adjustment, and MFP adjustment in this final rule. Since that time we have received an updated FY 2016 market basket percentage increase, which is based on the second quarter 2015 IHS Global Insight forecast of the FY 2010-based SNF market basket. The revised market basket growth rate is 2.3 percent. In section III.B.2.e. of this final rule, we discuss the specific application

of this adjustment to the forthcoming annual update of the SNF PPS payment rates.

b. Use of the SNF Market Basket Percentage

Section 1888(e)(5)(B) of the Act defines the SNF market basket percentage as the percentage change in the SNF market basket index from the midpoint of the previous FY to the midpoint of the current FY. For the federal rates set forth in this final rule, we use the percentage change in the SNF market basket index to compute the update factor for FY 2016. This is based on the IGI second quarter 2015 forecast (with historical data through the first quarter 2015) of the FY 2016 percentage increase in the FY 2010-based SNF market basket index for routine, ancillary, and capital-related expenses, which is used to compute the update factor in this final rule. As discussed in sections III.B.2.c. and III.B.2.d. of this final rule, this market basket percentage change is reduced by the applicable forecast error correction (as described in § 413.337(d)(2)) and by the multifactor productivity adjustment as required by section 1888(e)(5)(B)(ii) of the Act. Finally, as discussed in section II.B. of this final rule, we no longer compute update factors to adjust a facility-specific portion of the SNF PPS rates, because the initial three-phase transition period from facility-specific to full federal rates that started with cost reporting periods beginning in July 1998 has expired.

c. Forecast Error Adjustment

As discussed in the June 10, 2003 supplemental proposed rule (68 FR 34768) and finalized in the August 4, 2003, final rule (68 FR 46057 through 46059), the regulations at § 413.337(d)(2) provide for an adjustment to account for market basket forecast error. The initial adjustment for market basket forecast error applied to

the update of the FY 2003 rate for FY 2004, and took into account the cumulative forecast error for the period from FY 2000 through FY 2002, resulting in an increase of 3.26 percent to the FY 2004 update. Subsequent adjustments in succeeding FYs take into account the forecast error from the most recently available FY for which there is final data, and apply the difference between the forecasted and actual change in the market basket when the difference exceeds a specified threshold. We originally used a 0.25 percentage point threshold for this purpose; however, for the reasons specified in the FY 2008 SNF PPS final rule (72 FR 43425, August 3, 2007), we adopted a 0.5 percentage point threshold effective for FY 2008 and subsequent FYs. As we stated in the final rule for FY 2004 that first issued the market basket forecast error adjustment (68 FR 46058, August 4, 2003), the adjustment will reflect both upward and downward adjustments, as appropriate.

For FY 2014 (the most recently available FY for which there is final data), the estimated increase in the market basket index was 2.3 percentage points, while the actual increase for FY 2014 was 1.7 percentage points, resulting in the actual increase being 0.6 percentage point lower than the estimated increase. Accordingly, as the difference between the estimated and actual amount of change in the market basket index exceeds the 0.5 percentage point threshold and because, in this instance, the estimated amount of change exceeded the actual amount of change, the FY 2016 market basket percentage change of 2.3 percent would be adjusted downward by the forecast error correction of 0.6 percentage point, resulting in a SNF market basket increase of 1.7 percent, before application of the productivity adjustment discussed in this section. Table 1 shows the forecasted and actual market basket amounts for FY 2014.

TABLE 1—DIFFERENCE BETWEEN THE FORECASTED AND ACTUAL MARKET BASKET INCREASES FOR FY 2014

Index	Forecasted FY 2014 increase*	Actual FY 2014 increase**	FY 2014 Difference
SNF	2.3	1.7	-0.6

* Published in **Federal Register**; based on second quarter 2013 IGI forecast (2010-based index).

** Based on the first quarter 2015 IGI forecast, with historical data through the fourth quarter 2014 (2010-based index).

A discussion of the general comments that we received on the forecast error adjustment, and our responses to those comments, appears below.

Comment: One commenter requested that in determining the need for a

market basket forecast error adjustment in a given year, CMS consider recalculating the wage index budget neutrality factor (discussed in section III.B.4 of this final rule) based on more recent data and utilize any error found

in the original budget neutrality factor calculation in CMS's determination of the need for a market basket forecast error adjustment.

Response: The commenter appears to be requesting a wage index budget

neutrality factor error adjustment. However, we note at the outset that given the limited year-to-year variance in the wage index budget neutrality factor, any calculation of a budget neutrality factor error would likely represent an error of no more than a few thousandths of a percentage point, and thus we do not believe a wage index budget neutrality factor error adjustment would be necessary. Moreover, the market basket forecast error adjustment and the wage index budget neutrality factor serve fundamentally different purposes and involve entirely separate aspects of the SNF PPS. As such, we do not believe it would be appropriate to apply a wage index budget neutrality factor error to a market basket forecast error in order to determine if the market basket forecast error adjustment should be made.

Comment: One commenter stated that the forecast error adjustment of 0.6 percentage point represents a significant reduction and recommended that we implement the forecast error correction over a 2-year period.

Response: The forecast error adjustment is an essential aspect of ensuring that SNF PPS payments are as accurate as possible. Therefore, consistent with the way we have applied forecast error adjustments in the past, we do not believe that it is either appropriate or beneficial to the overall integrity of the SNF PPS to implement this adjustment over a multiple-year period.

d. Multifactor Productivity Adjustment

Section 3401(b) of the Affordable Care Act requires that, in FY 2012 (and in subsequent FYs), the market basket percentage under the SNF payment system as described in section 1888(e)(5)(B)(i) of the Act is to be reduced annually by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1886(b)(3)(B)(xi)(II) of the Act, added by section 3401(a) of the Affordable Care Act, sets forth the definition of this productivity adjustment. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multi-factor productivity (as projected by the Secretary for the 10-year period ending with the applicable FY, year, cost-reporting period, or other annual period) (the MFP adjustment). The Bureau of Labor Statistics (BLS) is the agency that publishes the official measure of private nonfarm business multifactor productivity (MFP). We refer readers to the BLS Web site at [http://](http://www.bls.gov/mfp)

www.bls.gov/mfp for the BLS historical published MFP data.

MFP is derived by subtracting the contribution of labor and capital inputs growth from output growth. The projections of the components of MFP are currently produced by IGI, a nationally recognized economic forecasting firm with which CMS contracts to forecast the components of the market baskets and MFP. To generate a forecast of MFP, IGI replicates the MFP measure calculated by the BLS, using a series of proxy variables derived from IGI's U.S. macroeconomic models. In section III.F.3. of the FY 2012 SNF PPS final rule (76 FR 48527 through 48529), we identified each of the major MFP component series employed by the BLS to measure MFP as well as provided the corresponding concepts determined to be the best available proxies for the BLS series.

Beginning with the FY 2016 rulemaking cycle, the MFP adjustment is calculated using a revised series developed by IGI to proxy the aggregate capital inputs. Specifically, IGI has replaced the Real Effective Capital Stock used for Full Employment GDP with a forecast of BLS aggregate capital inputs recently developed by IGI using a regression model. This series provides a better fit to the BLS capital inputs as measured by the differences between the actual BLS capital input growth rates and the estimated model growth rates over the historical time period. Therefore, we are using IGI's most recent forecast of the BLS capital inputs series in the MFP calculations beginning with the FY 2016 rulemaking cycle. A complete description of the MFP projection methodology is available on our Web site at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html>. Although we discuss the IGI changes to the MFP proxy series in this final rule, in the future, when IGI makes changes to the MFP methodology, we will announce them on our Web site rather than in the annual rulemaking.

(1) Incorporating the Multifactor Productivity Adjustment Into the Market Basket Update

According to section 1888(e)(5)(A) of the Act, the Secretary shall establish a SNF market basket index that reflects changes over time in the prices of an appropriate mix of goods and services included in covered SNF services. Section 1888(e)(5)(B)(ii) of the Act, added by section 3401(b) of the Affordable Care Act, requires that for FY

2012 and each subsequent FY, after determining the market basket percentage described in section 1888(e)(5)(B)(i) of the Act, the Secretary shall reduce such percentage by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) (which we refer to as the MFP adjustment). Section 1888(e)(5)(B)(ii) of the Act further states that the reduction of the market basket percentage by the MFP adjustment may result in the market basket percentage being less than zero for a FY, and may result in payment rates under section 1888(e) of the Act for a FY being less than such payment rates for the preceding FY. Thus, if the application of the MFP adjustment to the market basket percentage calculated under section 1888(e)(5)(B)(i) of the Act results in an MFP-adjusted market basket percentage that is less than zero, then the annual update to the unadjusted federal per diem rates under section 1888(e)(4)(E)(ii) of the Act would be negative, and such rates would decrease relative to the prior FY.

For the FY 2016 update, the MFP adjustment is calculated as the 10-year moving average of changes in MFP for the period ending September 30, 2016. In the FY 2016 SNF PPS proposed rule, this adjustment was calculated to be 0.6 percent. However, as discussed in the FY 2016 SNF PPS proposed rule (80 FR 22049), we proposed that if more recent data become available (for example, a more recent estimate of the FY 2010-based SNF market basket and/or MFP adjustment), we would use such data, if appropriate, to determine, among other things, the FY 2016 SNF market basket percentage change and the MFP adjustment in this final rule. Therefore, based on IGI's most recent second quarter 2015 forecast (with historical data through first quarter 2015), the MFP adjustment for FY 2016 is 0.5 percent. Consistent with section 1888(e)(5)(B)(i) of the Act and § 413.337(d)(2) of the regulations, the market basket percentage for FY 2016 for the SNF PPS is based on IGI's second quarter 2015 forecast of the SNF market basket update (2.3 percent) as adjusted by the forecast error adjustment (0.6 percentage point), and is estimated to be 1.7 percent. In accordance with section 1888(e)(5)(B)(ii) of the Act (as added by section 3401(b) of the Affordable Care Act) and § 413.337(d)(3), this market basket percentage is then reduced by the MFP adjustment (the 10-year moving average of changes in MFP for the period ending September 30, 2016) of 0.5 percent, which is calculated as described above and based on IGI's second quarter 2015 forecast. The

resulting MFP-adjusted SNF market basket update is equal to 1.2 percent, or 1.7 percent less 0.5 percentage point.

e. Market Basket Update Factor for FY 2016

Sections 1888(e)(4)(E)(ii)(IV) and 1888(e)(5)(i) of the Act require that the update factor used to establish the FY 2016 unadjusted federal rates be at a level equal to the market basket index percentage change. Accordingly, we determined the total growth from the average market basket level for the period of October 1, 2014 through September 30, 2015 to the average market basket level for the period of October 1, 2015 through September 30, 2016. This process yields a percentage change in the market basket of 2.3 percent.

As further explained in section III.B.2.c. of this final rule, as applicable, we adjust the market basket percentage change by the forecast error from the most recently available FY for which there is final data and apply this adjustment whenever the difference between the forecasted and actual percentage change in the market basket exceeds a 0.5 percentage point threshold. Since the forecasted FY 2014 SNF market basket percentage change exceeded the actual FY 2014 SNF market basket percentage change (FY 2014 is the most recently available FY for which there is final data) by more than 0.5 percentage point, the FY 2016 market basket percentage change of 2.3 percent would be adjusted downward by the applicable difference, which for FY 2014 is 0.6 percent.

In addition, for FY 2016, section 1888(e)(5)(B)(ii) of the Act requires us to reduce the market basket percentage change by the MFP adjustment (the 10-year moving average of changes in MFP for the period ending September 30, 2016) of 0.5 percent, as described in section III.B.2.d. of this final rule. The resulting net SNF market basket update would equal 1.2 percent, or 2.3 percent less the 0.6 percentage point forecast error adjustment, less the 0.5 percentage point MFP adjustment. We proposed in the FY 2016 SNF PPS proposed rule (80 FR 22049) that if more recent data become available (for example, a more recent estimate of the FY 2010-based SNF market basket and/or MFP adjustment), we would use such data, if appropriate, to determine the FY 2016 SNF market basket percentage change, labor-related share relative importance, forecast error adjustment, and MFP adjustment in this final rule. As noted above, more recent data were used to update the market basket update and MFP adjustment in this final rule.

A discussion of the general comments that we received on the market basket update factor for FY 2016, and our responses to those comments, appears below.

Comment: We received a number of comments in relation to applying the FY 2016 market basket update factor in the determination of the FY 2016 unadjusted federal per diem rates, with some commenters supporting its application in determining the FY 2016 unadjusted per diem rates, while others opposed its application. In their March 2015 report (available at: [http://www.medpac.gov/documents/reports/chapter-8-skilled-nursing-facility-services-\(march-2015-report\).pdf?sfvrsn=0](http://www.medpac.gov/documents/reports/chapter-8-skilled-nursing-facility-services-(march-2015-report).pdf?sfvrsn=0)) and in their comment on the FY 2016 SNF PPS proposed rule, MedPAC recommended that CMS eliminate the market basket update for SNFs altogether and rebase payments for the SNF PPS, beginning with a 4 percent reduction in the base payment rates.

Response: We appreciate all of the comments received on the proposed market basket update for FY 2016. In response to those comments which opposed our applying the FY 2016 market basket update factor in determining the FY 2016 unadjusted federal per diem rates, specifically MedPAC's proposal to eliminate the market basket update for SNFs and to implement a 4 percent reduction to the SNF PPS base rates, we would need statutory authority to act on these proposals at the current time.

Comment: One commenter stated that in their preliminary analyses, they observed a gap between the market basket and costs indexed to 2001 dollars (which we assume to mean an index based on 2001 dollars) which occurs even in rebasing years. They also observed a growing gap in non-labor components. They stated that further research is needed to understand the gap and they respectfully request that CMS engage in an ongoing dialogue.

Response: We appreciate the commenter's review of the SNF market basket methodology and look forward to the commenter's analysis. While any comments on the SNF market basket methodology, including any analyses, can be emailed to DNHS@cms.hhs.gov, we would be happy to engage in further dialogue on this issue.

Comment: One commenter noted that the weights used in calculating the market basket update should continue to use the most updated cost data available. They suggested that the market basket be revised and reweighted with greater frequency—on the same schedule as the hospital market basket,

particularly given the new Medicare provisions, such as the IMPACT Act and also if the SNF wage index continues to be directly linked to the hospital wage index. The commenter also suggested that CMS update the market basket each year; alternatively, should such a process be too onerous, CMS should calculate the six major cost weights derived from the Medicare cost report (wages and salaries, employee benefits, contract labor, pharmaceuticals, professional liability insurance and capital-related) every year and update the market basket every 4 years (rather than every 6), as well as whenever the aggregate percentage change of the six major cost weights, when taken together, exceeds some set amount.

Response: We appreciate the commenter's request for the SNF market basket to be revised and reweighted more frequently. As discussed in the FY 2006 IPPS final rule (70 FR 47387), we established a rebasing frequency of every 4 years for the hospital market basket, in accordance with section 404 of Public Law 108–173. We typically rebase and revise the SNF market baskets approximately every 6 years. Our prior analysis has shown that the major cost weights do not vary that much from year to year. However, we do understand the commenter's concern for more frequent rebasings given that any changes in the Medicare law could alter the way in which SNFs provide Medicare services—which, in turn, potentially could affect the SNF cost structures (that is, the market basket cost weights). Accordingly, we will consider the methodology presented by the commenter and evaluate the possible impact on the SNF market basket update by monitoring the percent change of the six major cost weights derived from the Medicare cost report (wages and salaries, employee benefits, contract labor, pharmaceuticals, professional liability insurance and capital-related).

Accordingly, for the reasons specified in this final rule and in the FY 2016 SNF PPS proposed rule (80 FR 22047 through 22049), we are applying the FY 2016 market basket increase factor, as adjusted by the forecast error correction and MFP adjustment as described above, in our determination of the FY 2016 SNF PPS unadjusted federal per diem rates. We used the SNF market basket, adjusted as described in this section, to adjust each per diem component of the federal rates forward to reflect the change in the average prices for FY 2016 from average prices for FY 2015. We would further adjust the rates by a wage index budget neutrality factor, described later in this

section. Tables 2 and 3 reflect the updated components of the unadjusted federal rates for FY 2016, prior to adjustment for case-mix.

TABLE 2—FY 2016 UNADJUSTED FEDERAL RATE PER DIEM URBAN

Rate component	Nursing—case-mix	Therapy—case-mix	Therapy—non-case-mix	Non-case-mix
Per Diem Amount	\$171.17	\$128.94	\$16.98	\$87.36

TABLE 3—FY 2016 UNADJUSTED FEDERAL RATE PER DIEM RURAL

Rate component	Nursing—case-mix	Therapy—case-mix	Therapy—non-case-mix	Non-case-mix
Per Diem Amount	\$163.53	\$148.67	\$18.14	\$88.97

3. Case-Mix Adjustment

Under section 1888(e)(4)(G)(i) of the Act, the federal rate also incorporates an adjustment to account for facility case-mix, using a classification system that accounts for the relative resource utilization of different patient types. The statute specifies that the adjustment is to reflect both a resident classification system that the Secretary establishes to account for the relative resource use of different patient types, as well as resident assessment data and other data that the Secretary considers appropriate. In the interim final rule with comment period that initially implemented the SNF PPS (63 FR 26252, May 12, 1998), we developed the RUG-III case-mix classification system, which tied the amount of payment to resident resource use in combination with resident characteristic information. Staff time measurement (STM) studies conducted in 1990, 1995, and 1997 provided information on resource use (time spent by staff members on residents) and resident characteristics that enabled us not only to establish RUG-III, but also to create case-mix indexes (CMIs). The original RUG-III grouper logic was based on clinical data collected in 1990, 1995, and 1997. As discussed in the SNF PPS proposed rule for FY 2010 (74 FR 22208), we subsequently conducted a multi-year data collection and analysis under the Staff Time and Resource Intensity Verification (STRIVE) project to update the case-mix classification system for FY 2011. The resulting Resource Utilization Groups, Version 4 (RUG-IV) case-mix classification system reflected the data collected in 2006 through 2007 during the STRIVE project, and was finalized in the FY 2010 SNF PPS final rule (74 FR 40288) to take effect in FY 2011 concurrently with an updated new resident assessment instrument, version 3.0 of the Minimum Data Set (MDS 3.0),

which collects the clinical data used for case-mix classification under RUG-IV.

We note that case-mix classification is based, in part, on the beneficiary's need for skilled nursing care and therapy services. The case-mix classification system uses clinical data from the MDS to assign a case-mix group to each patient that is then used to calculate a per diem payment under the SNF PPS. As discussed in section III.C.1. of this final rule, the clinical orientation of the case-mix classification system supports the SNF PPS's use of an administrative presumption that considers a beneficiary's initial case-mix classification to assist in making certain SNF level of care determinations. Further, because the MDS is used as a basis for payment, as well as a clinical assessment, we have provided extensive training on proper coding and the time frames for MDS completion in our Resident Assessment Instrument (RAI) Manual. For an MDS to be considered valid for use in determining payment, the MDS assessment must be completed in compliance with the instructions in the RAI Manual in effect at the time the assessment is completed. For payment and quality monitoring purposes, the RAI Manual consists of both the Manual instructions and the interpretive guidance and policy clarifications posted on the appropriate MDS Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/MDS30RAIManual.html>.

In addition, we note that section 511 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA, Pub. L. 108-173) amended section 1888(e)(12) of the Act to provide for a temporary increase of 128 percent in the PPS per diem payment for any SNF residents with Acquired Immune Deficiency Syndrome (AIDS), effective with services furnished on or after October 1, 2004. This special add-on for SNF residents with AIDS was to remain

in effect until the Secretary certifies that there is an appropriate adjustment in the case mix to compensate for the increased costs associated with such residents. The add-on for SNF residents with AIDS is also discussed in Program Transmittal #160 (Change Request #3291), issued on April 30, 2004, which is available online at www.cms.gov/transmittals/downloads/r160cp.pdf. In the SNF PPS final rule for FY 2010 (74 FR 40288), we did not address the certification related to the add-on for SNF residents with AIDS in that final rule's implementation of the case-mix refinements for RUG-IV, thus allowing the add-on payment required by section 511 of the MMA to remain in effect. For the limited number of SNF residents that qualify for this add-on, there is a significant increase in payments. For example, using FY 2013 data, we identified fewer than 4,800 SNF residents with a diagnosis code of 042 (Human Immunodeficiency Virus (HIV) Infection). For FY 2016, an urban facility with a resident with AIDS in RUG-IV group "HC2" would have a case-mix adjusted per diem payment of \$427.85 (see Table 4) before the application of the MMA adjustment. After an increase of 128 percent, this urban facility would receive a case-mix adjusted per diem payment of approximately \$975.50.

Currently, we use the International Classification of Diseases, 9th revision, Clinical Modification (ICD-9-CM) code 042 to identify those residents for whom it is appropriate to apply the AIDS add-on established by section 511 of the MMA. In this context, we note that the Department published a final rule in the September 5, 2012 **Federal Register** (77 FR 54664) which requires us to stop using ICD-9-CM on September 30, 2014, and begin using the International Classification of Diseases, 10th revision, Clinical Modification (ICD-10-CM), on October 1, 2014. Regarding the above-referenced ICD-9-CM diagnosis code of

042, in the FY 2014 SNF PPS proposed rule (78 FR 26444, May 6, 2013), we proposed to transition to the equivalent ICD-10-CM diagnosis code of B20 upon the overall conversion to ICD-10-CM on October 1, 2014, and we subsequently finalized that proposal in the FY 2014 SNF PPS final rule (78 FR 47951 through 47952).

However, on April 1, 2014, PAMA was enacted. Section 212 of PAMA, titled "Delay in Transition from ICD-9 to ICD-10 Code Sets," provides that the Secretary of Health and Human Services may not, prior to October 1, 2015, adopt ICD-10 code sets as the standard for code sets under section 1173(c) of the Act (42 U.S.C. 1320d-2(c)) and 45 CFR 162.1002. In the FY 2015 SNF PPS final rule (79 FR 45633), we stated that the Department expected to release an interim final rule in the near future that would include a new compliance date that would require the use of ICD-10 beginning October 1, 2015. In light of this, in the FY 2015 SNF PPS final rule,

we stated that the effective date of the change from ICD-9-CM code 042 to ICD-10-CM code B20 for purposes of applying the AIDS add-on is October 1, 2015, and that until that time we would continue to use the ICD-9-CM code 042 for this purpose. On August 4, 2014, HHS released a final rule in the **Federal Register** (79 FR 45128 through 45134) that included a new compliance date that requires the use of ICD-10 beginning October 1, 2015. The August 4, 2014 final rule is available for viewing on the Internet at <http://www.gpo.gov/fdsys/pkg/FR-2014-08-04/pdf/2014-18347.pdf>. That final rule also requires HIPAA covered entities to continue to use ICD-9-CM through September 30, 2015. Thus, as we finalized in the FY 2015 SNF PPS final rule, the effective date of the change from ICD-9-CM code 042 to ICD-10-CM code B20 for the purpose of applying the AIDS add-on enacted by section 511 of the MMA is October 1, 2015.

Under section 1888(e)(4)(H), each update of the payment rates must include the case-mix classification methodology applicable for the upcoming FY. The payment rates set forth in this final rule reflect the use of the RUG-IV case-mix classification system from October 1, 2015, through September 30, 2016. We list the proposed case-mix adjusted RUG-IV payment rates, provided separately for urban and rural SNFs, in Tables 4 and 5 with corresponding case-mix values. We use the revised OMB delineations adopted in the FY 2015 SNF PPS final rule (79 FR 45632, 45634) to identify a facility's urban or rural status for the purpose of determining which set of rate tables apply to the facility. These tables do not reflect the add-on for SNF residents with AIDS enacted by section 511 of the MMA, which we apply only after making all other adjustments (such as wage index and case-mix).

TABLE 4—RUG-IV CASE-MIX ADJUSTED FEDERAL RATES AND ASSOCIATED INDEXES URBAN

RUG-IV Category	Nursing index	Therapy index	Nursing component	Therapy component	Non-case mix therapy comp	Non-case mix component	Total rate
RUX	2.67	1.87	\$457.02	\$241.12	\$87.36	\$785.50
RUL	2.57	1.87	439.91	241.12	87.36	768.39
RVX	2.61	1.28	446.75	165.04	87.36	699.15
RVL	2.19	1.28	374.86	165.04	87.36	627.26
RHX	2.55	0.85	436.48	109.60	87.36	633.44
RHL	2.15	0.85	368.02	109.60	87.36	564.98
RMX	2.47	0.55	422.79	70.92	87.36	581.07
RML	2.19	0.55	374.86	70.92	87.36	533.14
RLX	2.26	0.28	386.84	36.10	87.36	510.30
RUC	1.56	1.87	267.03	241.12	87.36	595.51
RUB	1.56	1.87	267.03	241.12	87.36	595.51
RUA	0.99	1.87	169.46	241.12	87.36	497.94
RVC	1.51	1.28	258.47	165.04	87.36	510.87
RVB	1.11	1.28	190.00	165.04	87.36	442.40
RVA	1.10	1.28	188.29	165.04	87.36	440.69
RHC	1.45	0.85	248.20	109.60	87.36	445.16
RHB	1.19	0.85	203.69	109.60	87.36	400.65
RHA	0.91	0.85	155.76	109.60	87.36	352.72
RMC	1.36	0.55	232.79	70.92	87.36	391.07
RMB	1.22	0.55	208.83	70.92	87.36	367.11
RMA	0.84	0.55	143.78	70.92	87.36	302.06
RLB	1.50	0.28	256.76	36.10	87.36	380.22
RLA	0.71	0.28	121.53	36.10	87.36	244.99
ES3	3.58	612.79	16.98	87.36	717.13
ES2	2.67	457.02	16.98	87.36	561.36
ES1	2.32	397.11	16.98	87.36	501.45
HE2	2.22	380.00	16.98	87.36	484.34
HE1	1.74	297.84	16.98	87.36	402.18
HD2	2.04	349.19	16.98	87.36	453.53
HD1	1.60	273.87	16.98	87.36	378.21
HC2	1.89	323.51	16.98	87.36	427.85
HC1	1.48	253.33	16.98	87.36	357.67
HB2	1.86	318.38	16.98	87.36	422.72
HB1	1.46	249.91	16.98	87.36	354.25
LE2	1.96	335.49	16.98	87.36	439.83
LE1	1.54	263.60	16.98	87.36	367.94
LD2	1.86	318.38	16.98	87.36	422.72
LD1	1.46	249.91	16.98	87.36	354.25
LC2	1.56	267.03	16.98	87.36	371.37
LC1	1.22	208.83	16.98	87.36	313.17
LB2	1.45	248.20	16.98	87.36	352.54
LB1	1.14	195.13	16.98	87.36	299.47

TABLE 4—RUG-IV CASE-MIX ADJUSTED FEDERAL RATES AND ASSOCIATED INDEXES URBAN—Continued

RUG-IV Category	Nursing index	Therapy index	Nursing component	Therapy component	Non-case mix therapy comp	Non-case mix component	Total rate
CE2	1.68		287.57		16.98	87.36	391.91
CE1	1.50		256.76		16.98	87.36	361.10
CD2	1.56		267.03		16.98	87.36	371.37
CD1	1.38		236.21		16.98	87.36	340.55
CC2	1.29		220.81		16.98	87.36	325.15
CC1	1.15		196.85		16.98	87.36	301.19
CB2	1.15		196.85		16.98	87.36	301.19
CB1	1.02		174.59		16.98	87.36	278.93
CA2	0.88		150.63		16.98	87.36	254.97
CA1	0.78		133.51		16.98	87.36	237.85
BB2	0.97		166.03		16.98	87.36	270.37
BB1	0.90		154.05		16.98	87.36	258.39
BA2	0.70		119.82		16.98	87.36	224.16
BA1	0.64		109.55		16.98	87.36	213.89
PE2	1.50		256.76		16.98	87.36	361.10
PE1	1.40		239.64		16.98	87.36	343.98
PD2	1.38		236.21		16.98	87.36	340.55
PD1	1.28		219.10		16.98	87.36	323.44
PC2	1.10		188.29		16.98	87.36	292.63
PC1	1.02		174.59		16.98	87.36	278.93
PB2	0.84		143.78		16.98	87.36	248.12
PB1	0.78		133.51		16.98	87.36	237.85
PA2	0.59		100.99		16.98	87.36	205.33
PA1	0.54		92.43		16.98	87.36	196.77

TABLE 5—RUG-IV CASE-MIX ADJUSTED FEDERAL RATES AND ASSOCIATED INDEXES RURAL

RUG-IV Category	Nursing index	Therapy index	Nursing component	Therapy component	Non-case mix therapy comp	Non-case mix component	Total rate
RUX	2.67	1.87	\$436.63	\$278.01		\$88.97	\$803.61
RUL	2.57	1.87	420.27	278.01		88.97	787.25
RVX	2.61	1.28	426.81	190.30		88.97	706.08
RVL	2.19	1.28	358.13	190.30		88.97	637.40
RHX	2.55	0.85	417.00	126.37		88.97	632.34
RHL	2.15	0.85	351.59	126.37		88.97	566.93
RMX	2.47	0.55	403.92	81.77		88.97	574.66
RML	2.19	0.55	358.13	81.77		88.97	528.87
RLX	2.26	0.28	369.58	41.63		88.97	500.18
RUC	1.56	1.87	255.11	278.01		88.97	622.09
RUB	1.56	1.87	255.11	278.01		88.97	622.09
RUA	0.99	1.87	161.89	278.01		88.97	528.87
RVC	1.51	1.28	246.93	190.30		88.97	526.20
RVB	1.11	1.28	181.52	190.30		88.97	460.79
RVA	1.10	1.28	179.88	190.30		88.97	459.15
RHC	1.45	0.85	237.12	126.37		88.97	452.46
RHB	1.19	0.85	194.60	126.37		88.97	409.94
RHA	0.91	0.85	148.81	126.37		88.97	364.15
RMC	1.36	0.55	222.40	81.77		88.97	393.14
RMB	1.22	0.55	199.51	81.77		88.97	370.25
RMA	0.84	0.55	137.37	81.77		88.97	308.11
RLB	1.50	0.28	245.30	41.63		88.97	375.90
RLA	0.71	0.28	116.11	41.63		88.97	246.71
ES3	3.58		585.44		18.14	88.97	692.55
ES2	2.67		436.63		18.14	88.97	543.74
ES1	2.32		379.39		18.14	88.97	486.50
HE2	2.22		363.04		18.14	88.97	470.15
HE1	1.74		284.54		18.14	88.97	391.65
HD2	2.04		333.60		18.14	88.97	440.71
HD1	1.60		261.65		18.14	88.97	368.76
HC2	1.89		309.07		18.14	88.97	416.18
HC1	1.48		242.02		18.14	88.97	349.13
HB2	1.86		304.17		18.14	88.97	411.28
HB1	1.46		238.75		18.14	88.97	345.86
LE2	1.96		320.52		18.14	88.97	427.63
LE1	1.54		251.84		18.14	88.97	358.95
LD2	1.86		304.17		18.14	88.97	411.28
LD1	1.46		238.75		18.14	88.97	345.86
LC2	1.56		255.11		18.14	88.97	362.22
LC1	1.22		199.51		18.14	88.97	306.62

TABLE 5—RUG—IV CASE-MIX ADJUSTED FEDERAL RATES AND ASSOCIATED INDEXES RURAL—Continued

RUG—IV Category	Nursing index	Therapy index	Nursing component	Therapy component	Non-case mix therapy comp	Non-case mix component	Total rate
LB2	1.45		237.12		18.14	88.97	344.23
LB1	1.14		186.42		18.14	88.97	293.53
CE2	1.68		274.73		18.14	88.97	381.84
CE1	1.50		245.30		18.14	88.97	352.41
CD2	1.56		255.11		18.14	88.97	362.22
CD1	1.38		225.67		18.14	88.97	332.78
CC2	1.29		210.95		18.14	88.97	318.06
CC1	1.15		188.06		18.14	88.97	295.17
CB2	1.15		188.06		18.14	88.97	295.17
CB1	1.02		166.80		18.14	88.97	273.91
CA2	0.88		143.91		18.14	88.97	251.02
CA1	0.78		127.55		18.14	88.97	234.66
BB2	0.97		158.62		18.14	88.97	265.73
BB1	0.90		147.18		18.14	88.97	254.29
BA2	0.70		114.47		18.14	88.97	221.58
BA1	0.64		104.66		18.14	88.97	211.77
PE2	1.50		245.30		18.14	88.97	352.41
PE1	1.40		228.94		18.14	88.97	336.05
PD2	1.38		225.67		18.14	88.97	332.78
PD1	1.28		209.32		18.14	88.97	316.43
PC2	1.10		179.88		18.14	88.97	286.99
PC1	1.02		166.80		18.14	88.97	273.91
PB2	0.84		137.37		18.14	88.97	244.48
PB1	0.78		127.55		18.14	88.97	234.66
PA2	0.59		96.48		18.14	88.97	203.59
PA1	0.54		88.31		18.14	88.97	195.42

4. Wage Index Adjustment

Section 1888(e)(4)(G)(ii) of the Act requires that we adjust the federal rates to account for differences in area wage levels, using a wage index that the Secretary determines appropriate. Since the inception of the SNF PPS, we have used hospital inpatient wage data in developing a wage index to be applied to SNFs. We proposed to continue this practice for FY 2016, as we continue to believe that in the absence of SNF-specific wage data, using the hospital inpatient wage index data is appropriate and reasonable for the SNF PPS. As explained in the update notice for FY 2005 (69 FR 45786), the SNF PPS does not use the hospital area wage index’s occupational mix adjustment, as this adjustment serves specifically to define the occupational categories more clearly in a hospital setting; moreover, the collection of the occupational wage data also excludes any wage data related to SNFs. Therefore, we believe that using the updated wage data exclusive of the occupational mix adjustment continues to be appropriate for SNF payments. For FY 2016, the updated wage data are for hospital cost reporting periods beginning on or after October 1, 2011 and before October 1, 2012 (FY 2012 cost report data).

We note that section 315 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA, Pub. L. 106–554)

authorized us to establish a geographic reclassification procedure that is specific to SNFs, but only after collecting the data necessary to establish a SNF wage index that is based on wage data from nursing homes. However, to date, this has proven to be unfeasible due to the volatility of existing SNF wage data and the significant amount of resources that would be required to improve the quality of that data.

In addition, we proposed to continue to use the same methodology discussed in the SNF PPS final rule for FY 2008 (72 FR 43423) to address those geographic areas in which there are no hospitals, and thus, no hospital wage index data on which to base the calculation of the FY 2016 SNF PPS wage index. For rural geographic areas that do not have hospitals, and therefore, lack hospital wage data on which to base an area wage adjustment, we would use the average wage index from all contiguous Core-Based Statistical Areas (CBSAs) as a reasonable proxy. For FY 2016, there are no rural geographic areas that do not have hospitals, and thus, this methodology will not be applied. For rural Puerto Rico, we will not apply this methodology due to the distinct economic circumstances that exist there (for example, due to the close proximity to one another of almost all of Puerto Rico’s various urban and non-urban areas, this methodology would produce a wage index for rural Puerto Rico that

is higher than that in half of its urban areas); instead, we will continue to use the most recent wage index previously available for that area. For urban areas without specific hospital wage index data, we will use the average wage indexes of all of the urban areas within the state to serve as a reasonable proxy for the wage index of that urban CBSA. For FY 2016, the only urban area without wage index data available is CBSA 25980, Hinesville-Fort Stewart, GA. The wage index applicable to FY 2016 is set forth in Table A available on the CMS Web site at <http://cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/WageIndex.html>.

Once calculated, we will apply the wage index adjustment to the labor-related portion of the federal rate. Each year, we calculate a revised labor-related share, based on the relative importance of labor-related cost categories (that is, those cost categories that are labor-intensive and vary with the local labor market) in the input price index. In the SNF PPS final rule for FY 2014 (78 FR 47944 through 47946), we finalized a proposal to revise the labor-related share to reflect the relative importance of the revised FY 2010-based SNF market basket cost weights for the following cost categories: Wages and salaries; employee benefits; the labor-related portion of nonmedical professional fees; administrative and facilities support services; all other:

Labor-related services; and a proportion of capital-related expenses.

We calculate the labor-related relative importance from the SNF market basket, and it approximates the labor-related portion of the total costs after taking into account historical and projected price changes between the base year and FY 2016. The price proxies that move the different cost categories in the market basket do not necessarily change at the same rate, and the relative importance captures these changes. Accordingly, the relative importance figure more closely reflects the cost share weights for FY 2016 than the base year weights from the SNF market basket.

We calculate the labor-related relative importance for FY 2016 in four steps. First, we compute the FY 2016 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 2016 price index level for that cost category by the total market basket price index level. Third, we determine the FY 2016 relative importance for each cost category by multiplying this ratio by the base year (FY 2010) weight. Finally, we add the FY 2016 relative importance for each of the labor-related cost categories (wages and salaries, employee benefits, the labor-related portion of non-medical professional fees, administrative and facilities support services, all other: labor-related services, and a portion of capital-related expenses) to produce the FY 2016 labor-related relative importance. Table 6 summarizes the updated labor-related share for FY 2016, compared to the labor-related share that was used for the FY 2015 SNF PPS final rule.

We proposed for FY 2016 and subsequent FYs, to report and apply the SNF PPS labor-related share at a tenth of a percentage point (rather than at a thousandth of a percentage point) consistent with the manner in which we report and apply the market basket update percentage under the SNF PPS and the IPPS and the manner in which we report and apply the IPPS labor-related share. The level of precision specified for the IPPS labor-related share is three decimal places or a tenth of a percentage point (0.696 or 69.6 percent), which we believe provides a reasonable level of precision. We believe it is appropriate to maintain such consistency across all payment systems so that the level of precision specified is both reasonable and similar for all providers. Additionally, we proposed in the FY 2016 SNF PPS proposed rule (80 FR 22049) that if more recent data become available (for

example, a more recent estimate of the FY 2010-based SNF market basket and/or MFP adjustment), we would use such data, if appropriate, to determine the FY 2016 SNF market basket percentage change, labor-related share relative importance, forecast error adjustment, and MFP adjustment in this final rule. We note that more recent data did become available and that the proposed labor related share for FY 2016 of 69.2 percent has been updated, based on IGI's second quarter 2015 forecast, to an FY 2016 labor related share of 69.1 percent.

We invited public comments on these proposals. A discussion of the comments we received on these proposals, as well as a discussion of the general comments that we received on the wage index adjustment, and our responses to those comments, appears below.

Comment: Several commenters stated that hospital cost data may not be the most reliable resource when determining geographical differences in salary structure for SNFs. These commenters urged CMS to establish a SNF-specific wage index. One commenter stated that new SNF cost reports, required by section 6104 of the Affordable Care Act, provide the requisite data in order for CMS to establish a SNF-specific wage index that could replace the current use of the inpatient hospital wage index data as the basis for the current SNF wage index.

Response: We appreciate the commenters raising these concerns, particularly the one commenter who provided significant details on how new SNF cost-report data could be used to develop a SNF-specific wage index. While CMS may consider this new data source as a potential stepping-stone towards developing a SNF-specific wage index, we note that consistent with our previous responses to these recurring comments (most recently published in the FY 2015 SNF PPS final rule (79 FR 45636)), developing such a wage index would require a resource-intensive audit process similar to that used for IPPS hospital data, to improve the quality of the SNF cost report data in order for it to be used as part of this analysis. Ultimately, while we continue to review all available data and contemplate the potential methodological approaches for a SNF-specific wage index in the future, we do not believe that the current state of the data is sufficiently refined to permit any such use of this data at this time.

Comment: Some commenters urged that CMS, to the extent that we plan to continue to use hospital cost data as the

basis for SNF wage index adjustments, consider adopting certain wage index policies in use under the IPPS, such as reclassification or rural floor, because SNFs compete in a similar labor pool as acute care hospitals. Commenters also stated that CMS should use post-reclassification hospital wage data to influence SNF PPS wage index policy decisions. These commenters further stated that in addition to considering such policies as reclassification and a rural floor, CMS should consider implementing a floor and ceiling for annual changes to the wage index in order to smooth perceived volatility of such changes.

Response: Consistent with our previous responses to these recurring comments (most recently published in the FY 2015 SNF PPS final rule (79 FR 45636 through 45637)), we continue to believe that in the absence of the appropriate SNF-specific wage data, using the pre-reclassified hospital inpatient wage data (without the occupational mix adjustment) is appropriate and reasonable for the SNF PPS. As discussed above, section 315 of BIPA authorized us to establish a geographic reclassification procedure that is specific to SNFs, only after collecting the data necessary to establish a SNF-specific wage index that is based on data from nursing homes. However, to date this has been infeasible due to the volatility of existing SNF wage data and the significant amount of resources that would be required to improve the quality of that data. Furthermore, we do not believe that using hospital reclassification data would be appropriate as this data is specific to the requesting hospitals and it may or may not apply to a given SNF in a given instance. With regard to implementing a rural floor, we do not believe it would be prudent at this time to adopt such a policy, because MedPAC has recommended eliminating the rural floor policy from the calculation of the IPPS wage index (see, for example, Chapter 3 of MedPAC's March 2013 Report to Congress on Medicare Payment Policy, available at http://medpac.gov/documents/reports/mar13_entirereport.pdf, which notes on page 65 that in 2007, MedPAC had “. . . recommended eliminating these special wage index adjustments and adopting a new wage index system to avoid geographic inequities that can occur due to current wage index policies (Medicare Payment Advisory Commission 2007b.’’) If we adopted the rural floor at this time under the SNF PPS, we believe that, the SNF PPS wage index could become vulnerable to

problems similar to those that MedPAC identified in its March 2013 Report to Congress. Additionally, at this time, we do not believe it would be appropriate to establish a floor and ceiling for annual wage index changes. Any perceived volatility in the wage index is predicated upon volatility in actual wages in that area and reflects real differences in area wage levels that should be accounted for timely. As stated above, under 1888(e)(4)(G)(ii) of the Act and § 413.337(a)(1)(ii) of the regulations, we adjust the SNF PPS rates to account for differences in area wage levels. We believe that applying a ceiling or floor to annual wage index changes would make the wage index for a given area less reflective of the area wage levels and changes. Additionally, we note that establishing an artificial ceiling for annual changes in the wage index could not only result in an inaccurate wage index, but also

potentially have an adverse impact on those providers that would otherwise experience a larger increase in their wage index absent such a ceiling.

Comment: One commenter requested that CMS provide more detail on the processes and procedures that are used in determining what hospital data may be excluded from forming the inpatient hospital wage index, which serves as the basis for the SNF wage index.

Response: The processes and procedures for how the inpatient hospital wage index is developed are discussed in the Inpatient Prospective Payment System (IPPS) rule each year, with the most recent discussion appearing in the FY 2016 IPPS proposed rule (80 FR 24463 through 24477) and subsequent FY 2016 IPPS final rule.

After considering the comments received and for the reasons discussed above and in the FY 2016 SNF PPS proposed rule (80 FR 22052 through

22056), we are finalizing the FY 2016 wage index adjustment and related policies as proposed in the FY 2016 SNF PPS proposed rule without modification. For FY 2016, the updated wage data are for hospital cost reporting periods beginning on or after October 1, 2011 and before October 1, 2012 (FY 2012 cost report data). We are also finalizing our proposal that for FY 2016 and subsequent FYs, we will report and apply the SNF PPS labor-related share at a tenth of a percentage point (rather than at a thousandth of a percentage point) consistent with the manner in which we report and apply the market basket update percentage under the SNF PPS and the IPPS and the manner in which we report and apply the IPPS labor-related share. Table 6 summarizes the updated labor-related share for FY 2016, compared to the labor-related share that was used for the FY 2015 SNF PPS final rule.

TABLE 6—LABOR-RELATED RELATIVE IMPORTANCE, FY 2015 AND FY 2016

	Relative importance, labor-related, FY 2015 14:2 forecast ¹	Relative importance, labor-related, FY 2016 15:2 forecast ²
Wages and salaries	48.816	48.8
Employee benefits	11.365	11.3
Nonmedical Professional fees: labor-related	3.450	3.5
Administrative and facilities support services	0.502	0.5
All Other: Labor-related services	2.276	2.3
Capital-related (.391)	2.771	2.7
Total	69.180	69.1

¹ Published in the **Federal Register**; based on second quarter 2014 IGI forecast

² Based on second quarter 2015 IGI forecast, with historical data through first quarter 2015.

Tables 7 and 8 show the RUG-IV related and non-labor-related case-mix adjusted federal rates by labor- components.

TABLE 7—RUG-IV CASE-MIX ADJUSTED FEDERAL RATES FOR URBAN SNFs BY LABOR AND NON-LABOR COMPONENT

RUG-IV Category	Total rate	Labor portion	Non-labor portion
RUX	785.50	\$542.78	\$242.72
RUL	768.39	530.96	237.43
RVX	699.15	483.11	216.04
RVL	627.26	433.44	193.82
RHX	633.44	437.71	195.73
RHL	564.98	390.40	174.58
RMX	581.07	401.52	179.55
RML	533.14	368.40	164.74
RLX	510.30	352.62	157.68
RUC	595.51	411.50	184.01
RUB	595.51	411.50	184.01
RUA	497.94	344.08	153.86
RVC	510.87	353.01	157.86
RVB	442.40	305.70	136.70
RVA	440.69	304.52	136.17
RHC	445.16	307.61	137.55
RHB	400.65	276.85	123.80
RHA	352.72	243.73	108.99
RMC	391.07	270.23	120.84
RMB	367.11	253.67	113.44
RMA	302.06	208.72	93.34
RLB	380.22	262.73	117.49

TABLE 7—RUG—IV CASE-MIX ADJUSTED FEDERAL RATES FOR URBAN SNFS BY LABOR AND NON-LABOR COMPONENT—
Continued

RUG—IV Category	Total rate	Labor portion	Non-labor portion
RLA	244.99	169.29	75.70
ES3	717.13	495.54	221.59
ES2	561.36	387.90	173.46
ES1	501.45	346.50	154.95
HE2	484.34	334.68	149.66
HE1	402.18	277.91	124.27
HD2	453.53	313.39	140.14
HD1	378.21	261.34	116.87
HC2	427.85	295.64	132.21
HC1	357.67	247.15	110.52
HB2	422.72	292.10	130.62
HB1	354.25	244.79	109.46
LE2	439.83	303.92	135.91
LE1	367.94	254.25	113.69
LD2	422.72	292.10	130.62
LD1	354.25	244.79	109.46
LC2	371.37	256.62	114.75
LC1	313.17	216.40	96.77
LB2	352.54	243.61	108.93
LB1	299.47	206.93	92.54
CE2	391.91	270.81	121.10
CE1	361.10	249.52	111.58
CD2	371.37	256.62	114.75
CD1	340.55	235.32	105.23
CC2	325.15	224.68	100.47
CC1	301.19	208.12	93.07
CB2	301.19	208.12	93.07
CB1	278.93	192.74	86.19
CA2	254.97	176.18	78.79
CA1	237.85	164.35	73.50
BB2	270.37	186.83	83.54
BB1	258.39	178.55	79.84
BA2	224.16	154.89	69.27
BA1	213.89	147.80	66.09
PE2	361.10	249.52	111.58
PE1	343.98	237.69	106.29
PD2	340.55	235.32	105.23
PD1	323.44	223.50	99.94
PC2	292.63	202.21	90.42
PC1	278.93	192.74	86.19
PB2	248.12	171.45	76.67
PB1	237.85	164.35	73.50
PA2	205.33	141.88	63.45
PA1	196.77	135.97	60.80

TABLE 8—RUG—IV CASE-MIX ADJUSTED FEDERAL RATES FOR RURAL SNFS BY LABOR AND NON-LABOR COMPONENT

RUG—IV category	Total rate	Labor portion	Non-labor portion
RUX	803.61	\$555.29	\$248.32
RUL	787.25	543.99	243.26
RVX	706.08	487.90	218.18
RVL	637.40	440.44	196.96
RHX	632.34	436.95	195.39
RHL	566.93	391.75	175.18
RMX	574.66	397.09	177.57
RML	528.87	365.45	163.42
RLX	500.18	345.62	154.56
RUC	622.09	429.86	192.23
RUB	622.09	429.86	192.23
RUA	528.87	365.45	163.42
RVC	526.20	363.60	162.60
RVB	460.79	318.41	142.38
RVA	459.15	317.27	141.88
RHC	452.46	312.65	139.81
RHB	409.94	283.27	126.67
RHA	364.15	251.63	112.52
RMC	393.14	271.66	121.48
RMB	370.25	255.84	114.41
RMA	308.11	212.90	95.21

TABLE 8—RUG—IV CASE-MIX ADJUSTED FEDERAL RATES FOR RURAL SNFS BY LABOR AND NON-LABOR COMPONENT—Continued

RUG—IV category	Total rate	Labor portion	Non-labor portion
RLB	375.90	259.75	116.15
RLA	246.71	170.48	76.23
ES3	692.55	478.55	214.00
ES2	543.74	375.72	168.02
ES1	486.50	336.17	150.33
HE2	470.15	324.87	145.28
HE1	391.65	270.63	121.02
HD2	440.71	304.53	136.18
HD1	368.76	254.81	113.95
HC2	416.18	287.58	128.60
HC1	349.13	241.25	107.88
HB2	411.28	284.19	127.09
HB1	345.86	238.99	106.87
LE2	427.63	295.49	132.14
LE1	358.95	248.03	110.92
LD2	411.28	284.19	127.09
LD1	345.86	238.99	106.87
LC2	362.22	250.29	111.93
LC1	306.62	211.87	94.75
LB2	344.23	237.86	106.37
LB1	293.53	202.83	90.70
CE2	381.84	263.85	117.99
CE1	352.41	243.52	108.89
CD2	362.22	250.29	111.93
CD1	332.78	229.95	102.83
CC2	318.06	219.78	98.28
CC1	295.17	203.96	91.21
CB2	295.17	203.96	91.21
CB1	273.91	189.27	84.64
CA2	251.02	173.45	77.57
CA1	234.66	162.15	72.51
BB2	265.73	183.62	82.11
BB1	254.29	175.71	78.58
BA2	221.58	153.11	68.47
BA1	211.77	146.33	65.44
PE2	352.41	243.52	108.89
PE1	336.05	232.21	103.84
PD2	332.78	229.95	102.83
PD1	316.43	218.65	97.78
PC2	286.99	198.31	88.68
PC1	273.91	189.27	84.64
PB2	244.48	168.94	75.54
PB1	234.66	162.15	72.51
PA2	203.59	140.68	62.91
PA1	195.42	135.04	60.38

Section 1888(e)(4)(G)(ii) of the Act also requires that we apply this wage index in a manner that does not result in aggregate payments under the SNF PPS that are greater or less than would otherwise be made if the wage adjustment had not been made. For FY 2016 (federal rates effective October 1, 2015), we will apply an adjustment to fulfill the budget neutrality requirement. We meet this requirement by multiplying each of the components of the unadjusted federal rates by a budget neutrality factor equal to the ratio of the weighted average wage adjustment factor for FY 2015 to the weighted average wage adjustment factor for FY 2016. For this calculation, we use the same FY 2014 claims utilization data for both the numerator and denominator of

this ratio. We define the wage adjustment factor used in this calculation as the labor share of the rate component multiplied by the wage index plus the non-labor share of the rate component. The budget neutrality factor for FY 2016 would be 0.9992.

In the SNF PPS final rule for FY 2006 (70 FR 45026, August 4, 2005), we adopted the changes discussed in the OMB Bulletin No. 03–04 (June 6, 2003), available online at www.whitehouse.gov/omb/bulletins/b03-04.html, which announced revised definitions for MSAs and the creation of micropolitan statistical areas and combined statistical areas.

In adopting the CBSA geographic designations, we provided for a 1-year transition in FY 2006 with a blended

wage index for all providers. For FY 2006, the wage index for each provider consisted of a blend of 50 percent of the FY 2006 MSA-based wage index and 50 percent of the FY 2006 CBSA-based wage index (both using FY 2002 hospital data). We referred to the blended wage index as the FY 2006 SNF PPS transition wage index. As discussed in the SNF PPS final rule for FY 2006 (70 FR 45041), since the expiration of this 1-year transition on September 30, 2006, we have used the full CBSA-based wage index values.

On February 28, 2013, OMB issued OMB Bulletin No. 13–01, announcing revisions to the delineation of MSAs, Micropolitan Statistical Areas, and Combined Statistical Areas, and guidance on uses of the delineation of

these areas. This bulletin, which is available online at <http://www.whitehouse.gov/sites/default/files/omb/bulletins/2013/b-13-01.pdf>, provides the delineations of all Metropolitan Statistical Areas, Metropolitan Divisions, Micropolitan Statistical Areas, Combined Statistical Areas, and New England City and Town Areas in the United States and Puerto Rico based on the standards published on June 28, 2010, in the **Federal Register** (75 FR 37246 through 37252) and Census Bureau data.

While the revisions OMB published on February 28, 2013 are not as sweeping as the changes made when we adopted the CBSA geographic designations for FY 2006, the February

28, 2013 bulletin does contain a number of significant changes. For example, there are new CBSAs, urban counties that became rural, rural counties that became urban, and existing CBSAs that were split apart.

In the FY 2015 SNF PPS final rule (79 FR 45644 through 45646), we finalized changes to the SNF PPS wage index based on the newest OMB delineations, as described in OMB Bulletin No. 13–01, beginning in FY 2015, including a 1-year transition with a blended wage index for FY 2015. Because the 1-year transition period expires at the end of FY 2015, the SNF PPS wage index for FY 2016 is fully based on the revised OMB delineations adopted in FY 2015. As noted in this section, the wage index

applicable to FY 2016 is set forth in Table A available on the CMS Web site at <http://cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/WageIndex.html>.

5. Adjusted Rate Computation Example

Using the hypothetical SNF XYZ described below, Table 9 shows the adjustments made to the federal per diem rates to compute the provider's actual per diem PPS payment. We derive the Labor and Non-labor columns from Table 7. The wage index used in this example is based on the wage index found in Table A as referenced in this section. As illustrated in Table 9, SNF XYZ's total PPS payment would equal \$45,256.24.

TABLE 9—ADJUSTED RATE COMPUTATION EXAMPLE SNF XYZ: LOCATED IN FREDERICK, MD (URBAN CBSA 43524)
WAGE INDEX: 0.9640
[See wage index in table A]¹

RUG–IV Group	Labor	Wage index	Adjusted labor	Non-labor	Adjusted rate	Percent adjustment	Medicare days	Payment
RVX	\$483.11	0.9640	\$465.72	\$216.04	\$681.76	\$681.76	14	\$9,544.64
ES2	387.90	0.9640	373.94	173.46	547.40	547.40	30	16,422.00
RHA	243.73	0.9640	234.96	108.99	343.95	343.95	16	5,503.20
CC2*	224.68	0.9640	216.59	100.47	317.06	722.90	10	7,229.00
BA2	154.89	0.9640	149.31	69.27	218.58	218.58	30	6,557.40
.....	100	45,256.24

* Reflects a 128 percent adjustment from section 511 of the MMA.

¹ Available on the CMS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/WageIndex.html>.

C. Additional Aspects of the SNF PPS

1. SNF Level of Care—Administrative Presumption

The establishment of the SNF PPS did not change Medicare's fundamental requirements for SNF coverage. However, because the case-mix classification is based, in part, on the beneficiary's need for skilled nursing care and therapy, we have attempted, where possible, to coordinate claims review procedures with the existing resident assessment process and case-mix classification system discussed in section III.B.3 of this final rule. This approach includes an administrative presumption that utilizes a beneficiary's initial classification in one of the upper 52 RUGs of the 66-group RUG–IV case-mix classification system to assist in making certain SNF level of care determinations.

In accordance with section 1888(e)(4)(H)(ii) of the Act and the regulations at § 413.345, we include in each update of the federal payment rates in the **Federal Register** the designation of those specific RUGs under the classification system that represent the required SNF level of care, as provided in § 409.30. As set forth in the FY 2011 SNF PPS update notice (75 FR 42910), this designation reflects an

administrative presumption under the 66-group RUG–IV system that beneficiaries who are correctly assigned to one of the upper 52 RUG–IV groups on the initial 5-day, Medicare-required assessment are automatically classified as meeting the SNF level of care definition up to and including the assessment reference date on the five-day Medicare-required assessment.

A beneficiary assigned to any of the lower 14 RUG–IV groups is not automatically classified as either meeting or not meeting the definition, but instead receives an individual level of care determination using the existing administrative criteria. This presumption recognizes the strong likelihood that beneficiaries assigned to one of the upper 52 RUG–IV groups during the immediate post-hospital period require a covered level of care, which would be less likely for those beneficiaries assigned to one of the lower 14 RUG–IV groups.

In the July 30, 1999 final rule (64 FR 41670), we indicated that we would announce any changes to the guidelines for Medicare level of care determinations related to modifications in the case-mix classification structure. In this final rule, we will continue to designate the upper 52 RUG–IV groups for purposes of this administrative

presumption, consisting of all groups encompassed by the following RUG–IV categories:

- Rehabilitation plus Extensive Services.
- Ultra High Rehabilitation.
- Very High Rehabilitation.
- High Rehabilitation.
- Medium Rehabilitation.
- Low Rehabilitation.
- Extensive Services.
- Special Care High.
- Special Care Low.
- Clinically Complex.

However, we note that this administrative presumption policy does not supersede the SNF's responsibility to ensure that its decisions relating to level of care are appropriate and timely, including a review to confirm that the services prompting the beneficiary's assignment to one of the upper 52 RUG–IV groups (which, in turn, serves to trigger the administrative presumption) are themselves medically necessary. As we explained in the FY 2000 SNF PPS final rule (64 FR 41667), the administrative presumption:

. . . is itself rebuttable in those individual cases in which the services actually received by the resident do not meet the basic statutory criterion of being reasonable and necessary to diagnose or treat a beneficiary's condition (according to section 1862(a)(1) of

the Act). Accordingly, the presumption would not apply, for example, in those situations in which a resident's assignment to one of the upper . . . groups is itself based on the receipt of services that are subsequently determined to be not reasonable and necessary.

Moreover, we want to stress the importance of careful monitoring for changes in each patient's condition to determine the continuing need for Part A SNF benefits after the assessment reference date of the 5-day assessment.

We received one comment on this issue, which we discuss below along with our response.

Comment: One commenter requested that CMS consider further analysis of the administrative presumption that utilizes a beneficiary's initial classification in one of the upper 52 RUGs to assist in making certain SNF level of care determinations. The commenter expressed concern that the use of such presumptions could disadvantage members of certain vulnerable specialty populations who might not typically group to one of the upper 52 RUGs, and yet still require a sufficient intensity of services to qualify for coverage.

Response: While it is true that those SNF residents who group to one of the lower 14 RUGs on the initial 5-day, Medicare-required assessment are not automatically *presumed* to require a skilled level of care, neither are they automatically classified as requiring nonskilled care. Instead, as we have noted in this and previous SNF PPS rules, any such resident “. . . receives an individual level of care determination using the existing administrative criteria.” We adopted this approach specifically to ensure that the presumption does not disadvantage such residents, by providing them with an individualized level of care determination that fully considers all pertinent factors. Nevertheless, as we noted previously in the FY 2000 SNF PPS final rule (64 FR 41668, July 30, 1999), while we believe that the use of the administrative level of care presumption “. . . represents a significant advancement toward achieving greater simplicity, predictability, and consistency in the coverage process, we will continue to monitor coverage determinations under the SNF PPS with a view toward the possibility of making further refinements and improvements in the future.” Accordingly, we will keep the commenter's concerns in mind as we continue our ongoing SNF PPS research and analysis.

2. Consolidated Billing

Sections 1842(b)(6)(E) and 1862(a)(18) of the Act (as added by section 4432(b) of the BBA) require a SNF to submit consolidated Medicare bills to its Medicare Administrative Contractor for almost all of the services that its residents receive during the course of a covered Part A stay. In addition, section 1862(a)(18) of the Act places the responsibility with the SNF for billing Medicare for physical therapy, occupational therapy, and speech-language pathology services that the resident receives during a noncovered stay. Section 1888(e)(2)(A) of the Act excludes a small list of services from the consolidated billing provision (primarily those services furnished by physicians and certain other types of practitioners), which remain separately billable under Part B when furnished to a SNF's Part A resident. These excluded service categories are discussed in greater detail in section V.B.2. of the May 12, 1998 interim final rule (63 FR 26295 through 26297).

A detailed discussion of the legislative history of the consolidated billing provision is available on the SNF PPS Web site at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/Downloads/Legislative_History_07302013.pdf. In particular, section 103 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA, Pub. L. 106–113) amended section 1888(e)(2)(A) of the Act by further excluding a number of individual “high-cost, low probability” services, identified by Healthcare Common Procedure Coding System (HCPCS) codes, within several broader categories (chemotherapy items, chemotherapy administration services, radioisotope services, and customized prosthetic devices) that otherwise remained subject to the provision. We discussed this BBRA amendment in greater detail in the SNF PPS proposed and final rules for FY 2001 (65 FR 19231 through 19232, April 10, 2000, and 65 FR 46790 through 46795, July 31, 2000), as well as in Program Memorandum AB–00–18 (Change Request #1070), issued March 2000, which is available online at www.cms.gov/transmittals/downloads/ab001860.pdf.

As explained in the FY 2001 proposed rule (65 FR 19231 through 19232), the amendments enacted in section 103 of the BBRA not only identified for exclusion from this provision a number of particular service codes within four specified categories (that is, chemotherapy items, chemotherapy administration services, radioisotope services, and customized prosthetic

devices), but also gave the Secretary “. . . the authority to designate additional, individual services for exclusion within each of the specified service categories.” In the proposed rule for FY 2001, we also noted that the BBRA Conference report (H.R. Rep. No. 106–479 at 854 (1999) (Conf. Rep.)) characterizes the individual services that this legislation targets for exclusion as “. . . high-cost, low probability events that could have devastating financial impacts because their costs far exceed the payment [SNFs] receive under the prospective payment system. . . .” According to the conferees, section 103(a) of the BBRA “is an attempt to exclude from the PPS certain services and costly items that are provided infrequently in SNFs. . . .” By contrast, we noted that the Congress declined to designate for exclusion any of the remaining services within those four categories (thus, leaving all of those services subject to SNF consolidated billing), because they are relatively inexpensive and are furnished routinely in SNFs.

As we further explained in the final rule for FY 2001 (65 FR 46790), and as our longstanding policy, any additional service codes that we might designate for exclusion under our discretionary authority must meet the same statutory criteria used in identifying the original codes excluded from consolidated billing under section 103(a) of the BBRA: they must fall within one of the four service categories specified in the BBRA; and they also must meet the same standards of high cost and low probability in the SNF setting, as discussed in the BBRA Conference report. Accordingly, we characterized this statutory authority to identify additional service codes for exclusion “. . . as essentially affording the flexibility to revise the list of excluded codes in response to changes of major significance that may occur over time (for example, the development of new medical technologies or other advances in the state of medical practice)” (65 FR 46791), and since that time, we have periodically invited the public to submit comments identifying codes that might meet the criteria for exclusion. In the FY 2016 SNF PPS proposed rule (80 FR 22057–58), we specifically invited public comments identifying HCPCS codes in any of these four service categories (chemotherapy items, chemotherapy administration services, radioisotope services, and customized prosthetic devices) representing recent medical advances that might meet our criteria for exclusion from SNF consolidated billing, and we requested

commenters to identify in their comments the specific HCPCS code that is associated with the service in question, as well as their rationale for requesting that the identified HCPCS code(s) be excluded. A discussion of the public comments received on this topic, along with our responses, appears below.

Comment: One commenter recommended a new chemotherapy drug, BLINCYTO®, as meeting the statutory “high-cost, low probability” criteria for exclusion from consolidated billing. After noting that this drug currently is assigned a temporary C code, C9449 (Injection, blinatumomab, 1 mcg.), the commenter referred to our explanation in the FY 2015 SNF PPS final rule that “. . . a chemotherapy drug’s assignment to its own specific code has always served as the mechanism of designating that drug for exclusion, as well as the means by which the claims processing system is able to recognize that exclusion” (79 FR 45642, August 5, 2014). The commenter then suggested that until such time as this drug may be assigned a permanent J code of its own, CMS should devise an administrative alternative for effectuating its exclusion from consolidated billing, such as utilizing the drug’s existing C code for this purpose. The commenter further stated that the exclusion list’s current use of C codes for designating the excluded magnetic resonance imaging (MRI) services in Major Category I.C establishes the feasibility of similarly adopting such an approach for chemotherapy drugs like BLINCYTO® under Major Category III.A.

Response: We agree with the commenter that, as described, this drug would appear to meet the “high-cost, low probability” criteria to qualify for the statutory carve-out of certain highly intensive chemotherapy drugs from consolidated billing. We note that, as described in the National Institutes of Health’s *MedlinePlus* Web site at www.nlm.nih.gov/medlineplus/druginfo/meds/a614061.html, this is one of the types of drugs referenced in the BBRA Conference Report’s legislative history on the chemotherapy exclusion (H.R. Rep. No. 106–479 at 854 (1999) (Conf. Rep.)); namely, those chemotherapy drugs that “. . . are given as infusions, thus requiring special staff expertise to administer.” In addition, the comment itself notes that “In the six months since BLINCYTO® has been approved and available on the market, we are not aware of any patients who were treated with BLINCYTO® in the SNF setting” (emphasis added). However, we are unable to adopt the

commenter’s suggestion that until a specific J code is assigned, a C code appropriately could be used on an interim basis as a vehicle for designating a chemotherapy drug for exclusion from consolidated billing. While the commenter is correct in pointing out some excluded MRI services that are identified by C code, we note that these C codes are designed specifically for use under the outpatient *hospital* PPS (OPPS), and that in contrast to the administrative exclusion for MRIs—which is a *hospital-specific* exclusion—the statutory chemotherapy exclusion is a *categorical* one that applies equally to hospital and non-hospital settings alike. This means that a temporary C code would not be suitable for the purpose of excluding chemotherapy drugs from consolidated billing and that, as we indicated previously in the FY 2015 SNF PPS final rule, we are unable to designate a chemotherapy drug for exclusion from consolidated billing prior to the point at which it is actually assigned its own permanent J code. Accordingly, we plan to add this drug to the exclusion list, at such time as it may be assigned a specific J code of its own.

Comment: Several commenters expressed their continued support for the longstanding statutory exclusion from consolidated billing of certain specified types of customized prosthetic devices, and recommended the exclusion of two additional prosthetic device codes, L5969 (“ankle/foot power assist, including motors”) and L5987 (“all lower extremity prosthesis, shank foot system with vertical loading pylon”). One commenter further recommended that certain customized orthotic devices meeting the statutory “high-cost, low probability” criteria be excluded as well.

Response: We note that code L5969 actually appears on the exclusion list already under Major Category III.D (“Customized Prosthetic Devices”), where this particular L code has, in fact, been listed ever since its initial assignment in January 2014. Regarding code L5987, we note that this particular code had been recommended for exclusion previously during the FY 2012 rulemaking cycle, along with two other L codes that, like L5987, already existed—but were not designated by the Congress for exclusion—upon the original 1999 enactment of the customized prosthetic device exclusion in the BBRA. In the FY 2012 SNF PPS final rule (76 FR 48531, August 8, 2011), we issued our decision to “. . . decline to add these codes to the exclusion list,” explaining that

. . . our position has always been that the BBRA’s discretionary authority to exclude codes within certain designated service categories applies solely to codes that were created subsequent to the BBRA’s enactment, and not to those codes that were already in existence as of July 1, 1999 (the date that the legislation itself uses as the reference point for identifying the codes that it designates for exclusion). As we explained in the FY 2010 final rule (74 FR 40354), this position reflects the assumption that if a particular code was already in existence as of that date but not designated for exclusion, this meant that it was intended to remain within the SNF PPS bundle, subject to the BBRA Conference Report’s provision for a GAO review of the code set that was conducted the following year (H.R. Rep. No. 106–479 at 854 (1999) (Conf. Rep.)).

Regarding the suggestion on excluding certain customized orthotic devices under this authority, we have explained repeatedly in this and previous rules that the amendments enacted in section 103 of the BBRA *only* allow us to identify additional codes for exclusion *within* each of the four specified service categories: chemotherapy items, chemotherapy administration services, radioisotope services, and customized prosthetic devices (a category that is separate from and *does not* encompass orthotics). Accordingly, as we have already indicated previously in the SNF PPS final rules for FY 2001 (65 FR 46790, July 31, 2000) and FY 2009 (73 FR 46436, August 8, 2008), because orthotic devices do not fall within any of these four specified service categories, excluding them from consolidated billing would require legislation by the Congress to amend the law.

Comment: Several commenters on the VBP provision additionally alleged that there is an inherent “tension” between VBP and consolidated billing (the SNF PPS’s bundling requirement), particularly with respect to portable x-rays and other types of diagnostic imaging, services that the commenters characterized as playing a key role in providing high-quality patient care. The commenters stated that the inclusion of these services within the PPS bundle incentivizes SNFs to select suppliers of diagnostic services solely on the basis of price, without considering the quality of the services. They also stated that the current framework allows a practice in which a supplier offers to furnish deeply discounted services to the SNF’s Part A residents in return for being selected to handle the Part B services for those of the SNF’s Medicare-eligible residents who are in noncovered stays. The commenters recommended that diagnostic imaging services should be unbundled altogether (or, alternatively,

if left within the bundle, that the SNF should be required to pay its supplier the full Part B fee schedule amount for them). They suggested that unbundling these services would enable SNFs to focus more on the quality of the services themselves rather than on the details of the billing process. Some of the commenters additionally noted that certain diagnostic radiology services such as portable x-rays are split between a bundled technical component (TC, representing the diagnostic test itself) and a separately billable professional component (PC, representing the physician's interpretation of the test), and they asserted that the portable x-ray's transportation and setup should appropriately be classified under the separately billable PC rather than the bundled TC, stating that the assignment of a Level II HCPCS code is sufficient in itself to identify a service as being an excluded "physician" service in this context.

Response: We have long recognized the incentives to realize efficiencies in providing care that are inherent in any bundled payment requirement, along with the attendant concerns about the potential effect of those incentives on quality of care. However, we do not believe that the commenters, in citing the SNF VBP as a new basis for reiterating these recurring concerns, have established sufficient justification for unbundling diagnostic imaging services from consolidated billing—an action that, in any event, would require legislation by the Congress. We also note that the long-term care facility requirements for participation, which long predate the VBP legislation, contain at 42 CFR 483.25 an overall mandate for Medicare SNFs to provide “. . . the necessary care and services to attain or maintain [each resident's] highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care.” In addition, whenever a SNF elects to obtain such services from an outside source, the requirements at § 483.75(h)(2)(i) further confer on the SNF the specific responsibility to obtain “. . . services that meet professional standards and principles that apply to professionals providing services in such a facility.” Thus, a SNF that fails to provide the appropriate quantity *or quality* of care in accordance with this mandate would jeopardize its compliance with the requirements for participation in the Medicare program.

Moreover, we do not accept the commenters' premise that placing the billing responsibility with the SNF itself has the effect of distracting from a focus

on quality of care. To the contrary, the consolidated billing provision was itself established precisely to help *promote* the overall coordination of high-quality care in the SNF setting. We note that prior to the enactment of this provision, care for SNF residents could be fragmented among a wide variety of outside suppliers who were not required to bill through the SNF. The resulting dispersal of responsibility for resident care among various outside suppliers adversely affected quality (coordination of care) and program integrity, as documented in reports by both the Office of the Inspector General (OIG) and the Government Accountability Office (GAO) (see OIG report no. OEI-06-92-00863, "Medicare Services Provided to Residents of Skilled Nursing Facilities" (October 1994), available online at <https://oig.hhs.gov/oei/reports/oei-06-92-00863.pdf>, and GAO report no. HEHS-96-18, "Providers Target Medicare Patients in Nursing Facilities" (January 1996), available online at <http://www.gao.gov/products/HEHS-96-18>). Thus, the enactment of consolidated billing reflected a recognition that fully enabling SNFs to ensure the overall quality of their residents' services necessitated placing with the SNF itself not only the professional but also the *financial* responsibility for those services.

As for the commenters' suggestions on requiring SNFs to pay suppliers the full Part B fee schedule amount for a bundled service, in the FY 2000 SNF PPS final rule (64 FR 41677, July 30, 1999), we noted in response to previous, similar suggestions that

. . . under current law, an SNF's relationship with its supplier is essentially a private contractual matter, and the terms of the supplier's payment by the SNF must be arrived at through direct negotiations between the two parties themselves. Accordingly, we believe that the most effective way for a supplier to address any concerns that it may have about the adequacy or timeliness of the SNF's payment would be for the supplier to ensure that any terms to which it agrees in such negotiations satisfactorily address those concerns.

In that same final rule (64 FR 41677), we also noted in response to previous, similar concerns regarding supplier discounts that

. . . our discussion of the relationship between an SNF and its suppliers should not be construed as addressing in any manner the potential applicability of the statutory anti-kickback provisions, since matters relating specifically to the enforcement of these provisions lie exclusively within the purview of the Office of the Inspector General.

Finally, we do not share the view of those commenters who would categorize a portable x-ray service's transportation and setup as part of the separately billable PC; rather, as noted in § 90.5 of the Medicare Claims Processing Manual, Chapter 13 (available online at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c13.pdf>):

. . . When a SNF resident receives a portable x-ray service during the course of a Medicare-covered stay in the SNF, only the service's professional component (representing the physician's interpretation of the test results) is a separately billable physician service under Part B. . . . By contrast, the technical component representing the procedure itself, *including any associated transportation and setup costs*, would be subject to consolidated billing (the SNF "bundling" requirement for services furnished to the SNF's Part A residents), and must be included on the SNF's Part A bill for the resident's covered stay (Bill Type 21x) rather than being billed separately under Part B. . . . (emphasis added).

Moreover, notwithstanding the commenters' assertions, the assignment of a Level II HCPCS code to a particular service would in no way automatically equate to identifying it as an excluded "physician" service in this context. Rather, under the regulations at 42 CFR 411.15(p)(2)(i), the *only* services that can qualify for the physician service exclusion from consolidated billing are those that meet the criteria set forth in 42 CFR 415.102(a) for payment on a fee schedule basis as a *physician* service. Sections 415.102(a)(1) and (a)(3), in turn, specify that such a service must be *furnished personally by a physician*, and must be a type of service that *ordinarily requires* such performance. These are criteria that a portable x-ray service's transportation and setup would never meet, as the service's excluded PC relates solely to *reading* the x-ray rather than *taking* it, and the physician's personal performance clearly would not be required for activities such as driving the supplier's vehicle to the SNF, or setting up the equipment once it arrives there.

3. Payment for SNF-Level Swing-Bed Services

Section 1883 of the Act permits certain small, rural hospitals to enter into a Medicare swing-bed agreement, under which the hospital can use its beds to provide either acute- or SNF-level care, as needed. For critical access hospitals (CAHs), Part A pays on a reasonable cost basis for SNF-level services furnished under a swing-bed agreement. However, in accordance with section 1888(e)(7) of the Act, these services furnished by non-CAH rural

hospitals are paid under the SNF PPS, effective with cost reporting periods beginning on or after July 1, 2002. As explained in the FY 2002 final rule (66 FR 39562), this effective date is consistent with the statutory provision to integrate swing-bed rural hospitals into the SNF PPS by the end of the transition period, June 30, 2002.

Accordingly, all non-CAH swing-bed rural hospitals have now come under the SNF PPS. Therefore, all rates and wage indexes outlined in earlier sections of this final rule for the SNF PPS also apply to all non-CAH swing-bed rural hospitals. A complete discussion of assessment schedules, the MDS, and the transmission software (RAVEN-SB for Swing Beds) appears in the FY 2002 final rule (66 FR 39562) and in the FY 2010 final rule (74 FR 40288). As finalized in the FY 2010 SNF PPS final rule (74 FR 40356 through 40357), effective October 1, 2010, non-CAH swing-bed rural hospitals are required to complete an MDS 3.0 swing-bed assessment which is limited to the required demographic, payment, and quality items. The latest changes in the MDS for swing-bed rural hospitals appear on the SNF PPS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/index.html>. We received no comments on this aspect of the proposed rule.

D. Other Issues

1. SNF Value-Based Purchasing (VBP) Program

a. Background

(1) Overview

In recent years, we have undertaken a number of initiatives to promote higher quality and more efficient health care for Medicare beneficiaries. These initiatives, which include demonstration projects, QRPs, and VBP programs, have been implemented in various health care settings, including physician offices, ambulatory surgical centers (ASCs), hospitals, nursing homes, home health agencies (HHAs), and dialysis facilities. Many of these programs link a portion of Medicare payments to provider reporting or performance on quality measures. The overarching goal of these initiatives is to transform Medicare from a passive payer of claims to an active purchaser of quality health care for its beneficiaries.

We view VBP as an important step toward revamping how care is paid for, moving increasingly toward rewarding better value, outcomes, and innovations instead of merely volume.

(2) SNF VBP Report to Congress

Section 3006(a) of the Affordable Care Act required the Secretary to develop a plan to implement a VBP program under the Medicare program for SNFs (as defined in section 1819(a) of the Act) and to submit that plan to Congress. In developing the plan, this section required the Secretary to consider several issues, including the ongoing development, selection, and modification process for measures, the reporting, collection, and validation of quality data, the structure of value-based payment adjustments, methods for public disclosure of SNF performance, and any other issues determined appropriate by the Secretary. The Secretary was also required to consult with relevant affected parties and consider experience with demonstrations relevant to the SNF VBP Program.

HHS submitted the Report to Congress required under section 3006 of the Affordable Care Act in March 2012. The report explains that a significant number of elderly Americans receive care in SNFs/NFs, either as short-term post-acute care or as long-term custodial care, and that quality of care is a significant concern for a subset of SNFs/NFs. The report also states that the SNF PPS does not strongly incentivize SNFs to furnish high quality care to this very fragile patient population. The report concludes that the Medicare program could incentivize SNFs to improve the quality of care for their patients.

In the report, we explained our belief that the implementation of a SNF VBP Program is a central step in revamping Medicare's payments for health care services to reward better value, outcome, and innovations, rather than the volume of care. We also explained our belief that a SNF VBP Program should promote the development and use of robust quality measures, including measures that assess functional status, to promote timely, safe, and high-quality care for Medicare beneficiaries. We noted that the creation of a SNF VBP Program would align with numerous HHS and CMS efforts to improve care coordination, and would be consistent with the National Quality Strategy and its aims of Better Care, Healthy People and Communities, and Affordable Care.

The full report is available on our Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/Downloads/SNF-VBP-RTC.pdf>.

b. Statutory Basis for the SNF VBP Program

Section 215 of PAMA added sections 1888(g) and (h) to the Act. Section 1888(g)(1) of the Act requires the Secretary to specify a SNF all-cause all-condition hospital readmission measure (or any successor to such a measure) not later than October 1, 2015. Section 1888(g)(2) of the Act requires the Secretary to specify an all-condition risk-adjusted potentially preventable hospital readmission rate for SNFs not later than October 1, 2016. Section 1888(g)(3) of the Act directs the Secretary to develop a methodology to achieve high reliability and validity for these measures, especially for SNFs with a low volume of readmissions. Section 1888(g)(4) of the Act makes the pre-rulemaking Measure Applications Partnership process of Section 1890A of the Act optional for these measures. Under section 1888(g)(5) of the Act, the Secretary is directed to provide quarterly confidential feedback reports to SNFs on their performance on the readmission or resource use measure beginning on October 1, 2016. Under section 1888(g)(6) of the Act, not later than October 1, 2017, the Secretary must establish procedures for making performance data on readmission and resource use measures public on *Nursing Home Compare* or a successor Web site. That paragraph also requires that the procedures ensure that a SNF has the opportunity to review and submit corrections to the information that is to be made public for it before that information is made public.

Section 1888(h)(1)(A) of the Act requires the Secretary to establish a SNF VBP program under which value-based incentive payments are made in a FY to SNFs, and section 1888(h)(1)(B) of the Act requires that the Program apply to payments for services furnished on or after October 1, 2018. Under section 1888(h)(2)(A) of the Act, the Secretary must apply the readmission measure specified under section 1888(g)(1) of the Act for purposes of the Program, and section 1888(h)(1)(B) of the Act requires the Secretary to apply the resource use measure specified under section 1888(g)(2) of the Act instead of the readmission measure specified under section 1888(g)(1) as soon as practicable. Sections 1888(h)(3)(A) and (B) of the Act require the Secretary to establish performance standards for the measure applied under section 1888(h)(2) of the Act for a performance period for a FY and that those performance standards include levels of achievement and improvement. In addition, in calculating the SNF performance score for the

measure under the Program, section 1888(h)(3)(B) of the Act requires the Secretary to use the higher of achievement or improvement scores. Further, the performance standards established under section 1888(h)(3) of the Act must, under section 1888(h)(3)(C), be established and announced by the Secretary not later than 60 days prior to the beginning of the performance period for the FY involved.

Section 1888(h)(4) of the Act directs the Secretary to develop a methodology to assess each SNF's total performance based on the performance standards for the applicable measure for each performance period. Under section 1888(h)(4)(B) of the Act, SNF performance scores for the performance period for each FY must be ranked from low to high.

Section 1888(h)(5) of the Act outlines several requirements for value-based incentive payments under the SNF VBP Program. Under section 1888(h)(5)(A) of the Act, the Secretary is directed to increase the adjusted federal per diem rate determined under section 1888(e)(4)(G) for services furnished by a SNF by the value-based incentive payment amount determined under section 1888(h)(5)(B). This section also directs that the value-based incentive payment amount be equal to the product of the adjusted federal per diem rate and the value-based incentive payment percentage specified under section 1888(h)(5)(C) of the Act for the SNF for the FY. Section 1888(h)(5)(C) requires the Secretary to specify a value-based incentive payment percentage for a SNF for a FY, which may include a zero percentage. The Secretary is further directed under section 1888(h)(5)(C) to ensure that such percentage is based on the SNF performance score for the performance period for the FY, that the application of all such percentages in a FY results in an appropriate distribution of value-based incentive payments, and that the total amount of value-based incentive payments for all SNFs for a FY be greater than or equal to 50 percent, but not greater than 70 percent, of the total amount of the reductions to payments for the FY under section 1888(h)(6), as estimated by the Secretary.

Section 1888(h)(6) of the Act requires the Secretary to reduce the adjusted federal per diem rate for SNFs otherwise applicable to each SNF for services furnished by that SNF during the applicable FY by the applicable percent, which is defined in paragraph (b) as 2 percent for FY 2019 and subsequent years. Section 1888(h)(7) of the Act requires the Secretary to inform each

SNF of its payment adjustments under the Program not later than 60 days prior to the FY involved, and under section 1888(h)(8) of the Act, the value-based incentive payments calculated for a FY apply only for that FY.

Section 1888(h)(9)(A) of the Act requires the Secretary to publish SNF-specific performance information on the *Nursing Home Compare* Web site or a successor Web site, including SNF performance scores and rankings. Section 1888(h)(9)(B) of the Act requires the Secretary to post aggregate information on the SNF VBP Program, including the range of SNF performance scores and the number of SNFs receiving value-based incentive payments and the range and total amount of those payments.

We received a number of general comments on the SNF VBP Program.

Comment: Commenters suggested that we phase-in the SNFRM to ensure that providers are fully capable of reporting the measure accurately and to ensure that it is fully valid and accurate. Commenters suggested that such a phase-in should include a period of "hold-harmless reporting" and data collection that does not include penalties or incentive payments.

Response: We do not have the administrative discretion to phase-in the SNF VBP Program as the commenter suggests, since section 1888(h)(1)(B) of the Act requires us to apply the Program to payments for services furnished on or after October 1, 2018. However, section 1888(g)(5) requires us to provide quarterly, confidential feedback reports to SNFs on their performance on measures specified for the program beginning October 1, 2016. We believe those feedback reports will meet the commenter's request that we provide feedback on the measure during a time period that would not involve penalties or incentive payments. Additionally, we would remind commenters that the SNFRM is a claims-based measure, and therefore will not require any additional data to be submitted by SNFs.

Comment: Commenters recommended that proposed measures should align, where possible, with existing quality measures across settings and by payment type (such as ACO or bundled payments).

Response: We will take the recommendation into account as we further develop and implement the Program.

Comment: Commenters urged us to adopt an Extraordinary Circumstances Exception process for the SNF VBP Program to ensure that facilities do not incur penalties under the program

during major weather events or other circumstances beyond their control.

Response: We will take the recommendation into account as we further develop and implement the Program.

Comment: Commenters suggested that we set up a regular workgroup to discuss the SNF VBP Program's development with stakeholders.

Response: We intend to continue outreach efforts to the SNF community as we develop the Program.

Comment: Commenters suggested that we should adopt a rule prohibiting value-based incentive payments under the SNF VBP Program to any SNF that does not accurately report staffing data or does not have sufficient nursing staff to meet residents' needs.

Response: We thank the commenters for this suggestion and will consider it, if legally feasible, as part of the Program's scoring policies in the future.

Comment: Commenters suggested that we adopt a nutritional status domain and implement a malnutrition-related quality measure in the future for the SNF VBP Program. Other commenters suggested measures that are currently displayed on *Nursing Home Compare*, those that were part of the SNF VBP demonstration, or those that are part of the new SNF QRP.

Response: We do not believe we have the authority to adopt measures covering additional clinical topics beyond those specified in sections 1888(g)(1) and (2) of the Act at this time.

Comment: Commenters urged us to make SNF VBP Program data as contemporaneous as possible. Commenters noted that more recent hospitalization data allow SNFs to monitor their performance and better realize the connection between their performance rates and their payment rates.

Response: We intend to make SNFs' performance data available as quickly as is practicable to ensure that facilities are able to understand their performance and undertake quality improvement efforts.

Comment: Commenters encouraged us to develop the statutorily-mandated resource use measure specified under section 1888(g)(2) of the Act as soon as possible, and to share a timeline for when the measure will replace the SNFRM. Some commenters also stated that the potentially preventable hospital readmissions measure needs additional testing and more detailed public information.

Response: We thank the commenters for this request. At this time, we have not specified the resource use measure under section 1888(g)(2) of the Act. We

will make all details available, including technical reports presenting results of measure testing and technical expert input, in the future and will seek public comment.

We thank the commenters for this general feedback, and will take it into account in future rulemaking.

c. Skilled Nursing Facility 30-Day All-Cause Readmission Measure (SNFRM) (NQF #2510; Measure Steward: CMS)

(1) Overview

Reducing hospital readmissions is important for quality of care and patient safety. Readmission to a hospital may be an adverse event for patients and in many cases imposes a financial burden on the health care system. Successful efforts to reduce preventable readmission rates will improve the quality of care furnished to beneficiaries while simultaneously decreasing the cost of that care. Hospitals and other health care providers can work with their communities to lower readmission rates and improve patient care in a number of ways, such as by ensuring that patients are clinically ready to be discharged, reducing infection risk, reconciling medications, improving communication with community providers responsible for post-discharge patient care, improving care transitions, and ensuring that patients understand their care plans upon discharge.

Many studies have demonstrated the effectiveness of these types of in-hospital and post-discharge interventions in reducing the risk of readmission, confirming that hospitals and their partners have the ability to lower readmission rates.^{1 2 3} These types of efforts during and after a hospitalization have been shown to be effective in reducing readmission rates in geriatric populations generally,^{4 5} as well as for multiple specific conditions. Moreover, such interventions can result

in cost saving. Financial incentives to reduce readmissions will in turn promote improvement in care transitions and care coordination, as these are important means of reducing preventable readmissions.⁶ In its 2007 Report to Congress on Promoting Better Efficiency in Medicare,⁷ MedPAC noted the potential benefit to patients of lowering readmissions and suggested payment strategies that would incentivize hospitals to reduce these rates. Readmission rates are important markers of quality of care, particularly of the care of a patient in transition from an acute care setting to a non-acute care setting, and improving readmissions can positively influence patient outcomes and the cost of care.

We proposed to specify the SNF 30-Day All-Cause Readmission Measure (SNFRM) (NQF #2510) as the SNF all-cause, all-condition hospital readmission measure under section 1888(g)(1) of the Act. This measure assesses the risk-standardized rate of all-cause, all-condition, unplanned inpatient hospital readmissions of Medicare fee-for-service (FFS) SNF patients within 30 days of discharge from an admission to an inpatient prospective payment system (IPPS) hospital, CAH, or psychiatric hospital. This measure is claims-based, requiring no additional data collection or submission burden for SNFs.

We also proposed to apply this measure for purposes of the SNF VBP Program under section 1888(h)(2)(A) of the Act. We believe that this measure will (1) incentivize SNFs to make quality improvements that result in successful transitions of care for patients discharged from the hospital (IPPS, CAH or psychiatric hospital) setting to a SNF, and subsequently to the community or to another post-acute care setting, (2) reduce unplanned readmission rates of these patients to hospitals; and (3) align the SNF VBP Program with the National Quality Strategy priorities of safer, better coordinated care and lower costs.⁸

We developed this measure based upon the NQF-endorsed Hospital-Wide All-Cause Unplanned Readmission

Measure (HWR) (NQF #1789) (<http://www.qualityforum.org/QPS/1789>)⁹ implemented in the Hospital Inpatient QRP. To the extent methodologically and clinically appropriate, we harmonized the SNFRM with the HWR measure specifications.

A discussion of the general comments that we received on the SNFRM, and our responses to those comments, appears below.

Comment: One commenter expressed concern about our proposal to adopt the SNFRM, stating that it does not align with the unplanned readmission measure for IRFs (NQF #2502), particularly in reporting period duration. The commenter stated that we should strive for alignment between post-acute care settings, particularly given the ongoing implementation of the IMPACT Act.

Response: We thank the commenter for their comments regarding alignment of these measures. The SNFRM (NQF #2510) is based on 12 months of data as this ensures an accurate sample size for calculating the Risk-Standardized Readmission Rate (RSRR). However, 24 months of data were needed to ensure sufficient sample sizes to reliably estimate and develop the all-cause, unplanned hospital readmission measures used in the Inpatient Rehabilitation Facility Quality Reporting Program (NQF #2502) and the Long-Term Care Hospital Quality Reporting Program, due to the substantially lower number of IRF and LTCH stays.

While we recognize that the SNFRM does not align with the unplanned readmission measure for IRFs (#2502), we are currently developing an unplanned readmission measure for IRFs that is analogous to the SNFRM in that it assesses readmissions among IRF patients following discharge from an acute care hospital. This second IRF measure is intended to exist in tandem with the existing IRF measure #2502, which assesses readmissions for 30 days following discharge from the IRF.

Comment: Some commenters supported our proposal to adopt the SNFRM, noting that the measure is consistent with other CMS readmission measures, and that it will decrease costs, improve patient safety, and promote the best possible clinical outcomes. Commenters suggested that we consider adopting additional measures in the future in the SNF VBP Program that cover resource use,

¹ Gwady-Sridhar FH, Flintoft V, Lee DS, Lee H, Guyatt GH: A systematic review and meta-analysis of studies comparing readmission rates and mortality rates in patients with heart failure. *Arch Intern Med.* 2004;164(21):2315–2320.

² McAlister FA, Lawson FM, Teo KK, Armstrong PW: A systematic review of randomized trials of disease management programs in heart failure. *Am J Med.* 2001;110(5):378–384.

³ Krumholz HM, Amatruda J, Smith GL, et al.: Randomized trial of an education and support intervention to prevent readmission of patients with heart failure. *J Am Coll Cardiol.* 2002;39(1):83–89.

⁴ Coleman EA, Parry C, Chalmers S, Min SJ: The care transitions intervention: Results of a randomized controlled trial. *Arch Intern Med.* 2006;166:1822–8.

⁵ Naylor MD, Brooten D, Campbell R, Jacobsen BS, Mezey MD, Pauly MV, Schwartz JS: Comprehensive discharge planning and home follow-up of hospitalized elders: A randomized clinical trial. *JAMA.* 1999;281:613–20.

⁶ Coleman EA: 2005. Background Paper on Transitional Care Performance Measurement. Appendix I. In: Institute of Medicine, Performance Measurement: Accelerating Improvement. Washington, DC: National Academy Press.

⁷ Medicare Payment Advisory Commission (MedPAC). Report to Congress: Promoting Greater Efficiency in Medicare; 2007. Available at http://www.medpac.gov/documents/Jun07_EntireReport.pdf. Accessed January 10, 2011.

⁸ Wilson, N. U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality. (2014). National quality strategy: Overview.

⁹ Adopted for the Hospital IQR Program in the FY 2013 IPPS/LTCH PPS Final Rule (77 FR 53521 through 53528).

functional outcomes, and return to the community following discharge.

Response: We do not have the authority to adopt additional measures in the SNF VBP Program beyond those specified in sections 1888(g)(1) and (2) of the Act.

Comment: Some commenters suggested that we either adopt a readmission measure that includes all SNF patients, regardless of payer, or clarify that the SNFRM is an “all-cause fee-for-service measure” because it excludes Medicare Advantage beneficiaries.

Response: This measure is based on FFS claims, consistent with other hospital readmission measures used in other programs. The measure as specified requires Medicare claims to determine if any readmissions are deemed to be planned or unplanned and for comprehensive risk adjustment.

Comment: One commenter recommended that we ask the MAP to review PointRight OnPoint-30 SNF Rehospitalizations (NQF #2375) before taking a final position on the SNFRM (NQF #2510). The commenter explained that #2375 is an MDS-based measure that captures patients regardless of payer type and also includes observation admissions. The commenter further noted that #2375 risk adjusts for functional and clinical symptoms that are strong predictors of readmissions.

Response: We recognize the desirability of implementing an all-payer readmission measure. However, we have some concerns with including the measure (NQF #2375) in the SNF VBP program. The MDS-based measure excludes readmissions that occur after discharge from the SNF, which creates a perverse incentive for SNFs to discharge patients prematurely to avoid being penalized if the patients are considered a high risk for readmission. The MDS-based measure also does not exclude planned readmissions which are not indications of poor quality. Additionally, while NQF #2375 adjusts for functional and clinical symptoms, analyses conducted jointly by the developers of that measure and the SNFRM concluded that there is no substantial distinction in the risk models’ capacity to assess readmission rates at the facility level.

Comment: One commenter asked that we clarify that the MAP process is not restricted to reviewing and commenting only on CMS-sponsored measures or measures presented by CMS to the MAP, per section 1890 of the Act. The commenter also requested that we clarify that the input from the MAP is not with the view that the measure is used for VBP, as they believed that a

measure for payment should be evaluated in a different manner.

Response: It is correct that other measures are eligible for consideration in the MAP process. While the MAP provides input on measures selected by the Secretary, the pre-rulemaking provisions of the Act do not restrict the MAP from reviewing or recommending measures and methodologies in lieu of those under consideration by the Secretary. Therefore, we refer readers to the MAP Web site at <http://www.qualityforum.org/map/>. Additionally, we intend to provide the commenters’ input to the NQF.

In addition, at times we request additional measures from external stakeholders and measure developers, which are also reviewed by the MAP. The MAP’s input is responsive to the particular program for which its review was sought. In this case, the SNFRM was submitted via an ad hoc Measures Under Consideration list to the MAP for consideration in SNF-VBP. The MAP’s 2015 recommendations, available at <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=78711>, show that the MAP supported the SNFRM’s adoption for the SNF VBP Program.

Comment: One commenter opposed the proposed SNFRM, stating that the measure is self-reported because it is based on MDS information and that it is industry-developed and controlled.

Response: The proposed SNFRM is based on Medicare claims data and the measure does not use MDS information. Furthermore, the proposed measure was developed by CMS working with an independent CMS contractor, RTI International, and was not industry-developed. The proposed measure was endorsed by the National Quality Forum (NQF), and its specifications are available in our technical report, which is available on our Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Downloads/SNFRM-Technical-Report-3252015.pdf>.

Comment: Some commenters expressed concern that SNFs will not have access to the data used to calculate the SNFRM, and will therefore not be able to validate CMS’s calculations.

Response: While we intend to make as much information related to SNFRM performance as possible available to SNFs through confidential quarterly feedback reports required under section 1888(g)(5) of the Act, we understand that claims-based quality measurement is difficult for providers to replicate. It would require familiarity with a number of data sources that are used to develop

the risk-adjustment model for SNFRM in order to account for variation across SNFs in case-mix and patient characteristics predictive of readmission (including the MedPAR, Medicare Enrollment Database (EDB), Medicare Denominator files, Agency for Healthcare Research & Quality (AHRQ)’s Clinical Classification Software (CCS) groupings of ICD-9 codes, and CMS’s hierarchical condition category (HCC) mappings of ICD-9 codes). We view this as a necessary compromise to minimize reporting burden on participating SNFs by using claims data while ensuring that we obtain timely data for quality measurement.

Comment: One commenter suggested that our longer-term goal should be to align the SNFRM with other relevant hospitalization measures planned for use, such as those being developed by states under section 1115 waivers and new value-based initiatives for the Medicare fee-for-service program.

Response: We thank the commenter for this feedback, and will consider how best to align our programs with these efforts in the future.

Comment: Some commenters expressed concerns about our proposal to adopt the SNFRM, stating that further vetting of the measure is warranted given commenter’s belief that research cited on the measure is sparse and includes only effectiveness studies limited to certain conditions.

Response: The SNFRM was developed using the Measures Management System (MMS) Blueprint, a process that included input from a TEP and a public comment period. The measure was also reviewed by the NQF, and supported by that body for endorsement in December 2014. We believe that this represents sufficient vetting for the purpose of implementing a measure in a VBP program. We welcome additional input regarding the research supporting or questioning the appropriateness of this, or any other measure.

Comment: One commenter urged us to consider adjusting the SNFRM for situations beyond facilities’ control, such as family members insisting on a patient being hospitalized, and for patients with increased risks of hospitalization, including medically complex, frail elderly patients and those with certain primary diagnoses. The commenter also noted that avoidable hospital admissions frequently result from poorly managed transitions, and suggested that we investigate meaningful ways to capture and incentivize care transitions using this measure.

Response: The SNFRM, which was endorsed by the NQF, has been risk

adjusted for case-mix to account for differences in patient populations. The goal of risk adjustment is to account for these differences so that providers who treat sicker or more vulnerable patient populations are not unnecessarily penalized for factors that are outside of their control. The current measure accounts for: Principal diagnosis from the Medicare claim corresponding to the prior proximal hospitalization as categorized by AHRQ's CCS groupings, length of stay during the patient's prior proximal hospitalization, length of stay in the intensive care unit (ICU), end-stage renal disease (ESRD) status, whether the patient was disabled, the number of prior hospitalizations in the previous 365 days, system-specific surgical indicators, individual comorbidities as grouped by HCCs or other comorbidity indices, and a variable counting the number of comorbidities if the patient had more than two HCCs. Many of the factors, such as family preference, suggested by the commenter are not feasibly captured by any existing data source of which we are aware. The medical complexity of patients is captured to the extent possible through the comorbidity data described above. In this way, we are able to capture poorly managed transitions through risk adjusted readmissions rates.

Comment: One commenter encouraged us to consider creating safeguards for SNFs participating in the Program to ensure that patients are fully protected from unintended consequences resulting from the SNFRM's adoption, potentially including functional declines and resident deaths. The commenter suggested that a companion measure of death and decline of residents would determine whether SNFs improperly avoided hospitalizing residents who should have been hospitalized.

Response: We intend to monitor the effects of the SNFRM on clinical care closely, and we intend to take any necessary steps to ensure that SNFs do not avoid hospitalizing patients. Additional measures may be implemented in other SNF-related programs such as the QRP. However, as stated above, we do not have the authority to adopt additional measures under the Program beyond the ones required under sections 1888(g)(1) and (2) of the Act.

(2) Measure Calculation

The SNFRM estimates the risk-standardized rate of all-cause, unplanned, hospital readmissions for SNF Medicare FFS beneficiaries within 30 days of discharge from their prior

proximal acute hospitalization. The SNF admission must have occurred within one day after discharge from the prior proximal hospitalization. The prior proximal hospitalization is defined as an inpatient admission to an IPPS, CAH, or a psychiatric hospital. Because the measure denominator is based on SNF admissions, each Medicare beneficiary may be included in the measure multiple times within a given year if they have more than one SNF stay meeting all measure inclusion criteria including a prior proximal hospitalization.

Patient readmissions included in the measure are identified by examining Medicare claims data for readmissions of SNF Medicare FFS beneficiaries to an IPPS, or CAH occurring within 30 days of discharge from the prior proximal hospitalization. If the patient was admitted to the SNF within 1 day of discharge from the prior proximal hospitalization and the hospital readmission occurred within the 30-day risk window, it is counted in the numerator regardless of whether the patient is readmitted directly from the SNF or has been discharged from the SNF. 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 by the SNF. Details regarding how readmissions are identified are available in our SNFRM Technical Report.¹⁰

The SNFRM (NQF #2510) assesses readmission rates while accounting for patient demographics, principal diagnosis in the prior hospitalization, comorbidities, and other patient factors. While estimating the predictive power of patient characteristics, the model also estimates a facility-specific effect common to patients treated at that SNF.

The SNFRM is calculated based on the ratio, for each SNF, of the number of risk-adjusted all-cause, unplanned readmissions to an IPPS or CAH that occurred within 30 days of discharge from the prior proximal hospitalization, including the estimated facility effect, to the estimated number of risk-adjusted predicted unplanned inpatient hospital readmissions for the same patients treated at the average SNF. A ratio above 1.0 indicates a higher than expected readmission rate, or lower level of quality, while a ratio below 1.0 indicates a lower than expected

readmission rate, or higher level of quality. This ratio is referred to as the standardized risk ratio or SRR. The SRR is then multiplied by the overall national raw readmission rate for all SNF stays. The resulting rate is the risk-standardized readmission rate (RSRR). The full methodology is detailed in the SNFRM Technical Report.

The patient population includes SNF patients who:

- Had a prior hospital discharge (IPPS, CAH or psychiatric hospital) within 1 day of their admission to a SNF.
- Had at least 12 months of Medicare Part A, FFS coverage prior to their discharge date from the prior proximal hospitalization.
- Had Medicare Part A, FFS coverage during the 30 days (the 30-day risk window) following their discharge date from the prior proximal hospitalization.

A discussion of the general comments that we received on the SNFRM measure calculation, and our responses to those comments, appears below.

Comment: One commenter expressed concern about the SNFRM's readmission window, noting that just over one-third of SNF stays exceed the 30-day readmission window. The commenter suggested that adopting the 30-day window as proposed could relieve SNFs of accountability for longer-stay patients and could create incentives for SNFs to delay needed care until after day 30. The commenter further stated that SNFs should be responsible for every readmission that occurs while the beneficiary is in the SNF.

Response: We agree with the commenter's concerns that SNFs should be accountable for longer-stay patients who are admitted to an acute care hospital. The SNFRM is designed to assess failed transitions from an acute care hospital to the SNF, and is not intended to capture all hospitalizations that may occur in a SNF population. Including all admissions beyond 30 days in the population would attenuate the association between the transitions of care at the proximate discharge from an acute care hospital to the readmission.

Comment: Some commenters stated that the SNFRM does not hold SNFs fully accountable for transitions to the next care setting, and suggested that we should adopt separate measures of readmissions after discharge from the SNF and from the hospital. One commenter stated that the SNFRM's measurement period should capture rehospitalizations within 90 days, not just 30 days. The commenter noted that other efforts to reduce rehospitalizations

¹⁰ Available on the Nursing Home Quality Initiative Web site at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/index.html?redirect=/nursinghomequalityinits/>.

focus on a 90-day time period, and suggested that the 30-day period may reflect poor hospital care more than care problems in the SNF.

Response: The 30-day readmission window was developed to harmonize with other hospital readmission measures and reflects a transitional time period during which the acute care hospital and SNF are responsible for coordinating the care of a patient moving from one setting to another. While there is no definitive timeframe for which such a measure may be applied, the 30-day window is consistent with similar measures applied in other VBP programs, such as the ESRD Quality Incentive Program and the Hospital Readmission Reduction Program, as well as a number of QRPs. Furthermore, this 30-day post-hospital discharge window was reviewed by a TEP. Analysis of readmission rates showed no patterns indicating that using a shorter or longer period would produce very different comparative results, though the overall rates would change. In addition, the NQF Standing Committee generally agreed that 30 days post-hospital discharge is an accepted standard for measuring readmissions. Longer windows may be subject to greater “noise” or statistical variability in the readmission rate. The measure as specified has the potential for this unintended consequence of delaying hospital care beyond the 30-day readmission window, but this issue may occur with any selected day threshold. We will be closely monitoring this and continue to analyze whether there are changes in the number of days to hospital readmission over time to assess whether a change to the readmissions window is needed for this measure in the future.

Comment: One commenter expressed concern about the time lag between the end of the measurement period and the release of clean, adjudicated claims data. The commenter was concerned that these delays could affect timely notice and payment for SNFs participating in the Program.

Response: We share the commenters’ concern. As required by statute, we intend to provide quarterly feedback to SNFs to ensure that facilities have as much information as possible to inform their quality improvement efforts.

Comment: Commenters expressed concern that while the SNFRM accounts for principal diagnosis, that diagnosis may not be the reason for admission to a SNF. Commenters suggested that the SNFRM should also account for comorbidities, diagnoses from prior hospitalizations during the prior year,

length of stay during the prior proximal hospitalization, length of stay in the ICU, body system specific surgical indicators, ESRD status, disability status, and number of prior hospitalizations during the previous year. Commenters also requested that we develop a list of comorbidities that are being evaluated in the SNFRM’s risk adjustment model.

Response: We would like to clarify that the SNFRM is risk-adjusted for all of the factors cited by the commenter. The SNFRM accounts for all of the factors proposed in the comment above, including first diagnosis from the Medicare claim corresponding to the prior proximal hospitalization as coded by the AHRQ’s CCS, length of stay during the patient’s prior proximal hospitalization, indicator of a stay in the ICU, ESRD status, whether the patient was disabled, the number of prior hospitalizations in the previous 365 days, system-specific surgical indicators, individual comorbidities as grouped by CMS’s (HCCs, and a variable counting the number of comorbidities if the patient had more than two HCCs. To capture comorbidities, we used the secondary medical diagnoses listed on the patient’s prior proximal hospital claim as well as all diagnoses listed on acute care hospitalizations that occurred in the prior 12 months. We refer the commenter to the Technical Report for the SNFRM for additional information, which can be found on the Nursing Home Quality Initiative Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/index.html>.

Comment: Some commenters disagreed with our proposal to adopt a measure based on claims data, stating that determining readmission rates will be difficult for SNFs since claims data are cumbersome to use or access. Commenters stated that the SNFRM will not provide meaningful insights or otherwise impact quality improvement efforts when facilities are unable to interpret or access the data.

Response: This measure was developed to harmonize with other hospital-based measures that are claims-based. Despite the commenter’s concern that these data are difficult to access, the measure developer (RTI) cited evidence that these data are both reliable and valid. Further detail on this evidence is available in the SNFRM Technical Report, Section 3.5 (Validity Testing), available on the Nursing Home Quality Initiative Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment->

[Instruments/NursingHomeQualityInits/index.html](http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/index.html).

Furthermore, we intend to make performance reports available to facilities that are easy to interpret and present information on the facility-level readmission rates and relative standing on this measure, rather than information from the claims data directly. We intend to make SNFs’ performance data available as quickly as is practicable. This will serve to provide information on a facility’s performance and aid in informing quality improvement efforts at the facility level.

Comment: One commenter stated that readmission measures should be “normalized” instead of reported in simple percentage rates. The commenter believed that reductions in hospital admissions could result in more measured readmissions, even if the normalized readmission rate has remained constant. The commenter also suggested that undue variation may result for smaller facilities and fewer admissions.

Response: The percentages computed by the measure are normalized in the sense that they are computed with risk adjustment and may be compared to one another and to the national rate for SNFs. A ratio of the risk-adjusted predicted rate for each facility to the expected rate for the same patients at the average facility produces a normalized value (referred to as the standardized risk ratio) which is 1.0 for a facility with readmissions at the expected rate for its own patients, and higher or lower than 1.0 if the readmission rate is higher or lower. For ease of interpretation, this standardized risk ratio is converted to a standardized rate by multiplying it by the national raw rate. This is an accepted method for producing standardized rates that are comparable across facilities. There is no external percentage target that every facility must meet and the national mean rate is driven by the data for the measurement period. The national mean may go up or down over time reflecting a changing pool of patients, medical conditions, and treatments.

Variation in rates that may occur in facilities with low volume is dealt with by averaging the volatile facility data with the national mean when the hierarchical models are used. In addition, we will consider appropriate facility volume thresholds for reporting depending on the use of the measure.

Comment: One commenter recommended that we adopt a minimum of 30 qualified FFS admissions per 12-month period to calculate a statistically valid SNFRM rate. The commenter further stated that

any SNFs with fewer events should be excluded from the measure's calculation.

Response: We will consider whether we should establish a minimum number of qualifying admissions for the SNFRM in future rulemaking. The SNFRM utilizes shrinkage estimates to address the possibility of undue variation for smaller facilities. This is a design feature common to many of our readmission measures, including those implemented in the aforementioned programs, to ensure statistically valid rates.

Comment: One commenter stated that we should only count readmissions that occur while the patient resides in the SNF, not after discharge. The commenter stated that measure readmissions within the 30-day window but after SNF discharge necessitates measurement of 30-day rehospitalization rates for other providers as well. Commenters also noted that PAMA does not specify that the SNF measure align with the hospital's 30-day window and the Act uses "Skilled Nursing Facility Measure" throughout, which some commenters read to mean SNF only, not SNF plus follow on care after discharge.

Response: We agree that readmission rates for other providers are necessary, and this is one reason we have taken steps to implement readmissions measures in multiple settings across a wide variety of relevant quality programs. We believe that excluding readmissions that occur after discharge creates a perverse incentive for facilities to prematurely discharge patients who represent the highest risk for readmission to avoid penalty. Given that this measure is the sole determinant of a VBP program for SNFs, we believe it is appropriate to include readmissions that occur post-discharge but within the 30-day window, aligning with other readmission measures implemented by CMS. The goal of this measure is to capture readmissions that are attributable to care provided by the SNF, even those that occur after discharge. We have already established a panel of readmission measures (such as those utilized for hospitals, ESRD care, IRFs, and LTCHs) that similarly seek to identify readmissions attributable to care received within the facility, even if the patient has been discharged. Those developed for ESRD facilities and Home Health agencies follow a 30-day window as well. We believe that the 30-day window is consistent with PAMA and that it is also consistent with the standard implemented in multiple settings. Absent a compelling reason to limit the

measure to within stay, and given the potential for unintended consequences if such a measure were implemented as the sole determining factor of a VBP program, we believe remaining consistent with other programs is appropriate. We might consider a purely within-stay measure were it paired with a post-discharge measure, as this would allow us to avoid unintended consequences to patients, such as inappropriate early discharge from the SNF, but the statutory mandate does not allow us to implement additional measures in the SNF-VBP program.

Comment: One commenter requested that we clarify whether the SNFRM includes all hospitalizations billed to Medicare or if it is limited to hospitalizations of residents who are in a Part A stay in a SNF. The commenter suggested that a broader measure of readmissions, including Medicare claims for dually-eligible residents not in a Part A stay or for private-pay residents could be used.

Another commenter suggested that we explore merging FFS and Medicare Advantage data sets given the relative prevalence of MA patients in the SNF setting. The commenter also noted that the IMPACT Act does not separate Medicare beneficiaries by MA status. The commenter also recommended that facilities be allowed to complete and submit a combined Admission Assessment with the 5-day Assessment for Medicare Advantage beneficiaries to track readmission outcome data for all payer types in the facility.

Response: The index stays that are included in the proposed SNFRM are for those that have FFS Part A Medicare enrollment. We do not have claims data for managed care, private pay, or Medicaid residents who may be receiving skilled services. Thus, this measure only includes Medicare FFS patients.

For private-pay residents, we do not always have claims for the index hospital stay (the proximate stay at an acute-care hospital that precedes care with a SNF and defines the denominator), even if the related readmissions could be identified in Medicare data. In addition, we do not have reliable sources of data for Medicare Advantage patients. The most reliable data available for determining readmissions during a SNF stay are for Part A FFS beneficiaries.

We agree that as penetration of the Medicare Advantage market in the SNF setting increases, finding ways of including readmissions for these patients should be a priority. We will continue to explore ways to include

these patients in future years, given the differences in data sources.

Comment: Another commenter also expressed concern that the SNFRM captures only Medicare FFS beneficiaries. The commenter noted that the SNF VBP Program's statute does not specifically restrict the measure to FFS beneficiaries, and urged us to find an all-payer measure. The Commenter further noted that the SNFRM does not capture hospital admissions that are classified as "observation status," which are paid under Part B, and stated that the measure should be broadened to include residents not in a Medicare Part A stay.

Response: At present, we are not able to include all payers in the SNFRM, as the measure is dependent upon Medicare claims data to identify readmissions and risk-adjust for patient comorbidities. While an all-payer measure based on the MDS does exist, it has several characteristics that we believe are potentially problematic for use in a VBP program. The MDS-based measure excludes readmissions that occur after discharge from the SNF, which creates a perverse incentive for SNFs to discharge patients prematurely to avoid being penalized if they are considered a high risk for readmission. The MDS-based measure also does not exclude planned readmissions, which are not indications of poor quality. We do not believe observation stays are appropriate for inclusion in the readmission measure, because the statute requires a measure of readmissions, not of rehospitalizations, which could also include ED and outpatient visits, including observation stays. We have tested the inclusion of observation stays, and note that doing so would have little or no impact on facility assessment by the measure. In addition, evidence suggests that the number of observation stays of patients originating from a SNF is quite small in comparison to the total number of SNF stays (0.7 percent of all SNF stays), and very few readmissions occur after an observation stay. Including observation stays from the SNF hospital readmission measure will not make a meaningful difference in the SNF facility-level rate of hospital readmissions or in the relative ranking of SNF providers according to this measure.

Comment: One commenter requested that we clarify whether the SNFRM's condition list has been tested for the ICD-10 transition scheduled to be completed on October 1, 2015.

Response: We will monitor and test the measure performance and update the risk adjustment model with the transition to ICD-10. We are prepared

for the implementation of ICD-10 for this measure. Mappings of ICD-10 codes for the diagnoses and procedures have been prepared by the AHRQ for the CCS groups used in the risk-adjustment models. Similarly, mappings to the HCC groups have been done. These are used in the risk adjustment of the measure and the definition of planned readmissions. The effects of the change of codes will be system-wide and the models will be re-estimated when the necessary new data become available with the implementation of ICD-10.

Comment: One commenter suggested that we use SNFs' actual readmission rate rather than predicted actual. The commenter noted that the predicted actual rate mutes the differences in rates for small sample size (for example, a facility with an actual count of 0 readmissions could have a projected rate that is greater than 0).

Response: This measure and several other post-acute care measures were designed to align with the Hospital-Wide Readmission measure for all-cause readmissions, and these measures utilize a hierarchical modeling approach that relies on generating a predicted rate consistent with recommendations made in the 2011 Committee of Presidents of Statistical Societies commissioned paper *Statistical Issues in Assessing Hospital Performance*.¹¹ This decision was made based on the validity of calculating the standardized risk ratio (SRR), which is the predicted number of readmissions at the facility divided by the expected number of readmissions for the same patients if these patients had been treated at the average SNF. The predicted number of readmissions for each SNF is calculated as the sum of the predicted probability of readmission for each patient in the facility, including the SNF-specific (random) effect. The measure developer (RTI International) also designed a test to explore calibration over ranges of predicted probabilities by doing a comparison of the observed and predicted readmissions by decile (for a table of results, please refer to the SNFRM Technical Report, Section 3.3 Model Validation). These results indicate that the difference between the predicted number of readmissions and the observed number of readmissions in percentage points is minimal, less than

one percentage point across deciles of expected rates of readmission, which suggests that the differences in rates will not be muted by using the predicted rate.

Comment: One commenter suggested that we increase the minimum denominator size to address small volume variation. The commenter noted many SNFs admit fewer than 50 Medicare FFS beneficiaries per year and some of these would be excluded if the proposed minimum denominator size of 25 stays is adopted. They also noted that for facilities with Ns smaller than 40, the confidence intervals of the readmission rate start to increase; for Ns smaller than 30, the confidence intervals increase rapidly. The commenter recommended that we should show both the impact that different minimum denominator sizes have on the number of SNFs excluded and the range of confidence intervals of the SNFs rehospitalization rates for Ns smaller than 50 to below 20. They also recommended that bootstrap analysis be conducted to test minimum denominator size to see how the confidence interval around small facilities increases as the denominator decreases as was done for NQF #2375.

Response: We did not propose a minimum denominator size of 25 stays, nor did we specify any minimum SNF size for inclusion. We will consider whether we should establish a minimum denominator for the SNFRM in future rulemaking along with the scoring methodology we are developing for the SNF VBP Program.

(3) Exclusions

Patients whose prior proximal hospitalization was for the medical treatment for cancer are excluded. Analyses of this population during measure development showed them to have a different trajectory of illness and mortality than other patient populations, which is consistent with findings in studies in other patient populations.¹²

SNF stays excluded from the measure are:

- SNF stays where the patient had one or more intervening post-acute care (PAC) admissions (inpatient rehabilitation facility (IRF), long-term care hospital (LTCH), or another SNF) which occurred either between the prior proximal hospital discharge and SNF admission (from which the patient was readmitted) or after the SNF discharge

but before the readmission, within the 30-day risk window.

- SNF stays with a gap of greater than 1 day between discharge from the prior proximal hospitalization and the SNF admission.

- SNF stays in which the patient was discharged from the SNF against medical advice (AMA).

- SNF stays in which the principal diagnosis for the prior proximal hospitalization was for rehabilitation care; fitting of prostheses and for the adjustment of devices.

- SNF stays in which the prior proximal hospitalization was for pregnancy.

- SNF stays in which data were missing on any variable used in the SNFRM construction.

Readmissions within the 30-day risk window that are usually considered planned due to the nature of the procedures and principal diagnoses of the readmission are also excluded from the measure. In addition to the list of planned procedures is a list of diagnoses (provided in the SNFRM Technical Report), which, if found as the principal diagnosis on the readmission claim, would indicate that the usually planned procedure occurred during an unplanned acute readmission. In addition to the HWR Planned Readmission Algorithm, the SNFRM incorporates procedures that are considered planned in post-acute care settings as identified in consultation with TEPs. Full details on the planned readmissions criteria used, including the additional procedures considered planned for post-acute care may be found in the SNFRM Technical Report. Details regarding the TEP proceedings can be found in the SNFRM TEP Report.

A discussion of the general comments that we received on the SNFRM exclusions, and our responses to those comments, appears below.

Comment: One commenter suggested that we should not limit the SNFRM to a 30-day readmission window, and should hold SNFs accountable for all readmissions that occur while a beneficiary is in a SNF. The commenter also suggested that we adopt a SNF measure that holds SNFs accountable for readmissions 30 days after discharge from the SNF, which commenters stated would help ensure smooth care transitions.

Response: We agree with the commenter's concerns that SNFs should be accountable for longer-stay patients who are readmitted to an acute care hospital. The SNFRM is designed to assess failed transitions from acute care to the SNF, and is not intended to capture all hospitalizations that may

¹¹ The COPSS-CMS White Paper Committee: Arlene S. Ash, Ph.D.; Stephen E. Fienberg, Ph.D.; Thomas A. Louis, Ph.D.; Sharon-Lise T. Normand, Ph.D.; Therese A. Stukel, Ph.D.; Jessica Utts, Ph.D. Available for download here: <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Statistical-Issues-in-Assessing-Hospital-Performance.pdf>.

¹² National Quality Forum. "Patient Outcomes: All-Cause Readmissions Expedited Review 2011". July 2012. pp. 12.

occur in a SNF population. Including all admissions beyond 30 days in the population would attenuate the association between the transitions of care at the proximate discharge from an acute care hospital to the readmission. Adding additional measures to account for readmissions post discharge from the SNF seems a reasonable suggestion, but we lack the statutory authority to include additional quality measures in the SNF VBP program.

Comment: One commenter expressed concern about the SNFRM's exclusion of patients admitted to SNFs from inpatient rehabilitation facilities and long-term care hospitals. The commenter agreed that these patients may be in a different phase of recovery than acute care hospital patients, but suggested that they should still be included in the measure with a separate risk adjustment method.

Response: We excluded patients who have intervening IRF or LTCH admissions before their first SNF admission. While developing the measure specifications, we found that these patients started their SNF admission later in the 30-day readmission window and received other additional types of services as compared with patients admitted directly to the SNF from the prior proximal hospitalization. Thus, they are clinically different, and their risk for readmission is different from the rest of SNF admissions. We report details on this exclusion in the SNFRM Technical Report.¹³ SNF patients with intervening IRF/LTCH stays had the lowest rates of readmission (8.6 percent) as compared with those with no intervening IRF/LTCH stay.

Additionally, we found that those with intervening IRF/LTCH admissions had longer hospital lengths of stay and more prior proximal hospitalizations involving surgical procedures compared to those without an intervening stay. This observation supports the rationale that patients who had intervening IRF/LTCH stays are entering the SNF at a later stage of their recovery and are therefore at a different risk for readmission than patients who were admitted directly to the SNF from their prior proximal hospitalization. This issue also impacts a relatively small number of SNF stays; 6 percent have an intervening PAC stay (IRF, LTCH, or another SNF) or go home from their prior proximal hospitalization and are

later admitted to a SNF within the 30-day readmission window.

Combined, these analyses provide justification for excluding SNF admissions with intervening IRF or LTCH admissions, or with multiple SNF stays, by showing these exclusions will not have a substantial effect on the SNFRM. Patients with multiple PAC stays after a prior proximal hospitalization are not systematically different from those with only one SNF stay with regard to comorbidities, but are very different with regard to readmission risk. Additionally, concerns about attribution, given the mix of providers these patients have received services from during the risk period, argues for the appropriateness of excluding these patients. Lastly, patients with multiple PAC stays do not cluster in a small group of facilities, so no facilities are disproportionately impacted by these exclusions.

Comment: One commenter strongly disagreed with the SNFRM's exclusion criteria where the patient had one or more intervening admissions to an IRF which occurred either prior to the proximal hospital discharge and SNF admission or after the SNF discharge but before the readmission. The commenter stated that the criteria would not take into account medically complex patients who may be readmitted to the hospital for issues treated as comorbidities. The commenter stated that admission to an IRF should be considered as a proximal hospitalization.

Response: With regard to considering an IRF stay as a proximal hospitalization, we would like to clarify that this measure was developed to harmonize with other hospital readmission measures which do not consider post-acute care settings, like IRFs, as proximal hospitalizations. We have previously adopted a hospital readmission measure for the IRF QRP and have adopted the NQF-endorsed version of the All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from an IRF (NQF #2502) for the IRF QRP. Although IRFs are licensed as hospitals, we include them in the PAC continuum of care and as such, have proposed NQF #2502 to account for readmissions following discharge from the IRF setting.

Comment: One commenter suggested that we exclude ventilator-dependent residents from the readmission measure when those patients' prior proximal hospitalization required being placed on a ventilator for the first time. The commenter noted that these patients require frequent rehospitalizations as

part of the adjustment to ventilator dependency.

Response: This measure of all-cause unplanned hospital readmission measures was harmonized with measures adopted in other inpatient and post-acute care programs. Consistent with these other measures, we do not exclude these types of patients. Rather, the measure is designed to take into account a variety of patient-level risk factors through risk adjustment, including principal diagnoses or comorbidities that require use of mechanical ventilation.

Comment: One commenter supported our proposal to exclude from the measure those patients whose prior proximal hospitalization was for medical treatment of cancer, and encouraged us to examine whether other populations should be excluded from the measure as well.

Response: The rationale for excluding from the measure patients whose prior proximal hospitalization was for medical treatment of cancer is that these patients with these admissions have a very different mortality and readmission risk from the rest of the Medicare population, and outcomes for these admissions do not correlate well with outcomes for other patients, as determined in the development of the Hospital-Wide Readmission (HWR) measure (NQF #1789). Further detail and relevant analyses supporting this exclusion criterion are available in the SNFRM Technical Report, section 2.3.1. In the development of the HWR and SNFRM measures, we have not identified additional patient populations or medical conditions whose post-discharge trajectory of readmissions was not consistent with other patient groups such that they would require exclusion from the measure as well.

Comment: One commenter suggested that we include planned readmissions in the denominator but exclude them from the numerator of the SNFRM. The commenter noted that the way planned readmissions are counted is not clear in the rule. In one section, commenter noted, the rule stated that they are excluded; in another, it states that they are included in the denominator but excluded from the numerator.

Response: We would like to clarify that the measure includes planned readmissions in the denominator but excludes them from the numerator. This is consistent with how planned readmissions are treated in the Hospital-Wide All-Cause Unplanned Readmission Measure (HWR), upon which this measure is based.

¹³ Available at: <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Downloads/SNFRM-Technical-Report-3252015.pdf>.

(4) Eligible Readmissions

An eligible SNF admission is considered to be in the 30-day risk window from the date of discharge from the proximal acute hospitalization until: (1) The 30-day period ends; or (2) the patient is readmitted to an IPPS or CAH. If the readmission is unplanned, it is counted as a readmission in the numerator of the measure. If the readmission is planned, the readmission is not counted in the numerator of the measure. The occurrence of a planned readmission ends further tracking for readmissions in the 30-day period.

We did not receive any comments on the specific topic of eligible readmissions. However, we addressed comments on exclusions from the measure above.

(5) Risk Adjustment

Readmission rates are risk-adjusted for patient case-mix characteristics, independent of quality. The risk adjustment modeling estimates the effects of patient characteristics, comorbidities, and select health status variables on the probability of readmission. More specifically, the risk-adjustment model for SNFs accounts for demographic characteristics (age and sex), principal diagnosis during the prior proximal hospitalization, comorbidities based on the secondary medical diagnoses listed on the patient's prior proximal hospital claim and diagnoses from prior hospitalizations that occurred in the previous 365 days, length of stay during the patient's prior proximal hospitalization, length of stay in the ICU, body system specific surgical indicators, ESRD status, whether the patient was disabled, and the number of prior hospitalizations in the previous 365 days.

A discussion of the general comments that we received on the SNFRM risk adjustment, and our responses to those comments, appears below.

Comment: Some commenters urged us to adjust the proposed readmission measure for sociodemographic factors before the SNF VBP Program is implemented in FY 2019. Commenters stated that factors outside the control of the hospital, such as availability of primary care, mental health services, access to medications and appropriate food, may significantly influence the likelihood of a patient's health improving after hospital discharge and whether a readmission may be necessary. Commenters suggested that we consider using proxy data on sociodemographic status, such as census-derived data on income and education level, and claims data on the

proportion of patients dually eligible for Medicare and Medicaid, to adjust the SNFRM.

One commenter stated that we should submit the SNFRM to NQF under its pilot program for socioeconomic risk adjustment evaluation. The commenter stated that many SNFs provide care to the most vulnerable residents of their communities and that those patients present greater challenges in maintaining optimal medical and functional outcomes, including greater risk for readmission.

Another commenter stated that the SNFRM, and any other measures used in the VBP program, should be appropriately risk adjusted for the population served. The commenter stated that there is significant variation in size, patient populations, and scope of service that are not fully accounted for by current risk adjustments. The commenter also stated that readmission predictors are more highly linked to functional needs and family/caregiver support resources, neither of which are included in risk adjustment.

Response: While we appreciate these comments and the importance of the role that sociodemographic status plays in the care of patients, we continue to have concerns about holding providers to different standards for the outcomes of their patients of low sociodemographic status because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We routinely monitor the impact of sociodemographic status on facilities' results on our measures.

NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate for each measure. For 2 years, NQF will conduct a trial of a temporary policy change that will allow inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will determine whether to make this policy change permanent. Measure developers must submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model.

Furthermore, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) is conducting research to examine the impact of socioeconomic status on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act. We will

closely examine the findings of these reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

Comment: One commenter requested that residents identified as residing in a designated sub-acute unit within a SNF be considered under the "other health status" variable for risk adjustment.

Response: We undertake annual maintenance of our quality measures. We will consider this suggestion through this process. We thank the commenters for their contribution.

Comment: One commenter noted that certain SNFs specialize in serving certain patient populations that are associated with higher rates of hospitalization, and stated that our risk adjustment model should not inadvertently penalize SNFs that offer these programs.

Response: We believe that the risk adjustment model that we have proposed for the SNFRM will ensure that SNFs serving more complex patient populations will not be penalized inadvertently under the SNF VBP Program.

Comment: One commenter stated that we should consider adjusting the SNFRM using HCCs based on hospital and outpatient claims during the prior year rather than the number of prior hospital stays for a facility. The commenter suggested that HCCs are more likely to capture the full risk of a patient's comorbidities than secondary diagnoses coded during the immediately preceding hospital stay.

Response: To clarify, we note that this measure uses for risk adjustment the HCCs based on hospital claims from the prior year in addition to secondary diagnoses coded during the immediately preceding hospital stay. Consistent with other hospital readmission measures, this measure captures HCCs based only on inpatient claims and does not include outpatient claims.

(6) Measurement Period

The SNFRM utilizes 1 year of data to calculate the measure rate. Given that there are more than 2 million Medicare FFS SNF admissions per year in more than 15,000 SNFs, 1 year of data is sufficient to calculate this measure with a model in which the risk adjusters have sufficient sample size to have good precision. The relevant reliability testing may be found in the SNFRM Technical Report.

We sought public comments on the SNFRM's measurement period, and have responded to them in the "FY 2019 Performance Period and Baseline Period Considerations" section below.

(7) Stakeholder/MAP Input

Our measure development contractor convened a TEP which provided input on the technical specifications of this quality measure. The TEP was supportive of the design of this measure. We also solicited stakeholder feedback on the development of this measure through a public comment process from July 15th to 29th, 2013. In December 2014, the NQF endorsed the SNF 30-Day All-Cause Readmission Measure (NQF #2510).

We also considered input from the Measures Application Partnership (MAP) when selecting measures under the CMS SNF VBP Program. The MAP is composed of multi-stakeholder groups convened by the NQF, our current contractor under section 1890(a) of the Act. The MAP has noted the need for care transition measures in PAC/ Long Term Care (LTC) performance measurement programs and stated that setting-specific admission and readmission measures under consideration would address this need.¹⁴ We included the SNFRM on the December 1, 2014 List of Measures under Consideration (MUC List), and the MAP supported the measure. A spreadsheet of MAP's 2015 Final Recommendations is available at NQF's Web site at <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=78711>.

We sought public comments on our proposal to adopt the SNF 30-Day All-Cause Readmission Measure (SNFRM) (NQF #2510) for use in the SNF VBP Program, and our responses appear in subsections i. through vii. above, as well as in subsection viii. below.

(8) Feedback Reports to SNFs

Section 1888(g)(5) of the Act requires that beginning October 1, 2016, SNFs be provided quarterly confidential feedback reports on their performance on measures specified under sections 1888(g)(1) or (2) of the Act.

We intended to address this topic in future rulemaking. However, we requested public comment on the best means by which to communicate these reports to SNFs. For example, we could consider providing confidential, downloadable feedback reports to SNFs through a secure portal, such as QualityNet. We also invited comment on the level of detail that would be most helpful to SNFs in understanding their

performance on the new quality measures. The comments we received on these topics, with their responses, appear below.

Comment: One commenter supported our suggested plan to provide SNFRM feedback reports to SNFs via a secure portal such as QualityNet. The commenter suggested that we provide full details on how their scores were determined, including data on readmitted beneficiaries and details on SNFs' rankings, so that facilities may validate their performance and perform quality improvement efforts.

Response: We will provide information to providers on facilities' scores on this measure. As discussed further below, we intend to consider what information should be included in SNFRM feedback reports in the future, and we will further consider the commenter's feedback when we develop our proposals on that topic. However, while we may provide information pertaining to a patient's readmission episode, we cannot interpret such determinations and readmission rationales, or provide post-discharge information. As part of their quality improvement and care coordination efforts, SNFs are encouraged to monitor hospital readmissions and follow up with patients post discharge. Therefore, although we will not be providing specific information at the patient level in the feedback reports, we believe that SNFs will monitor their overall hospital readmission rates and assess their performance.

Comment: One commenter noted that the quarterly feedback reports required under the Program will use claims data, but that these data may not be accurate if SNFs do not submit their claims timely. The commenter noted that SNFs have up to 12 months to submit claims, which may affect performance measurement.

Response: We intend to monitor SNFRM performance to ensure that unintended consequences related to the time facilities have to submit or resubmit claims do not result.

After consideration of the public comments that we have received, we are finalizing our proposal to specify the SNF 30-Day All-Cause Readmission Measure (SNFRM) (NQF #2510) and to adopt the measure for the SNF VBP as the SNF all-cause, all-condition hospital readmission measure under section 1888(g)(1) of the Act as proposed.

d. Performance Standards

(1) Background

Section 1888(h)(3) of the Act requires the Secretary to establish performance

standards for the SNF VBP Program. The performance standards must include levels of achievement and improvement, and must be established and announced not later than 60 days prior to the beginning of the performance period for the FY involved. To assist us in developing our proposals to establish performance standards for the SNF VBP program, we reviewed a number of innovative health care programs and demonstration projects, both public and private, to discover if any could serve as a prototype for the SNF VBP program. One methodology of important note that provides us an analogous framework for implementation of performance standards is the Performance Assessment Model, implemented for our Hospital VBP program. We also reviewed the Hospital Acquired Conditions Reduction Program, as well as the Hospital Readmissions Reduction Program and the End-Stage Renal Disease Quality Incentive Program (ESRD QIP).

We invited comment on several potential approaches for calculating performance standards under the SNF VBP Program. The comments we received on this topic, with their responses, appear below after discussion of these potential approaches.

(a) Hospital Value-Based Purchasing Program

Under the Hospital VBP Program, a hospital's Total Performance Score is determined by aggregating and weighting domain scores, which are calculated based on hospital performance on measures within each domain. The domain scores are then weighted to calculate a TPS that ranges between 0 and 100 points. At this time, we do not anticipate proposing to adopt quality measurement domains akin to other CMS quality programs under the SNF VBP Program due to fact that this program is based on only one measure.

To calculate HVBP measure scores, hospital performance on specified quality measures is compared to performance standards established by the Secretary. These performance standards include levels of achievement and improvement and enable us to award between 0 and 10 points to each hospital based on its performance on each measure during the performance period. An achievement threshold, generally defined as the median of all hospital performance on most measures during a specified baseline period, is the minimum level of performance required to receive achievement points. The benchmark, generally defined as the

¹⁴ 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?LinkIdentifier=id&ItemID=72738>.

mean of the top decile of all hospital performance on a measure during the baseline period, is the performance level required for receiving the maximum number of points on a given measure. The Program also establishes an improvement threshold for each measure, set at each individual hospital's performance on the measure during the baseline period, to award points for improvement over time.

We believe that the Hospital VBP Program's performance standards methodology is a well-understood methodology under which health care providers and suppliers can be rewarded both for providing high-quality care and for improving their performance over time. The statutory authority for the Hospital VBP Program is structured similarly to the statutory authority for the SNF VBP Program, and we are considering adoption of a similar methodology for establishing performance standards under the SNF VBP Program. We also seek to align our pay-for-performance and QRPs as much as possible. Specifically, we could consider adopting performance standards based on all SNF performance during the baseline period on the measure specified under section 1888(g)(1) or (2) of the Act in the form of the achievement threshold—median of all SNF performance during a baseline period—and the benchmark—mean of the top decile of all SNF performance during a baseline period. We could then consider awarding points along a continuum relative to those performance levels.

(b) Hospital-Acquired Conditions Reduction Program

We also considered whether we should adopt any components of the scoring methodology that we have finalized for the HAC Reduction Program under the SNF VBP Program. The HAC Reduction Program requires the Secretary to reduce eligible hospitals' Medicare payments to 99 percent of what would otherwise have been paid for discharges when hospitals rank in the worst performing quartile for risk-adjusted HAC quality measures. These quality measures comprise efforts to promote quality of care by reducing the number of HACs in the acute inpatient hospital setting.

We determine a hospital's Total HAC Score by first assigning each hospital a score of between 1 and 10 for each measure based on the hospital's relative performance ranking in 10 groups (or deciles) for that measure. Second, the measure score is used to calculate the domain score. We discuss other details of the HAC Reduction Program's scoring

methodology in further detail in this section.

Although the HACRP statutory authority is not structured the same as the SNF VBP statutory authority, we view the HACRP's use of decile-based performance standards as one conceptual possibility for constructing performance standards under the SNF VBP Program. Specifically, we could consider setting performance standards based on SNFs' ranked performance on the measures specified under sections 1888(g)(1) or (2) of the Act during the performance period. We could divide SNFs' performance on the measures into deciles and award between 1 and 10 points to all SNFs within each decile. While this type of performance standards calculation would measure and reward achievement, we are concerned that it would not incorporate improvement, and we invited comment on the best means by which we could include improvement in this type of calculation.

(c) Hospital Readmissions Reduction Program (HRRP)

We also considered aspects of the Hospital Readmissions Reduction Program (HRRP) for adaptation under the SNF VBP Program. HRRP reduces Medicare payments to hospitals with a higher number of readmissions for applicable conditions over a specified time period.

Hospital readmissions are defined as Medicare patients who are readmitted to the same or another hospital within 30 days of a discharge from the same or another hospital, which includes short-term inpatient acute care hospitals. The initial hospital inpatient admission (the discharge from which starts the 30-day potential penalty clock) is termed the index admission. The hospital inpatient readmission (which can be used to determine application of a penalty if the readmission occurs within 30 days of the index inpatient admission stay) can be for any cause, that is, it does not have to be for the same cause as the index admission.

Using historical data, we determine whether eligible IPPS hospitals have readmission rates that are higher than expected, given the hospital's case mix, while accounting for the patient risk factors, including age, and chronic medical conditions identified from inpatient and outpatient claims for the 12 months prior to the hospitalization. A hospital's excess readmission ratio for each condition is a measure of a hospital's readmission performance compared to the national average for the hospital's set of patients with that applicable condition. If the hospital's

actual readmission rate, based on the hospital's actual performance, for the year is greater than its CMS-expected readmission rate, the hospital incurs a penalty up to the maximum cap. If a hospital performs better than an average hospital that admitted similar patients, the hospital will not be subjected to a payment reduction. If a hospital performs worse than average (below a 1.000 score), the poorer performance triggers a payment reduction. For FY 2013, the reduction was capped at 1 percent, for FY 2014 at 2 percent, and at 3 percent for FY 2015 and for subsequent years.

We view the Hospital Readmissions Reduction Program as a potential model for the SNF VBP Program because that program does not weight scores based on domains. That is, under the HRRP, hospitals' risk-adjusted readmissions ratios form the basis for Medicare payment adjustments. Under SNF VBP (and as discussed further in this section), the Program's statute requires us to select only one measure to form the basis for the SNF Performance Score. We believe that this conceptual similarity stands distinct from certain other CMS quality programs that incorporate quality measurement domains and domain weighting into the scoring calculations. However, the HRRP sets an effective performance standard based on the average readmissions adjustment factor of 1.000. We invited comment on whether we should adopt a similar form of performance standard under the SNF VBP Program.

This performance standard could take the form of the median or mean performance on the specified quality measure during the performance period. However, we believe we would also need to consider more granular delineations in SNF scoring to ensure an appropriate distribution of value-based incentive payments under the Program, and we invited comment on what additional policies we should consider adopting in this topic area.

(d) End-Stage Renal Disease Quality Incentive Program (ESRD QIP)

The ESRD QIP is authorized by section 1881(h) of the Act. The program promotes patient health by providing a financial incentive for renal dialysis facilities to deliver high-quality care to their patients.

Section 1881(h)(3)(A)(i) of the Act requires the Secretary to develop a methodology for assessing the total performance of each provider and facility based on performance standards. For each clinical measure adopted under the ESRD QIP, we assess

performance on both achievement and improvement. For the achievement score, facility performance on a measure during a performance period is compared against national facility performance on that measure during a specified baseline period. To calculate the improvement score, we compare a facility's performance during the performance period to its performance during a specified baseline period. In determining a clinical measure score for each measure, we take the higher of the improvement or achievement score.

For each reporting measure, we assess performance based on whether the facility completed the reporting for that measure as specified. If a facility reports data according to the specifications we have adopted, then the facility earns the maximum number of points on the measure. If the facility partially reports data according to the specifications we have adopted, the hospital earns some points on the measure, but less than the maximum.

We believe that the ESRD QIP performance standards methodology is a well-understood methodology under which health care providers and suppliers can be rewarded both for providing high-quality care and for improving their performance over time. The scoring methodology rewards achievement and improvement, and is generally aligned with other pay-for-performance and QRPs. Like the Hospital VBP Program statutory language, the ESRD QIP statutory language is structured similar to the SNF VBP Program statutory language, and we are considering adoption of a similar methodology for calculating performance standards under the SNF VBP Program. Specifically, we could consider adopting performance standards based on all SNF performance during the baseline period on the measure specified under sections 1888(g)(1) or (2) of the Act in the forms of the achievement threshold—median of all SNF performance—and the benchmark—mean of the top decile of all SNF performance. We could then consider awarding points for those performance levels.

A discussion of the comments that we received on potential approaches to calculating performance standards, and our responses to those comments, appears below.

Comment: One commenter suggested that we reconsider using the “higher of” achievement and improvement requirement when determining the performance score and we should focus the SNF VBP Program on having all providers furnish high quality of care.

Response: We do not believe we have the authority to reconsider using the “higher of” achievement and improvement requirement given the statutory requirement in section 1888(h)(3)(B) of the Act, which requires us to adopt performance standards that include levels of achievement and improvement, and further directs us to use the higher of either improvement or achievement in calculating the SNF performance score under paragraph (4).

Comment: Commenters urged us to establish performance standards prior to the beginning of the performance period, as we do in the Hospital VBP Program. Commenters stated that this policy enables providers to understand in advance what level of performance they must reach under the Program.

Response: We intend to establish and announce performance standards in advance of the performance period in accordance with the requirement in section 1888(h)(3)(C) of the Act.

We will consider these comments further in future rulemaking.

(2) Measuring Improvement

We are considering several methodologies for improvement scoring under the SNF VBP Program, and we invited public comments on these options or others that we should consider as we develop our SNF VBP Program policies for future rulemaking.

Section 1888(h)(4)(B) of the Act specifically requires us to construct a ranking of SNF performance scores. While we view such a ranking system as fairly straightforward when based on achievement scoring—for example, ranking SNFs based on their performance on a measure during the performance period could be achieved by ordering SNF performance rates on the measure specified for the Program year—we are considering several approaches for including improvement in the SNF scoring methodology because we are limited to one measure for each SNF Program year. These approaches include:

- Improvement points, awarded using a similar methodology as the one we use to award improvement points in the Hospital VBP Program.
- Measure rate increases, in which a SNF's performance rate on a measure would be increased as a result of its improvement over time.
- Ranking increases, in which a SNF's ranking relative to other SNFs would be increased as a result of improvement.
- Performance score increases, in which a SNF's performance score would be increased as a result of improvement.

We discuss each of these options in further detail in the FY 2016 SNF PPS proposed rule (80 FR 22063 through 22064).

The comments we received on this topic, along with their responses, appear below.

Comment: Commenters stated that we should not adjust SNFs' measure rates directly to reward improvement, cautioning that making those types of adjustments could make valid comparisons of SNF performance more difficult.

Response: We thank the commenters for this feedback.

Comment: Some commenters did not believe that improvement measurement should apply to providers in the top quartile of SNFRM performance. Commenters supported recognizing improvement efforts, but believed that the top quartile should recognize top performers.

Response: We thank the commenters for this feedback, and we will take it into account as we develop our performance standards policy proposals in the future.

Comment: One commenter suggested that we not adopt an achievement threshold under the SNF VBP Program to ensure that all SNFs may qualify for points. The commenter also suggested that we place equal emphasis on improvement under the program, and noted that the Hospital VBP Program separately calculates achievement and improvement and awards the higher of the two to participating hospitals.

Response: We thank the commenter for this feedback, and we will take it into account as we develop our performance standards policy proposals in the future.

Comment: One commenter urged us not to set an absolute level of performance to which SNFs would have to aspire to receive points. The commenter stated that adopting performance standards in this manner would disincentivize improvement, as some SNFs would be unable to receive value-based incentive payments.

Response: We thank the commenter for this feedback, and will consider it in the future.

Comment: One commenter requested that we solicit public comments on performance standards, performance scoring, and the exchange function after releasing detailed analysis of the various options, as well as performance data on the SNFRM.

Response: We thank the commenter for this feedback. We intend to provide as much information as possible on our proposals for this Program in the future.

Comment: One commenter recommended that we award points to SNFs for achievement and improvement, but ensure that low-performing SNFs that improve are not ranked higher than high-performing SNFs.

Response: We thank the commenter for this feedback and will take it into account when developing our proposals in the future.

We will consider these comments further in future rulemaking.

e. FY 2019 Performance Period and Baseline Period Considerations

(1) Performance Period

We intended to specify a performance period for a payment year close to the payment year's start date. We strive to link performance furnished by SNFs as closely as possible to the payment year to ensure clear connections between quality measurement and value-based payment. We also strive to measure performance using a sufficiently reliable population of patients that broadly represent the total care provided by SNFs. As such, we anticipate that our annual performance period end date must provide sufficient time for SNFs to submit claims for the patients included in our measure population. In other programs, such as HRRP and the Hospital Inpatient Quality Reporting Program (HIQR), this time lag between care delivered to patients who are included in the readmission measures and application of a payment consequence linked to reporting or performance on those measures has historically been close to 1 year. We also recognize that other factors contribute to this time lag, including the processing time we need to calculate measure rates using multiple sources of claims needed for statistical modeling, time for providers to review their measure rates and included patients, and processing time we need to determine whether a payment adjustment needs to be made to a provider's reimbursement rate under the applicable PPS based on its reporting or performance on measures.

For the FY 2019 SNF VBP Program's performance period, we are also considering the necessary timeline we need to complete measure scoring to announce the net result of the Program's adjustments to Medicare payments not later than 60 days prior to the FY, in accordance with section 1888(h)(7) of the Act. We are also considering the number of SNF stays typically covered by Medicare each year. As discussed previously, Medicare typically covers more than 2 million Medicare Part A stays per year in more than 15,000

SNFs. Therefore, we believe that 1 year of SNFRM data is sufficient to ensure that the measure rates are statistically reliable.

We intended to propose a performance period for the FY 2019 SNF VBP Program in future rulemaking. We invited public comment on the most appropriate performance period length. The comments we received on this topic, with their responses, appear below.

Comment: Commenters supported a one-year performance period, and suggested that we also consider establishing a minimum annual case count which data from multiple years could be pooled to create more statistically-reliable measure scores.

Response: We thank the commenters for their support. We will consider whether we should establish a minimum annual case count for the SNFRM in future rulemaking.

We will consider these comments further in future rulemaking.

(2) Baseline Period

As described previously, in other Medicare quality programs such as the Hospital VBP Program and the ESRD Quality Incentive Program, we generally adopt a baseline period that occurs prior to the performance period for a FY to measure improvement and establish performance standards.

We view the SNF VBP Program as necessitating a similarly-adopted baseline period for each FY to measure improvement (as required by section 1888(h)(3)(B) of the Act) and to enable us to calculate performance standards that we must establish and announce prior to the performance period (as required by section 1888(h)(3)(A) of the Act). As with the Hospital VBP Program, we intend to adopt baseline periods that are as close as possible in duration as the performance period specified for a FY. However, we may occasionally need to adopt a baseline period that is shorter than the performance period to meet operational timelines. We also intended to adopt baseline periods that are seasonally aligned with the performance periods to avoid any effects on quality measurement that may result from tracking SNF performance during different times of the calendar year.

We stated our intent to propose a baseline period for purposes of calculating performance standards and measuring improvement in future rulemaking. We invited public comment on the most appropriate baseline period for the FY 2019 Program, including what considerations we should take into account when developing this policy for future rulemaking. The comments we

received on this topic, with their responses, appear below.

Comment: Commenters supported our proposal to adopt a 12-month baseline period for purposes of quality measurement. Some commenters suggested that we test longer time periods, however, to see whether more time improves the measure's variation. Commenters further suggested that we align the baseline and performance periods under the SNF VBP Program to the calendar year.

Response: We thank the commenters for their support. We will consider testing longer time periods in the future.

We will consider these comments further in future rulemaking.

f. SNF Performance Scoring

(1) Considerations

As with our performance standards policy considerations described above, we considered how other Medicare quality programs score eligible facilities. Specifically, we considered how the Hospital VBP Program and the Hospital-Acquired Conditions Reduction Program score eligible hospitals. We discussed the Hospital Readmissions Reduction Program's scoring above in relation to performance standards.

(a) Hospital Value-Based Purchasing

A Hospital VBP domain score is calculated by combining the measure scores within that domain, weighting each measure equally. The domain score reflects the number of points the hospital has earned based on its performance on the measures within that domain for which it is eligible to receive a score. After summing the weighted domain scores, the TPS is translated using a linear exchange function into the percentage multiplier to be applied to each Medicare discharge claim submitted by the hospital during the applicable FY. (We discuss the Exchange Function in further detail below).

Unlike the Hospital VBP Program, the SNF VBP program focuses on a single readmission measure, one that will be replaced by a single resource use measure as soon as is practicable. As described above, we do not anticipate adopting quality measure domains akin to other CMS quality programs under the SNF VBP Program. We therefore invited comment on how, if at all, we should adapt the HVB Program's scoring methodology to accommodate both the smaller number of measures and the ranking required under the SNF VBP Program. We responded to comments on this topic below.

(b) Hospital-Acquired Conditions Reduction Program

The Hospital-Acquired Conditions (HAC) Reduction Program scores measures that have been categorized into domains, in a manner that is similar to the HVBP Program's domain structure. For Domain 1, the points awarded to the single assigned measure yield the Domain 1 score, since Domain 1 only contains one measure. For Domain 2, the points awarded for the domain measures are averaged to yield a Domain 2 score. A hospital's Total HAC Score is determined by the sum of weighted Domain 1 and Domain 2 scores. Higher scores indicate worse performance relative to the performance of all other eligible hospitals. Hospitals with a Total HAC Score above the 75th percentile of the Total HAC Score distribution are subject to a payment reduction.

Unlike the Hospital VBP program, referenced above, there is no requirement in the HAC Reduction Program that measures or performance standards must incorporate improvement and achievement scores. As with the HVBP Program above, we invited public comments on the extent to which, if at all, we should adopt components of the HAC Reduction Program's scoring methodology for purposes of the SNF VBP Program. We specifically invited comments on whether we should set an absolute level of performance that must be reached to receive a positive SNF value-based incentive payment. We responded to comments on this topic below.

(c) Other Considerations

We stated our intention to consider several additional factors when developing the performance scoring methodology. We believe that it is important to ensure that the performance scoring methodology is straightforward and transparent to SNFs, patients, and other stakeholders. SNFs must be able to clearly understand performance scoring methods and performance expectations to maximize their quality improvement efforts. The public must understand the scoring methodology to make the best use of the publicly reported information when choosing a SNF. We also believe that scoring methodologies for all Medicare VBP programs should be aligned as appropriate given their specific statutory requirements. This alignment will facilitate the public's understanding of quality information disseminated in these programs and foster more informed consumer decision making about health care. We believe

that differences in performance scores must reflect true differences in performance. To ensure that these beliefs are appropriately reflected in the SNF VBP Program, we stated our intention to assess the quantitative characteristics of the measures specified under sections 1888(g)(1) and (2) of the Act, including the current state of measure development, to ensure an appropriate distribution of value-based incentive payments as required by the SNF VBP statute.

We invited public comment on what other considerations we should take into account when developing our proposed scoring methodology for the SNF VBP Program in future rulemaking. The comments we received on this topic, as well as all other comments on considerations we should take into account when developing the SNF VBP Program's scoring methodology, along with their responses, appear below.

Comment: Some commenters agreed that adapting the Hospital VBP Program's scoring methodology is advantageous for the SNF VBP Program because it is well-understood and tested. Other commenters noted that we have substantial experience with this type of approach and stated that this approach provides the strongest incentive for all SNFs to improve their performance.

Response: We thank the commenters for their support and will take this feedback into account when developing our proposals in the future.

Comment: One commenter provided general suggestions for us as we develop the SNF VBP Program's scoring methodology, including the beliefs that the methodology should be easy to understand and that we should provide education to SNFs in the first years of the program. The commenter also expressed support for public reporting of SNF performance scores and quality measure performance, and suggested that we provide regular feedback to SNFs prior to publication.

Response: We thank the commenters for the feedback and support. We will take these recommendations into account in future rulemaking.

Comment: One commenter outlined several principles for our consideration while designing the SNF VBP Program, including aligning incentives, involving stakeholders, focusing on improving quality instead of cost-cutting, providing rewards that motivate change, implementing the program incrementally, rewarding both high levels of performance and substantial improvements, using measures developed in an open, consensus-based manner, including evidence-based

measures, and designing the program to avoid perpetuating care disparities.

Response: We thank the commenter for the feedback and will take it into account when developing our proposals in the future.

Comment: One commenter urged us to continue engaging stakeholders in discussions on the SNF VBP Program's design, particularly given the commenter's opinion that the program is more characteristic of a penalty program than an incentive program.

Response: We disagree with the commenter's characterization of the Program as a "penalty program." The SNF VBP Program is designed to reward SNFs based on their quality performance, whether accomplished through achievement or improvement over time.

Comment: One commenter urged us to consider the variations in the types and intensity of SNF-based care when developing performance standards and the ranking for the SNF VBP Program, stating that we should distinguish between primarily short-term, transitional care and medically complex, longer-term patients. The commenter suggested that we consider adopting a similar policy to the long-term care hospital interrupted stay policy for the SNF PPS to ensure that facilities are not provided with incentives to withhold medically necessary care for fear of loss of significant revenue.

Response: The SNFRM, which was endorsed by the NQF, has been risk adjusted for case-mix to account for differences in patient populations. The goal of risk adjustment is to account for these differences so that providers who treat sicker or more vulnerable patient populations are not unnecessarily penalized. The current measure accounts for all of the factors proposed in the comment above, including the following: principal diagnosis from the Medicare claim corresponding to the prior proximal hospitalization as categorized by AHRQ's CCS groupings, length of stay during the patient's prior proximal hospitalization, length of stay in the ICU, ESRD status, whether the patient was disabled, the number of prior hospitalizations in the previous 365 days, system-specific surgical indicators, individual comorbidities as grouped by CMS's HCC or other comorbidity indices, and a variable counting the number of comorbidities if the patient had more than two HCCs. However, as discussed above, this measure does not currently adjust for beneficiaries that are dually eligible in Medicare and Medicaid. Based on the results of the NQF trial period for risk-

adjustment for socioeconomic status, as well as work being conducted on this issue by ASPE, the measure specifications may be revised to include additional risk adjusters in the future related to socioeconomic status or sociodemographics.

Comment: One commenter suggested that we conduct data analyses to determine whether different measures or scoring should be applied to hospital-based and freestanding SNFs.

Response: We thank the commenter for this feedback and will consider whether this type of adjustment is appropriate in the future.

Comment: One commenter suggested that we modify the ESRD QIP's scoring methodology for adoption under the SNF VBP Program. The commenter stated that the other models described in the proposed rule do not meet the Program's statutory requirements.

Response: We thank the commenter for this feedback. We intend to ensure that any proposed scoring methodology under the SNF VBP Program complies fully with applicable statutory requirements.

We will consider these comments further in future rulemaking.

(2) Notification Procedures

As described above, we stated our intention to address the topic of quarterly feedback reports to SNFs related to measures specified under sections 1888(g)(1) and (2) of the Act in future rulemaking. We also stated that we intend to address how to notify SNFs of the adjustments to their PPS payments based on their performance scores and ranking under the SNF VBP Program, in accordance with the requirement in section 1888(h)(7) of the Act, in future rulemaking.

We invited public comment on the best means by which to so notify SNFs. We responded to comments on this topic below in the "SNF-Specific Performance Information" subsection.

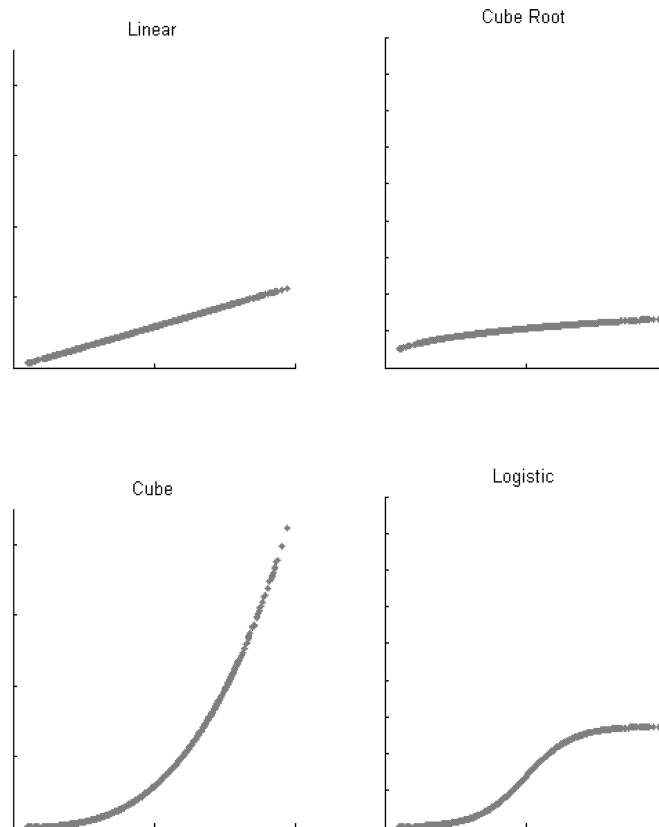
(3) Exchange Function

As described above in reference to the Hospital VBP Program's scoring methodology, we use a linear exchange function to translate a hospital's Total Performance Score under that Program into the percentage multiplier to be applied to each Medicare discharge claim submitted by the hospital during the applicable FY. We refer readers to the Hospital Inpatient VBP Program

Final Rule (76 FR 26531 through 26534) for detailed discussion of the Hospital VBP Program's Exchange Function, as well as responses to public comments on this issue.

We believe we could consider adopting a similar exchange function methodology to translate SNF performance scores into value-based incentive payments under the SNF VBP Program, and we invited comment on whether we should do so. However, as we did for the Hospital VBP Program, we believe we would need to consider the appropriate form and slope of the exchange function to determine how best to reward high performance and encourage SNFs to improve the quality of care provided to Medicare beneficiaries. As illustrated in figure 1, we could consider the following four mathematical exchange function options: Straight line (linear); concave curve (cube root function); convex curve (cube function); and S-shape (logistic function), and we seek comment on what form of the exchange function we should consider implementing if we adopt such a function under the SNF VBP Program.

Figure 1. Exchange Function Options.



We also invited comment on what considerations we should take into account when determining the appropriate form of the exchange function under the SNF VBP Program. We stated our intention to consider how such options would distribute the value-based incentive payments among SNFs, the potential differences between the value-based incentive payment amounts for SNFs that perform poorly and SNFs that perform very well, the different marginal incentives created by the different exchange function slopes, and the relative importance of having the exchange function be as simple and straightforward as possible. We requested public comments on what additional considerations, if any, we should take into account. The comments we received on this topic, with their responses, appear below.

Comment: One commenter expressed support for a linear exchange function under the SNF VBP Program, stating that such a function is easily understood by providers and may encourage practice pattern changes more easily than a more complex function. Commenters also noted that a linear exchange function gives equal importance to improvement for lower- and higher-performing SNFs, and gives all providers an equal opportunity to earn an incentive payment.

Response: We thank the commenter for the feedback on this topic. We will take these recommendations into account in future rulemaking.

Comment: One commenter suggested that we adopt a logistic exchange function and ensure that top-performing SNFs earn back more than 2 percent of their payments from the Program.

Response: We thank the commenter for the feedback on this topic. We will take these recommendations into account in future rulemaking.

We will consider these comments further in future rulemaking.

g. SNF Value-Based Incentive Payments

Sections 1888(h)(5) and (6) of the Act outline several requirements for value-based incentive payments under the SNF VBP Program, including the value-based incentive payment percentage that must be determined for each SNF and the funding available for value-based incentive payments.

We stated our intention to address this topic in future rulemaking. A discussion of the general comments that we received on the SNF Value-Based incentive payments, and our responses to those comments, appears below.

Comment: Commenters recommended that we distribute the maximum 70 percent of the funds withheld from

participating SNF payments under the SNF VBP Program to ensure that the program offers payment for value instead of becoming a penalty program. Some commenters also suggested that the remaining 30 percent of funds withheld be used to fund SNF quality improvement initiatives. Other commenters requested that we explain how the remaining 30–50 percent of funds will be used.

Response: We thank the commenters for this feedback. As the commenters noted, section 1888(h)(5)(C)(ii)(III) of the Act requires that the total amount of value-based incentive payments under the SNF VBP Program for all SNFs in a fiscal year must be greater than or equal to 50 percent, but not greater than 70 percent, of the total amount of the reductions to the SNF PPS payments for that fiscal year, as estimated by the Secretary. We do not believe we have the authority to use the balance of funds that will remain after paying out value-based incentive payments to SNFs under the Program for other SNF quality improvement initiatives. We believe these funds are required to remain in the Medicare Trust Fund.

We will consider these comments further in future rulemaking.

h. SNF VBP Public Reporting (1) SNF-Specific Performance Information

Section 1888(h)(9)(A) of the Act requires the Secretary to post information on the performance of individual SNFs under the SNF VBP Program on the *Nursing Home Compare* Web site or its successor. This information is to include the SNF performance score for the facility for the applicable FY and the SNF's ranking for the performance period for such FY.

We stated our intention to address this topic in future rulemaking. We invited public comment on how we should display this SNF-specific performance information, whether we should allow SNFs an opportunity to review and correct the SNF-specific performance information that we will post on *Nursing Home Compare*, and how such a review and correction process should operate. The comments we received on this topic, with their responses, appear below.

Comment: One commenter requested that SNFs have an opportunity to review and correct their performance information prior to its posting on *Nursing Home Compare*. Commenters requested that the information furnished to SNFs for this purpose should incorporate sufficient detail for SNFs to validate their performance and ranking.

The commenters also stated that any public reporting should include explanations of the SNFRM's methodology, what the measure is intended to show, and any of its limitations.

Response: We thank the commenters for this feedback. We will take it into account as we develop our policies on posting SNF-specific information in the future.

Comment: One commenter supported our intention to distribute confidential feedback reports to SNFs via a secure portal. However, the commenter suggested that we use QIES rather than QualityNet, as the former is familiar to SNFs.

Response: We thank the commenter for this feedback, and will take it into account in the future.

Comment: Other commenters suggested that we use the existing mechanism, QIES, for providing SNFs feedback reports and access to their quality measures as to provide quarterly performance reports. The commenters noted that these reports should provide information on performance relative to others and ranking relative to the payment adjustment. Commenters requested that the reports include actual, non-adjusted measures, predicted actual, expected rate, standardized RR, risk adjusted rate, actual numerator, actual denominator, list of patients in numerator, improvement score, achievement score, performance score and performance rank.

Response: We thank the commenters for these suggestions. We will provide details on infrastructure decisions such as this in future rulemaking. We interpret the comment to indicate that it would be useful for providers to receive from CMS readmission-related information so that they can better understand why a given patient was readmitted and for care-related improvement purposes. We support the intent to seek information that will drive improved quality; however, as described above, while we may provide information pertaining to a patient's readmission episode, we cannot interpret such determinations and readmission rationales, or provide post-discharge information. As part of their quality improvement and care coordination efforts, SNFs are encouraged to monitor hospital readmissions and follow up. Therefore, although this measure will not provide specific information at the patient level, we believe that SNFs will be able to monitor their overall hospital readmission rates and assess their performance.

Comment: Commenters requested that we make claims available to providers and others to calculate the SNFRM measure on an ongoing basis (for example quarterly) such as we are doing by providing claims data to the Bundled Payments for Care Improvement (BPCI) initiative participants. Commenters also recommended that we make available Part A claims on a much more frequent basis (for example, quarterly) so that organizations, vendors, and other stakeholders can calculate the rehospitalization rates for SNF patients and provide additional analyses and profiling that can help SNFs with their quality improvement efforts such as what is currently done with MDS data and quality measures.

Response: We thank the commenters for these suggestions. We will address data availability in future rulemaking.

We will consider these comments further in future rulemaking.

(2) Aggregate Performance Information

Section 1888(h)(9)(B) of the Act requires the Secretary to post aggregate information on the SNF VBP Program on the *Nursing Home Compare* Web site, or a successor Web site, to include the range of SNF performance scores and the number of SNFs that received value-based incentive payments and the range and total amount of such value-based incentive payments.

We stated our intention to address this topic in future rulemaking. We invited public comment on the most appropriate form for posting this aggregate information to make such information easily understandable for the public. The comments we received on this topic, with their responses, appear below.

Comment: One commenter suggested that we combine aggregate performance information with individual rehospitalization performance scores and rankings when posting SNFs' performance information on *Nursing Home Compare*. The commenter stated that the ranking and SNF performance score alone will be confusing because they will combine achievement and improvement.

Response: We thank the commenter for this feedback, and will take it into account in the future rulemaking.

2. Advancing Health Information Exchange

HHS has a number of initiatives designed to encourage and support the adoption of health information technology and to promote nationwide health information exchange (HIE) to improve health care. As discussed in the August 2013 Statement "Principles and

Strategies for Accelerating Health Information Exchange" (available at http://www.healthit.gov/sites/default/files/acceleratinghieprinciples_strategy.pdf), HHS believes that all individuals, their families, their healthcare and social service providers, and payers should have consistent and timely access to health information in a standardized format that can be securely exchanged between the patient, providers, and others involved in the individual's care. Health information technology (IT) that facilitates the secure, efficient and effective sharing and use of health-related information when and where it is needed is an important tool for settings across the continuum of care, including SNFs and NFs. While these facilities are not eligible for the Medicare and Medicaid EHR Incentive Programs, effective adoption and use of health information exchange and health IT tools will be essential as these settings seek to improve quality and lower costs through initiatives such as VBP.

The Office of the National Coordinator for Health Information Technology (ONC) has released a document entitled "Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap Draft Version 1.0 (draft Roadmap) (available at <http://www.healthit.gov/sites/default/files/nationwide-interoperability-roadmap-draft-version-1.0.pdf>) which describes barriers to interoperability across the current health IT landscape, the desired future state that the industry believes will be necessary to enable a learning health system, and a suggested path for moving from the current state to the desired future state. In the near term, the draft Roadmap focuses on actions that will enable a majority of individuals and providers across the care continuum to send, receive, find and use a common set of electronic clinical information at the nationwide level by the end of 2017. The draft Roadmap's goals also align with the IMPACT Act of 2014 which requires assessment data to be standardized and interoperable to allow for exchange of the data. Moreover, the vision described in the draft Roadmap significantly expands the types of electronic health information, information sources and information users well beyond clinical information derived from electronic health records (EHRs). This shared strategy is intended to reflect important actions that both public and private sector stakeholders can take to enable nationwide interoperability of electronic health IT such as: (1) Establishing a coordinated

governance framework and process for nationwide health IT interoperability; (2) improving technical standards and implementation guidance for sharing and using a common clinical data set; (3) enhancing incentives for sharing electronic health information according to common technical standards, starting with a common clinical data set; and (4) clarifying privacy and security requirements that enable interoperability.

In addition, ONC has released the draft version of the 2015 Interoperability Standards Advisory (available at <http://www.healthit.gov/standards-advisory>), which provides a list of the best available standards and implementation specifications to enable priority health information exchange functions. Providers, payers, and vendors are encouraged to take these "best available standards" into account as they implement HIE across the continuum of care, including care settings such as behavioral health, long-term and post-acute care, and home and community-based service providers.

We encourage stakeholders to utilize HIE and certified health IT to effectively and efficiently help providers improve internal care delivery practices, support management of care across the continuum, enable the reporting of electronically specified clinical quality measures (eCQMs), and improve efficiencies and reduce unnecessary costs. As adoption of certified health IT increases and interoperability standards continue to mature, HHS will seek to reinforce standards through relevant policies and programs.

The comments we received on this topic, with their responses, appear below.

Comment: All of the comments received on this topic supported the overall agency goal to accelerate HIE within SNFs, and among the post-acute care providers generally. One commenter asked CMS to keep in mind that certain types of clinicians, such as physical therapists, operate in different provider settings. Another commenter urged CMS to consider the potential impact of HIE regulations and policies on innovation and business practices. Finally, one commenter urged CMS to provide the same type of incentives and considerations to post-acute care providers as they do in other areas with regard to accelerating HIE.

Response: We appreciate the broad support for this initiative and the helpful suggestions provided by the commenters. We will share these comments with the appropriate CMS staff and other governmental agencies to ensure they are taken into account as we

continue to encourage adoption of health information technology.

3. SNF Quality Reporting Program (QRP)

a. Background and Statutory Authority

We seek to promote higher quality and more efficient health care for Medicare beneficiaries, and our efforts are furthered by QRPs coupled with public reporting of that information. Such QRPs already exist for various settings such as the Hospital Inpatient Quality Reporting (HIQR) Program, the Hospital Outpatient Quality Reporting (HOQR) Program, the Physician Quality Reporting System, the Long-Term Care Hospital (LTCH) QRP, the Inpatient Rehabilitation Facility (IRF) QRP, the Home Health Quality Reporting Program (HHQRP), and the Hospice Quality Reporting Program (HQRP). We have also implemented QRPs for home health agencies (HHAs) that are based on conditions of participation, and an ESRD QIP and a Hospital Value-Based Purchasing (HVBP) Program that link payment to performance.

SNFs are providers that must meet conditions of participation for Medicare to receive Medicare payments. Some SNFs are also certified under Medicaid as nursing facilities (NFs), and these types of long-term care facilities furnish services to both Medicare beneficiaries and Medicaid enrollees. SNFs provide short-term skilled nursing services, including but not limited to rehabilitative therapy, physical therapy, occupational therapy, and speech-language pathology services. Such services are provided to beneficiaries who are recovering from surgical procedures, such as hip and knee replacements, or from medical conditions, such as stroke and pneumonia. SNF services are provided when needed to maintain or improve a beneficiary's current condition, or to prevent a condition from worsening. The care provided in a SNF (as a free-standing facility or part of a hospital), is aimed at enabling the beneficiary to maintain or improve his/her health and to function independently. SNF care is a benefit under Medicare Part A and such care is covered for up to 100 days in a benefit period if all coverage requirements are met.¹⁵ In 2014, 2.6 million covered Medicare Part A stays occurred within 15,421 SNFs.

Section 1888(e)(6)(B)(i)(II) of the Act requires that each SNF submit, for FYs beginning on or after the specified application date (as defined in section

1899B(a)(2)(E) of the Act), data on quality measures specified under section 1899B(c)(1) of the Act and data on resource use and other measures specified under section 1899B(d)(1) of the Act in a manner and within the timeframes specified by the Secretary. In addition, section 1888(e)(6)(B)(i)(III) of the Act requires, for FYs beginning on or after October 1, 2018, that each SNF submit standardized patient assessment data required under section 1899B(b)(1) of the Act in a manner and within the timeframes specified by the Secretary. Section 1888(e)(6)(A)(i) of the Act requires that, for FYs beginning with FY 2018, if a SNF does not submit data, as applicable, on quality and resource use and other measures in accordance with section 1888(e)(6)(B)(i)(II) of the Act and on standardized patient assessment in accordance with section 1888(e)(6)(B)(i)(III) of the Act for such FY, the Secretary reduce the market basket percentage described in section 1888(e)(5)(B)(ii) of the Act by 2 percentage points.

The IMPACT Act adds section 1899B to the Act that imposes new data reporting requirements for certain PAC providers, including SNFs. Sections 1899B(c)(1) and 1899B(d)(1) of the Act collectively require that the Secretary specify quality measures and resource use and other measures with respect to certain domains not later than the specified application date in section 1899B(a)(2)(E) of the Act that applies to each measure domain and PAC provider setting. The IMPACT Act also amends section 1886(e)(6) of the Act, to require the Secretary to reduce the PPS payments to a SNF that does not submit the data required in a form and manner, and at a time, specified by the Secretary. Section 1886(e)(6)(A)(i) of the Act would require the Secretary in a FY beginning with FY 2018 to reduce by 2 percentage points the market basket percentage increase as adjusted by the productivity adjustment for SNFs that do not submit the required data.

Under the SNF QRP, we proposed that the general timeline and sequencing of measure implementation would occur as follows: (1) Specification of measures; (2) proposal and finalization of measures through notice-and-comment rulemaking; (3) SNF submission of data on the adopted measures; analysis and processing of the submitted data; (4) notification to SNFs regarding their quality reporting compliance with respect to a particular FY; (5) review of any reconsideration requests; and (6) imposition of a payment reduction in a particular FY for failure to satisfactorily submit data with respect to that FY. We also proposed

that any payment reductions that are taken for a FY for the QRP would begin approximately 1 year after the end of the data submission period for that FY and approximately 2 years after we first adopt the measure.

This timeline, which is similar in the other QRPs, reflects operational and other practical constraints, including the time needed to specify and adopt valid and reliable measures, collect the data, and determine whether a SNF has complied with our quality reporting requirements. It also takes into consideration our desire to give SNFs enough notice of new data reporting obligations so that they are prepared to start reporting the data in a timely fashion. Therefore, we stated our intention to follow the same timing and sequence of events for measures specified under section 1899B(c)(1) and (d)(1) of the Act that we currently follow for the other QRPs. We stated our intention to specify each of these measures no later than the specified application dates set forth in section 1899B(a)(2)(E) of the Act and proposed to adopt them consistent with the requirements in the Act and Administrative Procedure Act. To the extent that we finalize to adopt a measure for the SNF QRP that satisfies an IMPACT Act measure domain, we stated our intention to require SNFs to report data on the measure for the FY that begins 2 years after the specified application date for that measure. Likewise, we stated our intention to require SNFs to begin reporting any other data specifically required under the IMPACT Act for the FY that begins 2 years after we adopt requirements that would govern the submission of that data.

We received multiple public comments pertaining to the general timeline and plan for implementation of the IMPACT Act, sequencing of measure implementation, standardization of PAC assessment tools, and timing of payment consequences for the failure to comply with reporting requirements. The following is a summary of the comments received on this topic and our responses.

Comment: We received several comments regarding the timing of the development of the IMPACT Act measures, the development of associated data elements, data collection and reporting. One commenter noted the considerable time constraints under which the Secretary is required to implement the provisions of the IMPACT Act. Several commenters requested that CMS communicate estimated implementation timelines for all data collection and reporting

¹⁵ Section 1812(a)(2) and (b)(2) of the Act; 42 CFR 409.61; <http://www.medicare.gov/Pubs/pdf/10153.pdf>.

requirements. One commenter requested that CMS provide more detailed information in the rule regarding multiple topics, including the replacement of existing data elements in the PAC assessment tools with a suggested common assessment tool, endorsement of quality measures, and the sequence and timeline of events for measure implementation.

Response: We appreciate the public's feedback regarding the timing issues related to IMPACT Act implementation. We recognize the need for transparency as we move forward to implement the provisions of the IMPACT Act and we intend to continue to engage stakeholders and ensure that our approach to implementation and timing is communicated in an open and informative manner. We will use the rulemaking process to communicate timelines for implementation, including timelines for the replacement of items in PAC assessment tools, timelines for implementation of new or revised quality measures and timelines for public reporting. We will also provide information through pre-rulemaking activities surrounding the development of quality measures, which includes public input as part of our process. Additionally, we intend to engage stakeholders and experts in developing the assessment instrument modifications necessary to meet data standardization requirements of the IMPACT Act.

We will also continue to provide information about measures at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014-and-Cross-Setting-Measures.html>.

Comment: We received several comments requesting the development of a comprehensive overall plan for implementation across all settings covered by the IMPACT Act. Commenters stated that a comprehensive implementation plan would give PAC providers an opportunity to plan for the potential impacts on their operations, and enable all stakeholders to understand CMS's approach to implementing the IMPACT Act across care settings. One commenter requested that CMS plans be communicated as soon as possible and that CMS develop setting-specific communications to facilitate understanding of the IMPACT Act requirements.

Response: We appreciate the request for a comprehensive plan to allow PAC providers to plan for implementation of the IMPACT Act, as well as the need for stakeholder input, the development of

reliable, accurate measures, clarity on the level of standardization of items and measures, and avoidance of unnecessary burden on PAC providers. Our intent has been to comply with these principles in the implementation and rollout of QRPs in the various care settings, and we will continue to adhere to these principles as the agency moves forward with implementing IMPACT Act requirements.

In addition, in implementing the IMPACT Act requirements, we will follow the strategy for identifying cross-cutting measures, timelines for data collection and timelines for reporting as outlined in the IMPACT Act. As described more fully above, the IMPACT Act requires CMS to specify measures that relate to at least five stated quality domains and three stated resource use and other measure domains. The IMPACT Act also outlines timelines for data collection and timelines for reporting. In addition, we must follow all processes in place for adoption of measures including the MAP and the notice and comment rulemaking process. In our selection and specification of measures, we employ a transparent process in which we seek input from stakeholders and national experts and engage in a process that allows for pre-rulemaking input on each measure, as required by section 1890A of the Act. This process is based on a private-public partnership, and it occurs via the MAP. The MAP is composed of multi-stakeholder groups convened by the NQF, our current contractor under section 1890 of the Act, to provide input on the selection of quality and efficiency measures described in section 1890(b)(7)(B). The NQF must convene these stakeholders and provide us with the stakeholders' input on the selection of such measures. We, in turn, must take this input into consideration in selecting such measures. In addition, the Secretary must make available to the public by December 1 of each year a list of such measures that the Secretary is considering under Title XVIII of the Act. Additionally, proposed measures and specifications are to be announced through the Notice of Proposed Rulemaking (NPRM) process in which proposed rules are published in the **Federal Register** and are available for public view and comment.

Comment: We received several comments about the level of standardization of data collection instruments across PAC settings as required by the IMPACT Act. Commenters noted the importance of standardized resident assessment data for cross-setting comparisons of patient outcomes. Some commenters recognized

the need to have as much standardization of measures and data collection across PAC settings as possible, while recognizing that some variations among settings may be necessary. Those commenters cautioned that complete standardization of PAC data may not be possible and urged CMS to consider standardization around topics or domains but allowing different settings to use assessment instruments that were most appropriate for the patient populations assessed. One commenter requested that the specific items added to achieve standardization to the Minimum Data Set (MDS) for NFs, the Outcome and Assessment Information Set (OASIS) for home healthcare, the Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF PAI), and Long-Term Care Hospitals Continuity Assessment Record and Evaluation data set (LTCH-CARE) be published for comments.

Response: We agree that standardization is important for data comparability and outcome analysis. The IMPACT Act requires the modification of the assessment instruments to include standardized data for multiple purposes including quality reporting, interoperability and data comparison, and we will work to ensure that items pertaining to measures required under the IMPACT Act that are used in assessment instruments are standardized. We agree that there may be instances where such data is not necessary or applicable to all four of the post-acute settings' assessment instruments, but is used in more than one assessment instrument. In that circumstance, we work to ensure that such data is standardized.

With regard to the commenter's suggestion that a common assessment tool be developed for PAC settings, we wish to clarify that while the IMPACT Act requires the modification of PAC assessment instruments to revise or replace certain existing patient assessment data with standardized patient assessment data as soon as practicable, it does not require a single data collection tool. We intend to modify the existing PAC assessment instruments as soon as practicable to ensure the collection of standardized data. While we agree that it is possible that within the PAC assessment instruments certain sections could incorporate a standardized assessment data collection tool, for example, the Brief Interview for Mental Status (BIMS), we have not yet concluded that this kind of modification of the PAC assessment instruments is necessary.

All proposed and finalized changes to the PAC instruments are, and will

continue to be, published on the applicable CMS Web sites. As previously mentioned, it is our intention to develop such standardization through clinical and expert input as well as stakeholder and public engagement where we would receive input.

Comment: We received many comments about the burden on PAC providers of meeting new requirements imposed as a result of the implementation of the IMPACT Act. Commenters requested that CMS consider minimizing the burden for PAC providers when possible and avoid duplication in data collection.

Response: We appreciate the importance of avoiding undue burden and will continue to evaluate and consider any burden the IMPACT Act and the SNF QRP places on SNFs. In implementing the IMPACT Act thus far, we have taken into consideration the new burden that our requirements place on PAC providers, and we believe that standardizing patient assessment data will allow for the exchange of data among PAC providers in order to facilitate care coordination and improve patient outcomes.

Comment: We received one comment requesting that, in the future, cross-setting measures and assessment data changes related to the IMPACT Act be addressed in one stand-alone notice and rule that applies to all four post-acute care settings.

Response: We will take this suggestion under consideration.

Comment: One commenter expressed support for the reduction of a SNF's annual update by 2 percentage points for failure to report the required quality data. Additionally, this commenter recommends that imposition of the financial penalty should be published on a public reporting Web site.

Response: We thank the commenter for its support of the SNF QRP reduction as mandated by the IMPACT Act, and the suggestion to publicize payment consequences imposed upon SNFs for failure to satisfactorily report quality data. We will take this under consideration.

Final Decision: After consideration of the public comments received, we are finalizing the adoption of general timeline and sequencing of measure implementation and that any payment reductions that are taken with respect to a FY would begin approximately 1 year after the end of the data submission period for that FY and approximately 2 years after we first adopt the measure as proposed for the SNF QRP.

As provided at section 1888(e)(6)(A)(ii) of the Act, depending

on the market basket percentage for a particular year, the 2 percentage point reduction under section 1888(e)(6)(A)(i) of the Act may result in this percentage, after application of the productivity adjustment under section 1888(e)(5)(B)(ii) of the Act, being less than 0.0 percent for a FY and may result in payment rates under the SNF PPS being less than payment rates for the preceding FY. In addition, as set forth at section 1888(e)(6)(A)(iii) of the Act, any reduction based on failure to comply with the SNF QRP reporting requirements applies only to the particular FY involved, and any such reduction must not be taken into account in computing the SNF PPS payment rates for subsequent FYs.

For purposes of meeting the reporting requirements under the SNF QRP, section 1888(e)(6)(B)(ii) of the Act states that SNFs or other facilities described in section 1888(e)(7)(B) of the Act (other than a CAH) may submit the resident assessment data required under section 1819(b)(3) of the Act using the standard instrument designated by the state under section 1819(e)(5) of the Act. Currently, the resident assessment instrument is titled the MDS 3.0. To the extent data required for submission under subclause (II) or (III) of section 1888(e)(6)(B)(i) of the Act duplicates other data required to be submitted under clause (i)(I), section 1888(e)(6)(B)(iii) provides that the submission of data under subclause (II) or (III) is to be in lieu of the submission of such data under clause (I), unless the Secretary makes a determination that such duplication is necessary to avoid delay in the implementation of section 1899B of the Act taking into account the different specified application dates under section 1899B(a)(2)(E) of the Act.

In addition to requiring a QRP for SNFs under new section 1888(e)(6), the IMPACT Act requires feedback to SNFs and public reporting of their performance. More specifically, section 1899B(f)(1) of the Act requires the Secretary to provide confidential feedback reports to SNFs on their performance on the quality measures and resource use and other measures specified under that section. The Secretary must make such confidential feedback reports available to SNFs beginning 1 year after the specified application date that applies to the measures in that section and, to the extent feasible, no less frequently than on a quarterly basis, except in the case of measures reported on an annual basis, as to which the confidential feedback reports may be made available annually.

Section 1899B(g)(1) of the Act requires the Secretary to provide for the public reporting of SNF performance on the quality measures specified under section 1899B(c)(1) of the Act and the resource use and other measures specified under section 1899B(d)(1) of the Act by establishing procedures for making the performance data available to the public. Such procedures must ensure, including through a process consistent with the process applied under section 1886(b)(3)(B)(viii)(VII) of the Act, that SNFs have the opportunity to review and submit corrections to the data and other information before it is made public as required by section 1899B(g)(2) of the Act. Section 1899B(g)(3) of the Act requires that the data and information is made publicly available beginning no later than 2 years after the specified application date applicable to such a measure and SNFs. Finally, section 1899B(g)(4)(B) of the Act requires that such procedures must provide that the data and information described in section 1899B(g)(1) of the Act for quality and resource use measures be made publicly available consistent with sections 1819(i) and 1919(i) of the Act.

b. General Considerations Used for Selection of Quality Measures for the SNF QRP

We strive to promote high quality and efficiency in the delivery of health care to the beneficiaries we serve. Performance improvement leading to the highest quality health care requires continuous evaluation to identify and address performance gaps and reduce the unintended consequences that may arise in treating a large, vulnerable, and aging population. QRPs, coupled with public reporting of quality information, are critical to the advancement of health care quality improvement efforts.

Valid, reliable, relevant quality measures are fundamental to the effectiveness of our QRPs. Therefore, selection of quality measures is a priority for CMS in all of its QRPs.

We proposed to adopt for the SNF QRP three measures that we are specifying under section 1899(B)(c)(1) of the Act for purposes of meeting the following three domains: (1) Functional status, cognitive function, and changes in function and cognitive function; (2) skin integrity and changes in skin integrity; and (3) incidence of major falls. These measures align with the CMS Quality Strategy,¹⁶ which

¹⁶ <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.html>.

incorporates the three broad aims of the National Quality Strategy:¹⁷

- *Better Care*: Improve the overall quality of care by making healthcare more patient-centered, reliable, accessible, and safe.
- *Healthy People, Healthy Communities*: Improve the health of the U.S. population by supporting proven interventions to address behavioral, social, and environmental determinants of health in addition to delivering higher-quality care.

- *Affordable Care*: Reduce the cost of quality healthcare for individuals, families, employers, and government.

In deciding to propose these measures, we also took into account national priorities, including those established by the National Priorities Partnership (http://www.qualityforum.org/Setting_Priorities/NPP/National_Priorities_Partnership.aspx), and the HHS Strategic Plan (<http://www.hhs.gov/secretary/about/priorities/priorities.html>).

These measures also incorporate common standards and definitions that can be used across post-acute care settings to allow for the exchange of data among post-acute care providers, to provide access to longitudinal information for such providers to facilitate coordinated and improved outcomes, and to enable comparison of such assessment data across all such providers as required by section 1899B(a) of the Act.

We received comments on the topic of the General Considerations Used for Selection of Quality Measures for the SNF QRP. The following is a summary of the comments received and our responses.

Comment: One commenter expressed support for the goals and principles outlined to improve quality and help guide the selection and specification of measures in the SNF QRP.

Response: We appreciate the support.

Comment: While we received some comments expressing appreciation for opportunities for stakeholder feedback regarding implementation of the IMPACT Act, we also received several comments regarding the need for more opportunities for stakeholder input into various aspects of the measure development process. Commenters requested opportunities to provide early and ongoing input into measure development. One commenter requested opportunities for input prior to the development of proposed measure specifications. Commenters requested

that CMS hold meetings with PAC providers on a frequent and regular basis to provide feedback on implementation and resolve any perceived inconsistencies in the proposed rule.

Response: We appreciate the commenter's feedback. It is our intent to move forward with IMPACT Act implementation in a manner in which the measure development process continues to be transparent, and includes input and collaboration from experts, the PAC provider community, and the public at large. It is of the utmost importance to CMS to continue to engage stakeholders, including patients and their families, throughout the measure development lifecycle through their participation in our measure development public comment periods; the pre-rulemaking process; participation in the TEPs provided by our measure development contractors, as well as open door forums and other opportunities. We have already provided multiple opportunities for stakeholder input, which include the following activities: our measure development contractor(s) convened a TEP that included stakeholder experts on February 3, 2015; we convened two separate listening sessions on February 10th and March 24, 2015; we heard stakeholder input during the February 9th 2015 ad hoc MAP meeting provided for the sole purpose of reviewing the measures adopted in response to the IMPACT Act. Additionally, we implemented a public mail box for the submission of comments in January 2015, PACQualityInitiative@cms.hhs.gov, which is listed on our post-acute care quality initiatives Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014-and-Cross-Setting-Measures.html>, and we held a Special Open Door Forum to seek input on the measures on February 25, 2015. The slides from the Special Open Door Forum are available at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014-and-Cross-Setting-Measures.html>.

Comment: One commenter expressed concern at the brief time between the passage of the IMPACT Act and the development of the proposed rule because it did not allow for extensive coordination with the professional community. While the commenter appreciated the opportunity to participate in the IMPACT Act listening session, the commenter viewed the proposed rule for the SNF QRP as hasty

and reactive, contrary to the deliberate and measured process that was recommended by stakeholders and sought by CMS through the collaborative listening session.

Response: We appreciate the public's interest in active participation in the measure development process. As noted in the proposed rule, the timeline and sequence of events proposed for the SNF QRP, which is generally followed in other quality reporting programs, requires that we give providers sufficient time after adoption of measures and before reporting obligations begin to enable them to prepare to report the data. We intend to propose measures consistent with the sequence we follow in other quality reporting programs. As noted above, we engaged in multiple activities to solicit stakeholder input including TEPs, listening sessions, ad hoc MAP meetings, Special Open Door Forums and a public email address. As described above, we also initiated an Ad Hoc MAP process to obtain input on the measures that we are finalizing in this final rule.

On February 5th, 2015, we made publicly available a list of Measures Under Consideration (called the "List of Ad Hoc Measures Under Consideration for the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014") (MUC list) as part of an Ad Hoc MAP convened by the NQF. The MAP Post-Acute Care/Long-Term Care Workgroup convened on February 9, 2015 to "review the measures technical properties as they are adapted for use in new settings and whether the new settings impact the measures' adherence to the NQF Scientific Acceptability criterion."¹⁸ The NQF published the MUC list on our behalf for public comment from February 11, 2015 through February 19, 2015 on its Web site. The MAP Coordinating Committee convened on February 27, 2015 to discuss the public comments received, and those public comments are listed here http://public.qualityforum.org/MAP/MAP%20Coordinating%20Committee/MAP_CC%20Feb%2027_Discussion_Guide.html#agenda.

The MAP issued a pre-rulemaking report on March 6, 2015. This Pre-Rulemaking Report is available for download at http://www.qualityforum.org/Project_Pages/MAP_Post-Acute_CareLong-Term_Care_Workgroup.aspx. The MAP's input for

¹⁸ Ad-hoc Review: Expansion of Settings . (n.d.). Retrieved March 5, 2015, from http://www.qualityforum.org/Projects/a-b/Ad_Hoc_Reviews/CMS/Ad_Hoc_Reviews-CMS.aspx.

¹⁷ <http://www.ahrq.gov/workingforquality/nqs/nqs2011annlrpt.htm>.

each of the proposed measures is discussed in this section.

Section 1899B(j) of the Act requires that we allow for stakeholder input as part of the pre-rulemaking process. Therefore, we sought stakeholder input on the measures we proposed to adopt in this final rule as follows: We implemented a public mail box for the submission of comments in January 2015, PACQualityInitiative@cms.hhs.gov which is located on our post-acute care quality initiatives Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014-and-Cross-Setting-Measures.html>; we convened a TEP that included stakeholder experts and patient representatives on February 3, 2015; and we sought public input during the February 2015 ad hoc MAP process. In addition, we held a National Stakeholder Special Open Door Forum on February 25, 2015 for the purpose of seeking input on these measures. Lastly, we held two separate listening sessions on February 10 and March 24, 2015, respectively. These sessions sought feedback from providers regarding best practices for collecting quality data with respect to the IMPACT Act requirements.

Comment: Multiple commenters expressed concern that the MAP process was not implemented properly and had concerns about when MAP Workgroup rosters are open for public comment, the inclusion of additional measures during the MAP, and other items such as MAP composition. Commenters also expressed concern that the open door forums and listening sessions designed to meet public input requirements did not include sufficient public discussion of the proposed quality measures. One commenter stated that there is confusion among NQF and MAP members over whether they can review all related NQF-endorsed measures or are restricted to reviewing only measures preferred by CMS and requested that CMS issue them written guidance. In addition, the commenter urged CMS to change the MAP public comment process.

Response: With regard to the commenters' concerns pertaining to the processes associated with the MAP such as when MAP Workgroup rosters are open for public comment, the inclusion of additional measures during the MAP, and other items such as MAP composition, we note that the operations of the MAP are directed by the NQF, and not by CMS. Further, while the MAP provides input on measures selected by the Secretary, the

pre rulemaking provisions of the Act do not restrict the MAP from reviewing or recommending alternative measures and methodologies to those proposed by the Secretary. Therefore, we refer readers to the MAP Web site at <http://www.qualityforum.org/map/>. Additionally, we intend to provide the commenters' input to the NQF.

We also, as part of our measure development process for the proposed measures, sought public input at the February 2015 Special Open Door Forum, during which we provided information pertaining to the IMPACT Act and the measures that were listed as Measures Under Consideration for the IMPACT Act of 2014 for review by the MAP. We also advised that interested parties could submit feedback and questions on the measures and other topics, via our mailbox, PACQualityInitiative@cms.hhs.gov. We also sought feedback from subject matter experts who responded to an open call to participate in the numerous TEPs held by our measure development contractor for all measures considered for adoption into the SNF QRP prior to rulemaking.

c. Policy for Retaining SNF QRP Measures for Future Payment Determinations

For the SNF QRP, for the purpose of streamlining the rulemaking process, we proposed that when we adopt a measure for the SNF QRP for a payment determination, this measure would be automatically retained in the SNF QRP for all subsequent payment determinations unless we propose to remove, suspend, or replace the measure.

Section 1899B(h)(1) of the Act provides that the Secretary may remove, suspend or add a quality measure or resource use or other measure specified under section 1899B(c)(1) or (d)(1) of the Act so long as the Secretary publishes a justification for the action in the **Federal Register** with a notice and comment period. Consistent with the policies of other QRPs including the HIQR Program, the HOQR Program, LTCH QRP, and the IRF QRP, we proposed that quality measures would be considered for removal if: (1) Measure performance among SNFs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made in which case the measure may be removed or suspended; (2) performance or improvement on a measure does not result in better resident outcomes; (3) a measure does not align with current clinical guidelines or practice; (4) a more broadly applicable measure (across settings, populations, or

conditions) for the particular topic is available; (5) a measure that is more proximal in time to desired resident outcomes for the particular topic is available; (6) a measure that is more strongly associated with desired resident outcomes for the particular topic is available; or (7) collection or public reporting of a measure leads to negative unintended consequences other than resident harm.

We also noted that under section 1899B(h)(2) of the Act, in the case of a quality measure or resource use or other measure for which there is a reason to believe that the continued collection raises possible safety concerns or would cause other unintended consequences, the Secretary may promptly suspend or remove the measure and publish the justification for the suspension or removal in the **Federal Register** during the next rulemaking cycle.

For any measure that meets this criterion (that is, a measure that raises safety concerns), we will take immediate action to remove the measure from SNF QRP, and, in addition to publishing a justification in the next rulemaking cycle, will immediately notify SNFs and the public through the usual communication channels, including listening session, memos, email notification, and web postings.

We invited public comment on this proposed policy for Retaining SNF QRP Measures for Future Payment Determinations. The following is a summary of the comments received and our responses.

Comment: One commenter supported several of the criteria for possible removal of a measure but opposed or recommended changes to other criteria. The commenter recommended changes to deleting criteria to remove measures that have high performance, remove or clarify phrases associated with the term "clinical practice," and also incorporating language to clarify how to add measures rather than remove them.

Response: We interpret the comment to mean that CMS should maintain measures that have high performance. We required reporting on measures with high performance rates in the past. We will continue to perform a case-by-case analysis through program monitoring to evaluate the importance of measure continuation vs. measure suppression or removal. Additionally, we will evaluate the application of language and phrases associated with the term clinical practice as necessary. We believe that we have addressed the approach we take in measure selection and proposal for adoption in our preamble, and when we present our measures under consideration. Generally, we apply an

approach that involves alignment with the National Quality Strategy, and the CMS Quality Strategy, with an effort to address gaps in quality and priority areas for achieving high quality care. We note that the proposed criteria for consideration for removal of measures in the SNF QRP are consistent with the policies of other QRPs in the Medicare Program, including the HIQR Program, the HOQR Program, LTCH QRP, and the IRF QRP.

After consideration of the public comments received, we are finalizing the adoption of the policy for retaining SNF QRP Measures for Future Payment Determinations as proposed.

d. Process for Adoption of Changes to SNF QRP Program Measures

Section 1899B(e)(2) required that quality measures under the IMPACT Act selected for the SNF QRP must be endorsed by the NQF unless they meet the criteria for exception in section 1899B(e)(2)(B) of the Act. The NQF is a voluntary consensus standard-setting organization with a diverse representation of consumer, purchaser, provider, academic, clinical, and other healthcare stakeholder organizations. The NQF was established to standardize healthcare quality measurement and reporting through its consensus development process (http://www.qualityforum.org/About_NQF/Mission_and_Vision.aspx). The NQF undertakes review of: (a) New quality measures and national consensus standards for measuring and publicly reporting on performance; (b) regular maintenance processes for endorsed quality measures; (c) measures with time-limited endorsement for consideration of full endorsement; and (d) ad hoc review of endorsed quality measures, practices, consensus standards, or events with adequate justification to substantiate the review (http://www.qualityforum.org/Masuring_Performance/Ad_Hoc_Reviews/Ad_Hoc_Review.aspx).

The NQF solicits information from measure stewards for annual reviews and to review measures for continued endorsement in a specific 3-year cycle. In this measure maintenance process, the measure steward is responsible for updating and maintaining the currency and relevance of the measure and for confirming existing specifications to the NQF on an annual basis. As part of the ad hoc review process, the ad hoc review requester and the measure steward are responsible for submitting evidence for review by a NQF TEP which, in turn, provides input to the Consensus Standards Approval Committee which then makes a decision

on endorsement status and/or specification changes for the measure, practice, or event.

The NQF regularly maintains its endorsed measures through annual and triennial reviews, which may result in the NQF making updates to the measures. We believe that it is important to have in place a subregulatory process to incorporate nonsubstantive updates made by the NQF into the measure specifications as we have adopted for the Hospital IQR Program so that these measures remain up-to-date. We also recognize that some changes the NQF might make to its endorsed measures are substantive in nature and might not be appropriate for adoption using a subregulatory process.

Therefore, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53504 through 53505), we finalized a policy under which we use a subregulatory process to make nonsubstantive updates to measures used for the Hospital IQR Program. For what constitutes substantive versus nonsubstantive changes, we expect to make this determination on a case-by-case basis. Examples of nonsubstantive changes to measures might include updated diagnosis or procedure codes, medication updates for categories of medications, broadening of age ranges, and exclusions for a measure (such as the addition of a hospice exclusion to the 30-day mortality measures). We believe that nonsubstantive changes may include updates to NQF-endorsed measures based upon changes to guidelines upon which the measures are based.

Therefore, we proposed to use rulemaking to adopt substantive updates made to measures as we have for the Hospital IQR Program. Examples of changes that we might consider to be substantive would be those in which the changes are so significant that the measure is no longer the same measure, or when a standard of performance assessed by a measure becomes more stringent (for example, changes in acceptable timing of medication, procedure/process, or test administration). Another example of a substantive change would be where the NQF has extended its endorsement of a previously endorsed measure to a new setting, such as extending a measure from the inpatient setting to hospice. These policies regarding what is considered substantive versus nonsubstantive would apply to all measures in the SNF QRP. We also note that the NQF process incorporates an opportunity for public comment and engagement in the measure maintenance process.

We believe this policy adequately balances our need to incorporate updates to the SNF QRP measures in the most expeditious manner possible while preserving the public's ability to comment on updates that so fundamentally change an endorsed measure that it is no longer the same measure that we originally adopted.

We invited public comment on our Proposed Process for the Adoption of Changes to SNF QRP Program Measures. The following is a summary of the comments received and our responses.

Comment: One commenter suggested that CMS more clearly define the subregulatory process criteria for determining what constitutes a non-substantive change and recommended that CMS not wait until rulemaking to make changes that are considered substantive and have progressed through the NQF process.

Response: We believe that it is important to have in place a subregulatory process to incorporate nonsubstantive updates made by the NQF into the measure specifications so that the measures remain up-to-date. For example, we could use the CMS Web site as a place to announce changes. As noted in the proposed rule, the subregulatory process proposed is the same process as we have adopted for the Hospital IQR Program and which has been used successfully in that program. We believe that the criteria for what constitutes a non-substantive change could vary widely and is best described by examples, as we have done in the proposed rule. As noted, what constitutes a substantive versus nonsubstantive changes is determined on a case-by-case basis.

Final Decision: After consideration of the public comments, we are finalizing the adoption of the Process for Adoption of Changes to SNF QRP Program Measures.

New Quality Measures for FY 2018 and Subsequent Payment Determinations

For the FY 2018 SNF QRP and subsequent years, we proposed to adopt three cross-setting quality measures to meet the requirements of the IMPACT Act. These measures address the following domains: (1) Skin integrity and changes in skin integrity; (2) incidence of major falls; and (3) functional status, cognitive function, and changes in function and cognitive function, which are all required measure domains under section 1899B(c)(1) of the Act. The proposed quality measure addressing skin integrity and changes in skin integrity is the NQF-endorsed measure, Percent of Residents or Patients with Pressure

Ulcers That Are New or Worsened (Short Stay) (NQF #0678) (<http://www.qualityforum.org/QPS/0678>). The proposed quality measure addressing the incidence of major falls is an application of the NQF-endorsed Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) (<http://www.qualityforum.org/QPS/0674>). Finally, the proposed quality measure addressing functional status, cognitive function, and changes in function and cognitive function is an application of the Percent of Long-Term Care Hospital Patients With an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631; endorsed on July 23, 2015) (<http://www.qualityforum.org/QPS/2631>).

The proposed quality measures addressing the domains of incidence of major falls and functional status, cognitive function, and changes in function and cognitive function, are not currently NQF-endorsed for the SNF population. We reviewed the NQF's endorsed measures and were unable to identify any NQF-endorsed cross-setting quality measures that focused on these domains. We are also unaware of any other cross-setting quality measures that have been endorsed or adopted by another consensus organization.

Section 1899B(e)(2) of the Act requires we use a NQF-endorsed measure unless the measure meets the exception. In the case of a specified area or medical topic determined by the Secretary for which a feasible and practical measure has not been NQF endorsed, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to a measure that has been endorsed or adopted by a consensus organization identified by the Secretary.

We received several general comments pertaining to the topic of our use of measures that are not endorsed or are not endorsed for use in the SNF resident population, as well as processes related to our adoption of such measures, their reliability and processes pertaining to the NQF endorsement process as well as the MAP review process. The following is a summary of the comments received and our responses.

Comment: We received several comments about the reliability and accuracy of the proposed measures. We also received several comments supporting and encouraging the use of NQF endorsed measures and commenters expressed concerns that not all of the measures proposed for the FY 2018 payment determination were NQF

endorsed. One commenter expressed concern that the statute's exemption allowing the use of measures that are not NQF endorsed provided that "due consideration" is given to endorsed measures is not well defined. One commenter urged CMS to use only measures that have been NQF endorsed as cross-setting measures and another commenter expressed that all measures should be reviewed by the MAP and a technical expert panel (TEP). Additionally, one commenter believed that all measures should be NQF endorsed before they are specified and if the measure is not endorsed, CMS should specify the criteria justifying the exception to endorsement. In addition, one commenter suggested that the NQF endorsement process does not take into account the expertise necessary for rehabilitation services and post-acute care services.

Response: We intend to consider and propose appropriate measures that meet the requirements of the IMPACT Act measure domains and that have been endorsed or adopted by a consensus organization, whenever possible. However, when this is not feasible because there is no NQF-endorsed measure that meets all the requirements for a specified IMPACT Act measure domain, we intend to rely on the exception authority given to the Secretary in section 1899B(e)(2)(B) of the Act. This statutory exception, allows the Secretary to specify a measure for the SNF QRP setting that is not NQF-endorsed where, as here, we have not been able to identify other measures on the topic that are endorsed or adopted by a consensus organization. With respect to the proposed measures for the SNF QRP, we sought MAP review, as well as expert opinion, on the validity and reliability of those measures. We disagree with the commenter who expressed concerns pertaining to the expertise applied in the panels overseeing the NQF endorsement proceedings; however, we intend to provide this feedback to the NQF.

(1) Quality Measure Addressing the Domain of Skin Integrity and Changes in Skin Integrity: Percent of Residents or Patients With Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678)

We proposed to adopt for the SNF QRP, beginning with the FY 2018 payment determination, the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) measure as a cross-setting quality measure that satisfies the skin integrity and changes in skin integrity domain. This measure

assesses the percentage of short-stay residents or patients in SNFs, IRFs, and LTCHs with Stage 2 through 4 pressure ulcers that are new or worsened since admission.

Pressure ulcers are a serious medical condition that result in pain, decreased quality of life, and increased mortality in aging populations.^{19 20 21 22} Pressure ulcers typically are the result of prolonged periods of uninterrupted pressure on the skin, soft tissue, muscle, and bone.^{23 24 25} Older adults in SNFs are prone to a wide range of medical conditions that increase their risk of developing pressure ulcers. These medical conditions include impaired mobility or sensation, malnutrition or under-nutrition, obesity, stroke, diabetes, dementia, cognitive impairments, circulatory diseases, dehydration, the use of wheelchairs, medical devices, and a history of pressure ulcers or a pressure ulcer at admission.^{26 27 28 29 30 31 32 33 34 35 36}

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

²⁰ Gorzoni, M. L. and S. L. Pires (2011). "Deaths in nursing homes." *Rev Assoc Med Bras* 57(3): 327–331.

²¹ Thomas, J. M., et al. (2013). "Systematic review: health-related characteristics of elderly hospitalized adults and nursing home residents associated with short-term mortality." *J Am Geriatr Soc* 61(6): 902–911.

²² White-Chu, E. F., et al. (2011). "Pressure ulcers in long-term care." *Clin Geriatr Med* 27(2): 241–258.

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

²⁴ Institute for Healthcare Improvement (IHI). *Relieve the pressure and reduce harm.* May 21, 2007. Available from <http://www.ihl.org/IHI/Topics/PatientSafety/SafetyGeneral/ImprovementStories/FSRelieveThePressureandReduceHarm.htm>

²⁵ Russo CA, Steiner C, Spector W. Hospitalizations related to pressure ulcers among adults 18 years and older, 2006 (Healthcare Cost and Utilization Project Statistical Brief No. 64). December 2008. Available from <http://www.hcupus.ahrq.gov/reports/statbriefs/sb64.pdf>.

²⁶ Agency for Healthcare Research and Quality (AHRQ). Agency news and notes: pressure ulcers are increasing among hospital patients. January 2009. Available from <http://www.ahrq.gov/research/jan09/0109RA22.htm>.

²⁷ Bates-Jensen BM. Quality indicators for prevention and management of pressure ulcers in vulnerable elders. *Ann Int Med.* 2001;135 (8 Part 2), 744–51.

²⁸ Cai, S., et al. (2013). "Obesity and pressure ulcers among nursing home residents." *Med Care* 51(6): 478–486.

²⁹ Casey, G. (2013). "Pressure ulcers reflect quality of nursing care." *Nurs N Z* 19(10): 20–24.

³⁰ Hurd D, Moore T, Radley D, Williams C. Pressure ulcer prevalence and incidence across post-acute care settings. Home Health Quality Measures & Data Analysis Project, Report of Findings, prepared for CMS/OCSQ, Baltimore, MD, under Contract No. 500–2005–000181 TO 0002. 2010.

³¹ MacLean DS. Preventing & managing pressure sores. *Caring for the Ages.* March 2003;4(3):34–7.

Section 1899B(a)(1)(B) of the IMPACT Act requires that the data submitted on quality measures under section 1899B(c)(1) of the Act be standardized and interoperable across PAC settings, and section 1899B(c)(2)(A) of the Act requires that the measures be reported through the use of a PAC assessment instrument. These requirements are in line with the NQF Steering Committee report, which stated that “to understand the impact of pressure ulcers across settings, quality measures addressing prevention, incidence, and prevalence of pressure ulcers must be harmonized and aligned.”³⁷ This measure has been implemented in nursing homes for resident population with stays of less than 100 days under CMS’s Nursing Home Quality Initiative. We also adopted the measure for use in the LTCH QRP (76 FR 51753 through 51756) beginning with the FY 2014 payment determination, and for use in the IRF QRP (76 FR 47876 through 47878) beginning with the FY 2014 payment determination. We have not, to date, adopted the measure for the home health setting. More information on the NQF endorsed quality measure the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), is available at <http://www.qualityforum.org/QPS/0678>.

A TEP convened by our measure development contractor provided input on the technical specifications of the quality measure, the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), including the feasibility of implementing the measure across PAC settings. The TEP supported

the measure’s implementation across PAC settings and was also supportive of our efforts to standardize the measure for cross-setting development. The MAP also supported the use of the quality measure the Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short Stay) (NQF #0678) in the SNF QRP as a cross-setting quality measure.

We proposed that the data for this quality measure would be collected using the MDS 3.0, currently submitted by SNFs through the Quality Improvement and Evaluation System (QIES) Assessment Submission and Processing (ASAP) system. We believe that this data collection method will minimize the reporting burden on SNFs because SNFs are already required to submit MDS data for multiple purposes, such as for payment purposes. For more information on SNF submission using the QIES ASAP system, readers are referred to <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/NHQIMDS30TechnicalInformation.html>.

The data items that we proposed to calculate the quality measure, the Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short Stay) (NQF #0678) include: M0800A (Worsening in Pressure Ulcer Status Since Prior Assessment (OBRA or scheduled PPS assessment) or Last Admission/Entry or Reentry, Stage 2), M0800B (Worsening in Pressure Ulcer Status Since Prior Assessment (OBRA or scheduled PPS assessment) or Last Admission/Entry or Reentry, Stage 3), and M0800C (Worsening in Pressure Ulcer Status Since Prior Assessment (OBRA or scheduled PPS assessment) or Last Admission/Entry or Reentry, Stage 4). This measure would be calculated at two points in time, at admission and discharge (see Form, Manner, and Timing of Quality Data Submission). The specifications and data items for the quality measure, the Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short Stay) (NQF #0678) are available in the MDS 3.0 Quality Measures User’s Manual available on our Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/NHQIQualityMeasures.html>.

We invited public comments on our proposal to adopt the Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short Stay) (NQF #0678) for the SNF QRP for the FY 2018 payment determination and subsequent years. The following is a

summary of the comments received and our responses.

Comment: We received many comments in support of our proposal to implement the Percent of Residents or Patients with Pressure Ulcers that are New or Worsened quality measure (Short Stay) (NQF #0678) to fulfill the requirements of the IMPACT Act. Commenters believed that measuring skin integrity and changes in skin integrity is important in the post-acute care setting and appreciated that the pressure ulcer measure is NQF-endorsed and is already collected for the Nursing Home Quality Initiative using the MDS 3.0 data.

Response: We thank the commenters for their support of the Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short Stay) (NQF #0678) to fulfill the requirements of the IMPACT Act. We agree that skin integrity and changes in skin integrity are high priority issues for PAC settings.

Comment: One commenter supported our proposal to use the MDS 3.0 as the source of data collection for this measure and to have SNFs submit the data via the QIES ASAP system.

Response: We thank the commenter for its support of the use of the MDS 3.0 and the QIES ASAP system for data collection and reporting of the pressure ulcer measure. The ongoing use of the MDS 3.0 and the QIES ASAP system will minimize burden for SNFs.

Comment: Several commenters were supportive of the intent of this measure but provided recommendations regarding risk adjustment of the pressure ulcer measure. Commenters highlighted the importance of risk adjusting all quality measures and expressed concern that the measure may not be risk adjusted appropriately for the diverse populations across PAC settings. The commenters encouraged CMS to engage in ongoing evaluation of the risk adjustment methodology used for this measure to ensure that the methodology is appropriate for standard cross-setting risk adjustment, as the current risk adjustment methodology is based on data collection tools specific to each PAC setting. Commenters recommended that CMS add several different risk factors to the risk adjustment model including: primary diagnosis; impairments; demographics; co-existing conditions/comorbidities; decreased sensory awareness; and patients or residents at the end of life. Commenters also encouraged CMS to ensure that the measure is fully tested prior to implementation in the QRPs.

One commenter was concerned that the measure is limited to only high risk

Available from <http://www.anda.com/publications/caring/march2003/policies.cfm>.

³² Michel, J. M., et al. (2012). “As of 2012, what are the key predictive risk factors for pressure ulcers? Developing French guidelines for clinical practice.” *Ann Phys Rehabil Med* 55(7): 454–465.

³³ National Pressure Ulcer Advisory Panel (NPUAP) Board of Directors; Cuddigan J, Berlowitz DR, Ayello EA (Eds). *Pressure ulcers in America: prevalence, incidence, and implications for the future. An executive summary of the National Pressure Ulcer Advisory Panel Monograph. Adv Skin Wound Care.* 2001;14(4):208–15.

³⁴ Park-Lee E, Caffrey C. *Pressure ulcers among nursing home residents: United States, 2004* (NCHS Data Brief No. 14). Hyattsville, MD: National Center for Health Statistics, 2009. Available from <http://www.cdc.gov/nchs/data/databriefs/db14.htm>.

³⁵ Reddy, M. (2011). “Pressure ulcers.” *Clin Evid* (Online) 2011.

³⁶ Teno, J. M., et al. (2012). “Feeding tubes and the prevention or healing of pressure ulcers.” *Arch Intern Med* 172(9): 697–701.

³⁷ National Quality Forum. *National voluntary consensus standards for developing a framework for measuring quality for prevention and management of pressure ulcers.* April 2008. Available from http://www.qualityforum.org/Projects/Pressure_Ulcers.aspx

patients or residents, and that the denominator size is decreased by excluding individuals who are low risk. The commenter indicated that pressure ulcers do develop in low risk individuals and that this exclusion will impact each PAC setting differently because the prevalence of low risk individuals varies across settings. The commenter recommended that CMS use a logistic regression model for risk adjustment to allow for an increase in the measure sample size by including all admissions, take into consideration low volume providers, and capture the development of pressure ulcers in low risk individuals. The commenter suggested that a patient or resident's risk is not dichotomous (for example, high risk vs. low risk) and recommended that CMS grade risk using an ordinal scale related to an increasing number and severity of risk factors. The commenter also expressed that the populations and types of risk for pressure ulcers varies significantly across PAC settings, and that using a logistic regression model would be a more robust way to include a wide range of risk factors to better reflect the population across PAC settings. The commenter noted that the TEP that evaluated this cross-setting pressure ulcer measure also recommended that CMS consider expanding the risk adjustment model and discussed excluding or risk adjusting for hospice patients and those at the end of life.

Response: We thank the commenters for their support of the intent of this measure and for their recommendations regarding risk adjustment for this measure. Section 1899B(c)(3)(B) of the Act states that quality measures shall be risk adjusted, as determined appropriate by the Secretary. In regards to the commenter who recommended we risk adjust using a logistic regression model and incorporate low risk patients into the measure, we believe that this commenter may have submitted comments regarding the wrong quality measure. Their comments apply to the quality measure Percent of High Risk Residents with Pressure Ulcers (Long Stay) (NQF #0679), which is not the measure that we proposed for the SNF QRP. The proposed measure is the Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (NQF #0678). This measure is currently risk adjusted using a logistic regression model and includes low risk residents. In the model, patients or residents are categorized as either high or low risk based on four risk factors: (1) Functional limitation; (2) bowel incontinence; (3) diabetes or peripheral

vascular disease/peripheral arterial disease; and (4) low body mass index (BMI). An expected score is calculated for each patient or resident using that patient or resident's risk level on the four risk factors described above. The patient/resident-level expected scores are then averaged to calculate the facility-level expected score, which is compared to the facility-level observed score to calculate the adjusted score for each facility. Additional detail regarding risk adjustment for this measure is available in the measure specifications, available at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.html>.

When developing the risk adjustment model for this measure, we reviewed the literature, conducted analyses to test additional risk factors, convened TEPs to seek stakeholder input, and obtained clinical guidance from subject matter experts and other stakeholders to identify additional risk factors. We have determined that risk adjustment is appropriate for this measure. Therefore, we have developed and implemented the risk adjustment model using the risk factors described above. Nonetheless, we will continue to analyze this measure as more data is collected and will consider changing the risk adjustment model, expanding the risk stratifications, and testing the inclusion of other risk factors as additional risk adjusters for future iterations of the measure. We will also take into consideration the TEP discussion and the commenter's feedback regarding the exclusion or risk adjustment for hospice patients and those at the end of life. As we transition to standardized data collection across PAC settings to meet the mandate of the IMPACT Act, we intend to continue our ongoing measure development and refinement activities to inform the ongoing evaluation of risk adjustment models and methodology. This continued refinement of the risk adjustment models will ensure that the measure remains valid and reliable to inform quality improvement within and across each PAC setting, and to fulfill the public reporting goals of QRPs, including the SNF QRP.

Comment: One commenter requested that CMS consider risk adjusting the quality measure for sociodemographic status, to better reflect the realities that affect the care of special populations and the need for coordination with hospitals within a geographic region. The commenter suggested that some beneficiaries in certain populations are

more complex, and therefore, their skin integrity may be compromised.

Response: While we appreciate these comments and the importance of the role that sociodemographic status plays in the care of patients, we continue to have concerns about holding providers to different standards for the outcomes of their patients of low sociodemographic status because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We routinely monitor the impact of sociodemographic status on facilities' results on our measures.

NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate for each measure. For 2 years, NQF will conduct a trial of a temporary policy change that will allow inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will determine whether to make this policy change permanent. Measure developers must submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model.

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

Comment: One commenter expressed concerns that although the MAP supports the cross-setting use of this measure, it is only NQF endorsed for the SNF setting and suggested that CMS delay implementing the cross-setting measure until it is NQF endorsed across all PAC settings. The commenter also pointed out that the specifications available on the NQF Web site are dated October 2013.

Response: Although the proposed pressure ulcer measure was originally developed for the SNF/nursing home resident population, it has been re-specified for the LTCH and IRF settings, underwent review for expansion to the LTCH and IRF settings by the NQF Consensus Standards Approval

Committee (CSAC) on July 11, 2012³⁸ and was subsequently ratified by the NQF Board of Directors for expansion to the LTCH and IRF settings on August 1, 2012.³⁹ As reflected on the NQF Web site the endorsed settings for this measure include Post-Acute/Long Term Care Facility: Inpatient Rehabilitation Facility, Post Acute/Long Term Care Facility: Long Term Acute Care Hospital, Post Acute/Long Term Care Facility: Nursing Home/Skilled Nursing Facility.⁴⁰ NQF endorsement of this measure indicates that NQF supports the use of this measure in the LTCH and IRF settings, as well as in the SNF setting. As one commenter indicated, this measure was fully supported by the MAP for cross-setting use at its meeting of February 9, 2015. With regard to the measure specifications posted on the NQF Web site, the most up-to-date version of the measure specifications were posted for stakeholder review at the time of the proposed rule on the CMS Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Downloads/Skilled-Nursing-Facility-Quality-Reporting-Program-Quality-Measure-Specifications-for-FY-2016-Notice-of-Proposed-Rule-Making-report.pdf>. The specifications currently posted on the NQF Web site are computationally equivalent and have the same measure components as those posted on the CMS Web site at the time of the proposed rule. However, we provided more detail in the specifications posted with the proposed rule, in an effort to more clearly explain aspects of the measure that were not as clear in the NQF specifications. Additionally, we clarified language to make phrasing more parallel across settings, and updated item numbers and labels to match the 2016 data sets (MDS 3.0, LTCH CARE Data Sets, and IRF-PAI). We are working closely with NQF to make updates and ensure that the most current language and clearest version of the specifications are available on the NQF Web site.

Comment: A few commenters expressed concern regarding the

reliability and validity of this measure across different PAC settings. The commenters were concerned that the reliability and validity testing for this measure was only conducted in the SNF setting.

Response: Although this measure was originally developed for the SNF setting, the NQF expanded its endorsement of the measure to the IRF and LTCH settings as a cross setting quality measure in 2012, and the expanded measure was finalized in the FY 2014 IRF PPS final rule (78 FR 47911 through 47912) and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50861 through 50863). As part of quality measure maintenance for this quality measure, we and our measure contractor will continue to perform reliability and validity testing. Early data analyses have shown that data continues to be valid and reliable.

We appreciate the commenters' concern that the SNF, LTCH, and IRF populations are not identical and that some differences may exist in the reliability and validity of the measure across settings. We are working towards standardizing data across PAC settings as mandated in the IMPACT Act. As such, we continue to conduct measure development and testing to explore the best way to standardize quality measures, while ensuring reliability and validity for the measures to appropriately account for the unique differences in populations across PAC settings.

Comment: Several commenters were concerned that the pressure ulcer measure is not standardized across PAC settings. The commenters stated that although the measure appears meets the goals and the intent of the IMPACT Act, it does not use a single data assessment tool.

One commenter specifically mentioned the frequency of assessments, highlighting the fact that the LTCH and IRF versions of the measure are calculated using two assessment time-points (admission and discharge), while the SNF version uses multiple assessment time-points. The commenter expressed concern that the higher frequency of assessments for the MDS could potentially result in higher rates of pressure ulcer counts for SNFs. Another commenter voiced particular concerns regarding differences in the look-back periods, for the items used on the IRF, SNF, and LTCH assessments (MDS=7-day assessment period, IRF=3-day assessment period, LTCH = 3-day assessment period) and suggested that this would result in different rates of detection of new or worsened ulcers. Commenters encouraged CMS to address all of these discrepancies, and

suggested that we should switch to using only an admission and discharge assessment in the SNF version of the measure.

Response: We appreciate the commenters' review of the measure specifications across the post-acute care settings. We wish to clarify that while the IMPACT Act requires the modification of PAC assessment instruments to revise or replace certain existing patient assessment data with standardized patient assessment data as soon as practicable, it does not require a single data collection tool. We intend to modify the existing PAC assessment instruments as soon as practicable to ensure the collection of standardized data. While we agree that it is possible that within the PAC assessment instruments certain sections could incorporate a standardized assessment data collection tool, for example, the Brief Interview for Mental Status (BIMS), we have not yet concluded that this kind of modification of the PAC assessment instruments is necessary.

As to the concern that the pressure ulcer measure calculation is based on more frequent assessments in the SNF setting than in the LTCH and IRF settings, we wish to clarify that result of the measure calculation for all three PAC providers is the same. For all three PAC providers, the measure calculation ultimately shows the difference between the number of pressure ulcers present on admission and the number of new or worsened pressure ulcers present on discharge. While SNF measure calculation arrives at that number differently than does the measure calculation in the IRF and LTCH settings, ultimately all three settings report the same result—as noted, the difference between the number of pressure ulcers present on admission and the new or worsened pressure ulcers at discharge. To explain, in IRFs and LTCHs, pressure ulcer assessment data is obtained only at two points in time—on admission and on discharge. Therefore, the calculation of the measure includes all new or worsened pressure ulcers since admission. In contrast, in SNFs pressure ulcer assessment data is obtained on admission, at intervals during the stay (referred to as “interim assessments”), and at discharge. Each interim assessment and the discharge assessment only look back to whether there were new or worsened pressure ulcers since the last interim assessment. The sum of number of new or worsened pressure ulcers identified at each interim assessment and at the time of discharge yields the total number of new or worsened pressure ulcers that

³⁸ Nation Quality Forum, Consensus Standardbreds Approval Committee. Meeting Minutes, July 11, 2012. 479–489.

³⁹ National Quality Forum. NQF Removes Time-Limited Endorsement for 13 Measures; Measures Now Have Endorsed Status. August 1, 2012. Available; http://www.qualityforum.org/News_And_Resources/Press_Releases/2012/NQF_Removes_Time-Limited_Endorsement_for_13_Measures;_Measures_Now_Have_Endorsed_Status.aspx.

⁴⁰ National Quality Forum. Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short-Stay). Available: <http://www.qualityforum.org/QPS/0678>.

occurred during the stay and that were present on discharge. In other words, the collection of pressure ulcer data in LTCHs and IRFs is cumulative, whereas in SNFs, data collection is sequential. In both cases the calculation reaches the same result—the total number of new or worsened pressured ulcers between admission and discharge. Thus, this is the same result of the measure calculation for SNFs as is obtained for IRFs and LTCHs. With respect to the commenter's concern that the use of interim assessment periods on the MDS will result in a higher frequency of pressure ulcers for SNF residents, we clarify that pressure ulcers found during interim assessments that heal before discharge are not included in the measure calculation.

In regards to the commenter's concern about different look-back periods, we acknowledge that although the LTCH CARE Data Set and IRF-PAI allow up to the third day starting on the day of admission as the assessment period and the MDS allows for an assessment period of admission up to day 7, we note that the training manuals for SNFs, LTCHs and IRFs provide specific and equivalent-coding instructions related to the items used to calculate this measure (found in Section M—skin conditions for all three assessments). These instructions ensure that the assessment of skin integrity occurs at the initiation of patients' or residents' PAC stays regardless of setting. All three manuals direct providers to complete the skin assessment for pressure ulcers present on admission as close to admission as possible, ensuring a harmonized approach to the timing of the initial skin assessment. Regardless of differences in the allowed assessment periods, providers across PAC settings should adhere to best clinical practices, established standards of care, and the instructions in their respective training manuals, to ensure that skin integrity information is collected as close to admission as possible. Although the manual instructions are harmonized to ensure assessment at the beginning of the stay, based on the commenter's feedback, we will take into consideration the incorporation of uniform assessment periods for this section of the assessments.

Comment: Commenters expressed concerns about the pressure ulcer measure not being standardized across PAC settings, specifically noting differences in the payers that are required to report patient or resident data for this measure resulting in differences in the denominators for each setting. Commenters also expressed concern with the exclusion of Medicare

Advantage beneficiaries from the numerator and denominator for this measure. One commenter noted that measures based on only Medicare FFS beneficiaries may be incomplete, because according to some estimates, only about half of SNF residents are covered by Medicare FFS.

In a related comment, a commenter expressed concern regarding differences in the populations across quality measures in the SNF QRP. The commenters stated that the falls measure (NQF #0674) and function measure (NQF #2631) include only Medicare FFS residents, while the pressure ulcer measure (NQF #0678) includes all short-stay NH residents. The commenter mentioned that this inconsistency could result in confusion for providers because of the varying denominators across measures.

Response: We appreciate the commenters' comments pertaining to the differences in the pressure ulcer quality measure denominators by payer type across the IRF, SNF and LTCH settings. Additionally, we appreciate the commenters' suggested expansion of the population used to calculate all measures to include payer sources beyond Medicare PPS Part A and agree that quality measures that include all persons treated in a facility are better able to capture the health outcomes of that facility's patients or residents, and that quality reporting on all patients or residents is a worthy goal. Although we currently collect data only on the SNF and the IRF Medicare populations, we believe that quality care is best assessed through the collection of patient data regardless of payer source and we agree that consistency in the data would reduce confusion in data interpretation and enable a more comprehensive evaluation of quality. We appreciate the commenter's concerns and although we had not proposed all payer data collection through this current rulemaking, we will take into consideration the expansion of the SNF QRP to include all payer sources through future rulemaking.

Comment: One commenter asked CMS to clarify how the addition of the proposed SNF PPS Part A Discharge Assessment will impact the measure specifications for the numerator and denominator of the pressure ulcer measure. The commenter noted that CMS proposed modifying the MDS discharge assessment to collect information for Part A FFS Medicare beneficiaries who continue in the SNF after ending their Part A stay, but did not clarify how this change will be implemented in the proposed pressure ulcer measure. The commenter is

concerned that if the new MDS discharge assessment is not modified to add the pressure ulcer measure assessment items, the measure will exclude individuals who are admitted but not discharged from the SNF during their PAC stay, which will limit CMS's ability to provide meaningful information to provider and consumers. Finally the commenter expressed concern regarding the increase in burden that will be required to complete this assessment, and encouraged CMS to only include the minimum information necessary to calculate the quality measures.

Response: We proposed that the SNF PPS Part A Discharge Assessment would include the pressure ulcer data elements for the quality measure, the Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short stay) (NQF #0678), in order to capture complete pressure ulcer information for Medicare beneficiaries who continue in the SNF after the end of a Part A stay (—all information between admission and discharge or end of a Part A stay). For more information on the Part A PPS Discharge assessment, we direct readers to the specifications posted on the SNF QRP Measures and Technical Information Web site, at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.html>.

Comment: Many commenters expressed concern with the accuracy of data used to calculate the pressure ulcer measure. One commenter was specifically concerned that CMS excludes residents or patients for whom missing data precludes calculation of the measure from the measure calculations. The commenter expressed that this exclusion may lead to miscoding because if a facility recognizes that a resident is declining, it can simply omit some data for that resident, ensuring that the resident is excluded from the measure. The commenter referenced several different media reports that highlight the seriousness of gaming of MDS 3.0 data. One commenter noted a recent survey that identified deficiencies in reporting by a small sample of SNFs.

Response: As discussed below, we are finalizing our proposal that beginning with the FY 2018 payment determination, any SNF that does not meet the requirement that 80 percent of all MDS assessments submitted contain 100 percent of all data items necessary to calculate the SNF QRP measures would be subject to a reduction of 2

percentage points to its FY 2018 market basket percentage. This requirement will provide an incentive to SNFs to submit complete MDS 3.0 assessments. Analysis of 2014 MDS 3.0 data submitted for the NHQI indicates that for each of the three items used to calculate the pressure ulcer measure (M0800A, M0800B, and M0800C), missing data for calculating measures were approximately 0.1 percent across all target assessments in a given quarter. Less than 0.1 percent of residents were excluded due to missing all three items needed to calculate the measure, suggesting that missing data is not a serious concern. Further, we intend to align with other QRPs and propose through future rulemaking a data validation process that will further ensure that data reported for the SNF QRP is accurate and complete.

Comment: One commenter asked CMS to clarify whether the pressure ulcer measure proposed for the SNF QRP can be reported using the current MDS 3.0 pressure ulcer items, or if new items would be required for this measure. The commenter asked if SNFs would be required to submit different data for the SNF QRP and the Nursing Home Quality Initiative.

Response: The proposed pressure ulcer measure is the same measure that nursing homes have been reporting for short stay residents through CMS's Nursing Home Quality Initiative since 2010. The items used to calculate the measure are the same in the SNF QRP and the Nursing Home Quality Initiative. SNFs will only be required to submit data for this measure once to fulfill the requirements of both programs.

Comment: One commenter was concerned that the MDS 3.0 data does not adequately capture multiple pressure ulcers and presence at admission for each wound. The commenter was concerned that this could result in confusion for SNFs as they may lose track of which ulcers were present on admission and which are new or worsened, resulting in inaccurate counts in the quality measure.

Response: The MDS 3.0 does not require SNF providers to provide individual tracking information for each pressure ulcer. However, we note that the MDS does not replace standard clinical practice. We expect that all SNFs are conducting comprehensive skin assessments throughout the stay and documenting all of the necessary information to fully prevent and manage pressure ulcers for all residents. As such SNFs are able to utilize the data they collect as part of standard clinical

practice to track and manage pressure ulcers, in order to complete the MDS 3.0 items related to the improvement and worsening of pressure ulcers during the resident's Part A covered stay in the facility.

Comment: One commenter did not support the proposed measure, the Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short Stay) (NQF #0678). The commenter was concerned that the measure timeframe is too short to properly capture pressure ulcer improvement, disadvantaging facilities that serve more frail populations. The commenter indicated that capturing a healed pressure ulcer is particularly difficult as SNFs have a very limited amount of time from admission to the end of a short-stay episode to heal a pressure ulcer.

Response: We would like to clarify that the proposed quality measure assesses the percent of residents or patients with Stage 2–4 pressure ulcers that are *new* or *worsened* since the prior assessment, and does not focus on capturing the improvement of pressure ulcers. This measure specifies that if a pressure ulcer is present on admission and worsened during the stay, it would be included in the numerator. Further, if the pressure ulcer is present on admission, and did not worsen during the stay, it would not be included in the numerator. We agree with the commenter that the timeframe is often too short to heal pressure ulcers amongst the frail and elderly population; therefore the measure does not capture information about healed pressure ulcers. Rather, the intent of the measure is to hold providers accountable for preventing the worsening of or onset of new pressure ulcers.

Comment: One commenter expressed concern that SNFs with a sub-acute unit will be at risk for reporting higher percentages of residents or patients with pressure ulcers than SNFs that do not have a designated sub-acute unit under the proposed measure.

Response: We agree that some SNF residents are at higher risk for developing new or worsened pressure ulcers. However, pressure ulcers are severe, life threatening, and high-cost adverse events, and many SNF residents may have medically complex conditions that put them at high risk for the development or worsening of pressure ulcers. Given their impact on mortality, morbidity, and quality of life, we believe that SNFs should be responsible for preventing and managing pressure ulcers among both high and low risk residents or patients and that facilities

with certain types of patients should not be exempt from reporting new or worsened pressure ulcers. In effort to account for the added challenges that facilities with more high risk residents may face, the proposed quality measure is risk adjusted for four risk factors: (1) Functional limitation, (2) bowel incontinence, (3) diabetes or peripheral vascular disease/peripheral arterial disease, and (4) low body mass index (BMI).

Comment: Many commenters encouraged CMS to align measures where possible with existing CMS initiatives, across settings, and payments types.

Response: We strive to harmonize and align quality measures across initiatives, settings, and payment types whenever possible and will continue to do so as we develop and implement quality measures under the IMPACT Act.

Final Decision: Having carefully considered the comments we received on the quality measure, the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), we are finalizing the adoption of this measure for use in the SNF QRP.

As part of our ongoing measure development efforts, we are considering a future update to the numerator of the quality measure, the Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short Stay) (NQF #0678). This update would require PAC providers to report the development of unstageable pressure ulcers, including suspected deep tissue injuries (sDTIs). Under this potential change we are considering, the numerator of the quality measure would be updated to include unstageable pressure ulcers, including sDTIs that are new/developed in the facility, as well as Stage 1 or 2 pressure ulcers that become unstageable due to slough or eschar (indicating progression to a stage 3 or 4 pressure ulcer) after admission. SNFs are already required to complete the unstageable pressure ulcer items on the MDS 3.0. As such, this update would require a change in the way the measure is calculated but would not increase the data collection burden for SNFs.

A TEP convened by our measure development contractor strongly recommended that CMS update the specifications for the measure to include these pressure ulcers in the numerator, although it acknowledged that unstageable pressure ulcers and sDTIs cannot and should not be assigned a numeric stage. The TEP also recommended that a Stage 1 or 2 pressure ulcer that becomes unstageable due to slough or eschar should be

considered worsened because the presence of slough or eschar indicates a full thickness (equivalent to Stage 3 or 4) wound.^{41 42} These recommendations were supported by technical and clinical advisors and the National Pressure Ulcer Advisory Panel.⁴³ Additionally, exploratory data analysis conducted by our measure development contractor suggests that the addition of unstageable pressure ulcers, including sDTIs, will increase the observed incidence of new or worsened pressure ulcers at the facility level and may improve the ability of the quality measure to discriminate between poor- and high-performing facilities.

We invited public comments to inform our consideration of the inclusion of unstageable pressure ulcers, including sDTIs in the numerator of the quality measure, the Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short Stay) (NQF #0678) as part of our future measure development efforts. The following is a summary of the comments received and our responses.

Comment: One commenter supported our proposal to include unstageable pressure ulcers and suspected deep tissue injuries in the numerator of the proposed quality measure as an area for future measure development. The commenter agreed that these cases should be included in the measure population.

Response: As noted, the recommendation addresses an important clinical concern, and may

improve the ability of the quality measure to discriminate between poor and high-performing facilities. As we consider the possibility of adding unstageable pressure ulcers and suspected deep tissue injuries to the numerator, we will carefully consider all comments received from stakeholders.

Comment: Several commenters were supportive of our proposal to include unstageable pressure ulcers (we interpret their comment as referring to unstageable pressure ulcers due to slough or eschar and due to non-removable dressing/device) in the numerator of the quality measure as an area for future measure development, but expressed reservations about the possible future inclusion of suspected deep tissue injuries (sDTIs) in the numerator of the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) quality measure. Commenters cited information from the National Pressure Ulcer Advisory Council suggesting that sDTIs can take between 72 hours and seven days to become visible, indicating that there is no reliable and consistent way to determine whether an sDTI at admission is facility acquired or not. Commenters also mentioned confusion surrounding pressure ulcers that are unavoidable or times when prevention is not possible. Finally, multiple commenters stated that the time frame during which sDTIs become visible varies and there is potential for miscoding, both of which may make this an unreliable quality measure.

One commenter requested more information about how this change would be incorporated into the measure specifications. The commenter also requested more information regarding the impact this change would have on the reliability and validity of the measure, as well as how it may impact the risk adjustment methodology. Finally the commenter encouraged CMS to submit any proposed changes through NQF review and specify all details in future rule making. Commenters also encouraged CMS to update the coding instructions for the RAI manual if this change is made, apply this change across all PAC settings, and gather additional stakeholder and expert input on this change prior to implementation.

Response: We appreciate the recommendations regarding the approach to future implementation. We will continue to conduct analyses and solicit input before making any final decisions regarding this possible change to the measure specifications. We intend to continue monitoring the literature,

conduct reliability and validity testing, seek input from subject matter experts and stakeholders, and participate in ongoing refinement activities to inform this measure before proposing to adopt any changes. Should we move forward with the addition of unstageable and sDTIs to the measure numerator, we intend to submit any changes through NQF, provide information that will allow providers to accurately interpret and complete quality reporting items, ensure that the MDS 3.0 Resident Assessment Instrument Manual and training materials provide accurate and up-to-date coding instructions for all items, and seek public comment on future measure concepts or revisions.

In regard to the commenters' concerns regarding sDTIs, we believe that it is important to do a thorough admission assessment on each resident or patient who is admitted to a SNF, including a thorough skin assessment documenting the presence of any pressure ulcers of any kind—including sDTIs. When considering the addition of sDTIs to the measure numerator, we convened cross-setting TEPs in June and November 2013, and obtained input from clinicians, experts, and other stakeholders. While we agree that ongoing research is needed, sDTIs are a serious medical condition and given their potential impact on mortality, morbidity, and quality of life, it may be detrimental to the quality of care to exclude them from future quality measures. We thank the commenters for their feedback and we will take into account the recommendations regarding the challenges in determining whether an sDTI at admission is facility acquired or not, the difficulty in coding sDTIs, and the confusion surrounding pressure ulcers that are unavoidable or times when prevention is not possible.

Comment: One commenter did not support the addition of unstageable pressure ulcers in the numerator of the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) quality measure. The commenter was concerned that the measure timeframe is too short to properly capture pressure ulcer improvement, disadvantaging facilities that serve more frail populations. The commenter indicated that capturing a healed unstageable pressure ulcer is particularly difficult as SNFs have a very limited amount of time from admission to the end of a short-stay episode to heal a pressure ulcer.

Response: We will take all stakeholder feedback into account as we consider the possibility of including unstageable pressure ulcers, including

⁴¹ Schwartz, M., Nguyen, K.H., Swinson Evans, T.M., Ignaczak, M.K., Thaker, S., and Bernard, S.L.: Development of a Cross-Setting Quality Measure for Pressure Ulcers: OY2 Information Gathering. Final Report. Centers for Medicare & Medicaid Services, November 2013. Available: <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Development-of-a-Cross-Setting-Quality-Measure-for-Pressure-Ulcers-Information-Gathering-Final-Report.pdf>.

⁴² Schwartz, M., Ignaczak, M.K., Swinson Evans, T.M., Thaker, S., and Smith, L.: The Development of a Cross-Setting Pressure Ulcer Quality Measure: Summary Report on November 15, 2013, Technical Expert Panel Follow-Up Webinar. Centers for Medicare & Medicaid Services, January 2014. Available: <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Development-of-a-Cross-Setting-Pressure-Ulcer-Quality-Measure-Summary-Report-on-November-15-2013-Technical-Expert-Pa.pdf>.

⁴³ Schwartz, M., Nguyen, K.H., Swinson Evans, T.M., Ignaczak, M.K., Thaker, S., and Bernard, S.L.: Development of a Cross-Setting Quality Measure for Pressure Ulcers: OY2 Information Gathering. Final Report. Centers for Medicare & Medicaid Services, November 2013. Available: <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Development-of-a-Cross-Setting-Quality-Measure-for-Pressure-Ulcers-Information-Gathering-Final-Report.pdf>.

sDTIs in the numerator of the quality measure in the future.

(2) Quality Measure Addressing the Domain of the Incidence of Major Falls: An Application of the Measure Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674)

We proposed to adopt beginning with the FY 2018 SNF QRP, an application to the SNF setting of the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) measure that satisfies the incidence of major falls domain. This outcome measure reports the percentage of residents who have experienced falls with major injury during episodes ending in a 3-month period. This measure was developed by CMS and is NQF-endorsed for long-stay residents of NFs.

Research indicates that fall-related injuries are the most common cause of accidental death in people aged 65 and older, responsible for approximately 41 percent of accidental deaths annually.⁴⁴ Rates increase to 70 percent of accidental deaths among individuals aged 75 and older.⁴⁵ In addition to death, falls can lead to fracture, soft tissue or head injury, fear of falling, anxiety, and depression.⁴⁶ Research also indicates that approximately 75 percent of nursing facility residents fall at least once a year. This is twice the rate of their counterparts in the community.⁴⁷ Further, it is estimated that 10 percent to 25 percent of nursing facility resident falls result in fractures and/or hospitalization.⁴⁸

Falls also represent a significant cost burden to the entire health care system, with injurious falls accounting for 6 percent of medical expenses among those age 65 and older.⁴⁹ In one study, Sorensen et al. estimated the costs associated with falls of varying severity among nursing home residents.⁵⁰ Their

work suggests that acute care costs incurred for falls among nursing home residents range from \$979 for a typical case with a simple fracture to \$14,716 for a typical case with multiple injuries. A similar study of hospitalizations of nursing home residents due to serious fall-related injuries (intracranial bleed, hip fracture, other fracture) found an average cost of \$23,723.⁵¹ Among the SNF population, the average 6-month cost of a resident with a hip fracture was estimated at \$11,719 in 1996 U.S. dollars.⁵²

According to Morse, 78 percent of falls are anticipated physiologic falls, which are falls among individuals who scored high on a risk assessment scale, meaning their risk could have been identified in advance of the fall.⁵³ To date, studies have identified a number of risk factors for falls.^{54 55 56 57 58 59 60 61 62} The identification of such risk factors suggests the potential for health care facilities to reduce and prevent the incidence of falls. The Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) quality measure is NQF-

endorsed and has been successfully implemented in the Nursing Home Quality Initiative for nursing facility long-stay residents since 2011. In addition, the quality measure is currently publicly reported on CMS's Nursing Home Compare Web site at <http://www.medicare.gov/nursinghomecompare/search.html>. Further, an application of the quality measure was adopted for use in the LTCH QRP in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50874 through 50877). In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50290), we revised the data collection period for this measure with data collection to begin starting April 1, 2016.

Although the quality measure, the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) is not currently endorsed for the SNF setting, we reviewed the NQF's consensus endorsed measures and were unable to identify any NQF-endorsed cross-setting quality measures for that setting that are focused on falls with major injury. We are aware of one NQF-endorsed measure, Falls with Injury (NQF #0202), which is a measure designed for adult acute inpatient and rehabilitation patients capturing "all documented patient falls with an injury level of minor or greater on eligible unit types in a calendar quarter, reported as injury falls per 100 days."⁶³ NQF #0202 is not appropriate to meet the IMPACT Act domain as it includes minor injury in the numerator definition. Additionally, including all falls could result in providers limiting the freedom of activity for individuals at higher risk for falls. We are unaware of any other cross-setting quality measures for falls with major injury that have been endorsed or adopted by another consensus organization for the SNF setting. Therefore, we proposed to adopt this measure under the Secretary's authority to specify non-NQF-endorsed measures under section 1899B(e)(2)(B) of the Act.

A TEP convened by our measure development contractor provided input on the technical specifications of an application of the quality measure, the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674), including the feasibility of implementing the measure across PAC settings. The TEP was supportive of the implementation of this measure across PAC settings and was also supportive of our efforts to standardize this measure for cross-

⁴⁴ Currie LM. Fall and injury prevention. *Annu Rev Nurs Res.* 2006;24:39–74.

⁴⁵ Fuller GF. Falls in the elderly. *Am Fam Physician.* Apr 1 2000;61(7):2159–2168, 2173–2154.

⁴⁶ Love K, Allen J. Falls: why they matter and what you can do. *Geriatr Nurs.* 2011; 32(3): 206–208.

⁴⁷ Rubenstein LZ, Josephson KR, Robbins AS. Falls in the nursing home. *Ann Intern Med.* 1994 Sep 15; 121(6):442–51.

⁴⁸ Vu MQ, Weintraub N, Rubenstein LZ. Falls in the nursing home: are they preventable? *J Am Med Dir Assoc.* 2004 Nov-Dec; 5(6):401–6. Review.

⁴⁹ Tinetti ME, Williams CS. The effect of falls and fall injuries on functioning in community-dwelling older persons. *J Gerontol A Biol Sci Med Sci.* 1998 Mar;53(2):M112–9.

⁵⁰ Sorensen SV, de Lissovoy G, Kunaprayoon D, Resnick B, Rupnow MF, Studenski S. A taxonomy and economic consequence of nursing home falls. *Drugs Aging.* 2006;23(3):251–62.

⁵¹ Quigley PA, Campbell RR, Bulat T, Olney RL, Buerhaus P, Needleman J. Incidence and cost of serious fall-related injuries in nursing homes. *Clin Nurs Res.* Feb 2012;21(1):10–23.

⁵² Kramer AM, Steiner JF, Schlenker RE, et al. Outcomes and costs after hip fracture and stroke: a comparison of rehabilitation settings. *JAMA.* 1997;277(5):396–404.

⁵³ Morse, J. M. (2002) Enhancing the safety of hospitalization by reducing patient falls. *Am J Infect Control* 2002; 30(6): 376–80.

⁵⁴ Rothschild JM, Bates DW, Leape LL. Preventable medical injuries in older patients. *Arch Intern Med.* 2000 Oct 9; 160(18):2717–28.

⁵⁵ Morris JN, Moore T, Jones R, et al. Validation of long-term and post-acute care quality indicators. CMS Contract No: 500–95–0062/T.O. #4. Cambridge, MA: Abt Associates, Inc., June 2003.

⁵⁶ Avidan AY, Fries BE, James ML, Szafara KL, Wright GT, Chervin RD. Insomnia and hypnotic use, recorded in the minimum data set, as predictors of falls and hip fractures in Michigan nursing homes. *J Am Geriatr Soc.* 2005 Jun; 53(6):955–62.

⁵⁷ Fonad E, Wahlin TB, Winblad B, Emami A, Sandmark H. Falls and fall risk among nursing home residents. *J Clin Nurs.* 2008 Jan; 17(1):126–34.

⁵⁸ Currie LM. Fall and injury prevention. *Annu Rev Nurs Res.* 2006; 24:39–74.

⁵⁹ Ellis AA, Trent RB. Do the risks and consequences of hospitalized fall injuries among older adults in California vary by type of fall? *J Gerontol A Biol Sci Med Sci.* Nov 2001; 56(11):M686–692.

⁶⁰ Chen XL, Liu YH, Chan DK, Shen Q, Van Nguyen H. *Chin Med J (Engl).* Characteristics associated with falls among the elderly within aged care wards in a tertiary hospital: a retrospective. 2010 Jul; 123(13):1668–72.

⁶¹ Frisina PG, Guellnitz R, Alverzo J. A time series analysis of falls and injury in the inpatient rehabilitation setting. *Rehabil Nurs.* 2010 Jul-Aug; 35(4):141–6, 166.

⁶² Lee JE, Stokic DS. Risk factors for falls during inpatient rehabilitation *Am J Phys Med Rehabil.* 2008 May; 87(5):341–50; quiz 351, 422.

⁶³ American Nurses Association (2014, April 9). Falls with injury. Retrieved from <http://www.qualityforum.org/QPS/0202>.

setting development. The MAP conditionally supported the use of an application of the quality measure, the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) in the SNF QRP as a cross-setting quality measure. More information about the MAP's recommendations for this measure is available in the report entitled MAP Off-Cycle Deliberations 2015: Measures under Consideration to Implement Provisions of the IMPACT Act are available at http://www.qualityforum.org/Project_Pages/MAP_Post-Acute_CareLong-Term_Care_Workgroup.aspx.

More information on the NQF-endorsed quality measure, the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) is available at <http://www.qualityforum.org/QPS/0674>.

We proposed that data for this quality measure would be collected using the MDS 3.0, currently submitted by SNFs through the QIES ASAP system for the reason noted previously.

The data items that we will use to calculate this proposed quality measure include: J1800 (Any Falls Since Admission/Entry (OBRA or Scheduled PPS) or Reentry or Prior Assessment, whichever is more recent); and J1900 (Number of Falls Since Admission/Entry (OBRA or Scheduled PPS) or Reentry or Prior Assessment, whichever is more recent). This measure will be calculated at the time of discharge (see Proposed Form, Manner, and Timing of Quality Data Submission). The specifications for an application of the quality measure, the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) for the SNF population are available on our SNF QRP measures and technical Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.html>.

We referred readers to the Form, Manner, and Timing of Quality Data Submission section of the FY 2016 SNF PPS proposed rule (79 FR 22076 through 22077) for more information on the proposed data collection and submission timeline for this proposed quality measure.

We invited public comments on our proposal to adopt an application of the quality measure, the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) for the SNF QRP beginning with the FY 2018 payment

determination. The comments we received on this topic, with their responses, appear below.

Comment: Several commenters supported our proposal to implement an application of the quality measure, the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) to fulfill the requirements of the IMPACT Act.

Response: We thank the commenters for their support.

Comment: One commenter supported measuring falls in SNFs, but stated a preference for measuring falls "with or without injury" and "assisted or non-assisted" and tracking by preventable falls (resident-related or environment- and other-related) and non-preventable (resident conditions like fainting).

Response: The proposed application of the quality measure, the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) assesses falls with major injuries, satisfying the domain in section 1899B(c)(1)(D) of the Act, the Incidence of Major Falls. We believe this domain mandates a quality measure related to falls with major injury. We agree that a provider's tracking of falls is important for the purpose of ensuring resident safety. The information suggested by the commenter for collection is already included in the MDS 3.0 enabling SNFs to track all falls, regardless of injury by including items indicating the number of falls with and without injury. The data elements used to track all falls, including major injury, J1800, J1900 A, B and C, are collected to ensure the reliability of the data. We note that Measure #0674 has been NQF-endorsed based on the manner in which it is calculated now, and its inter-rater reliability is based on the data collection of J1900 A, B and C. The measure has been tested, validated, and endorsed as it is currently collected, and to maintain our current accuracy, we have proposed to maintain those methods.

Comment: Several comments supported the addition of the proposed quality measure to the SNF QRP, but urged that the measure be risk adjusted, expressing concerns that public reporting of falls with injury rates across settings would be inappropriate without taking into account differences in resident acuity and other characteristics, such as cognition and socioeconomic status. One commenter stated that falls occur for various reasons, some of them unavoidable, and therefore, fall rates may not be suitable for quality comparison suggesting that it would be improper to use the measure in pay-for performance models. Another commenter suggested that falls with

major injuries "are a never event" (that is, events or medical errors that should never transpire, such as falls that happen in a health care setting that result in patient death or serious injury).⁶⁴ Another commenter cited American and British Geriatrics Society guidelines, which find no clear evidence on falls prevention. Some commenters pointed out that the TEP convened in 2015 recommended risk adjustment for cognitive impairment, which several commenters also supported, and one commenter asked whether the TEP was presented the current specifications of the cross-setting falls measure. One commenter provided support for risk adjustment by pointing out that the references cited in the proposed rule indicate that risks for falls vary by resident characteristics, that the State Operations Manual (SOM) for SNFs provides guidance for evaluating residents for risk for falls, and that documentation for not risk adjusting the measure was not provided in the proposed rule. The same commenter pointed to the PAC Payment Reform Demonstration (PAC PRD), in which the commenter stated that the research indicated that the risk of falls with injury differs across post-acute settings. Several commenters also stated that risk adjustment is required by the IMPACT Act, and that the MAP suggested that the measure should be risk adjusted.

Response: We appreciate the commenters' suggestions that the proposed application of the quality measure, the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) should be risk adjusted. The application of risk adjustment, as stated by the IMPACT Act, is "as determined appropriate by the Secretary" under section 1899B(c)(3)(B) of the Act.

While we acknowledge that resident characteristics that elevate risk for falls with major injury vary across the SNF population, a TEP convened in 2009 by the measurement development contractor concluded that risk adjustment of this quality measure concept was inappropriate because it is each facility's responsibility to take steps to reduce the rate of injurious falls, especially since such events are considered to be "never events." We note that the PAC PRD did not analyze falls with major injury, as falls with major injury was not an assessment item that was tested. However, as the commenter pointed out, the prevalence

⁶⁴ National Quality Forum (NQF), *Serious Reportable Events In Healthcare—2011 Update: A Consensus Report*, Washington, DC: NQF; 2011.

of a history of falls prior to the PAC admission did vary across post-acute settings (as assessed by Item B7 from the CARE tool: “History of Falls. Has the patient had two or more falls in the past year or any fall with injury in the past year?”). Nonetheless, we believe that as part of best clinical practice, SNFs should assess residents for falls risk and take steps to prevent future falls with major injury.

The numerator, denominator, and exclusions definitions provided to the TEP in 2015 are virtually identical to the specifications we proposed to adopt for this measure, and did not include risk adjustment. Two out of 11 members of the 2015 TEP supported risk adjustment of the falls measure for cognitive impairment, but it was not the majority position. For more information on the 2015 TEP, please visit <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/SUMMARY-OF-FEEDBACK-FROM-THE-TECHNICAL-EXPERT-PANEL-TEP-REGARDING-CROSS-SETTING-MEASURES-ALIGNED-WITH-THE-IMPACT-ACT-OF-2014-Report.pdf>.

We believe factors that increase the risk of falling, such as cognitive impairment, should be included by facilities in their risk assessment to support proper care planning. As cited in the proposed rule, research suggests that 78 percent of falls are anticipated falls, occurring in individuals who could have been identified as at-risk for a fall using a risk-assessment scale. Risk adjusting for falls with major injury could unintentionally lead to insufficient risk prevention by the provider. As required by the Deficit Reduction Act of 2007, the Hospital Acquired Conditions—Present On Admission (HAC—POA) Indicator Reporting provision requires a quality adjustment in the Medicare Severity-Diagnosis Related Groups (MS—DRG) payments for certain HACs, which include falls and trauma, and these payment reductions are not risk adjusted. Furthermore, we note that the State Operations Manual (SOM) provides guidance for SNFs to assess resident risk for falls with the intent to aid providers in prevention of falls. The need for risk assessment, based on varying risk factors among residents, does not remove the obligation of providers to minimize that risk.

With regard to the MAP recommendation to risk adjust this measure cited by the commenter, the MAP feedback regarding risk adjustment for this quality measure applied to the home health setting, not to the SNF

setting. We also refer readers to a more recent Cochrane review of 60 randomized controlled trials, which found that within care facilities, multifactorial interventions have the potential to reduce rates of falls and risk of falls.⁶⁵

Comment: One commenter requested that CMS consider risk adjusting the proposed application of the quality measure, the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) for sociodemographic status, to better reflect the realities that affect the care of special populations and the need for coordination with hospitals within a geographic region. The commenter suggested that some beneficiaries in certain populations are more complex and therefore, their risk for falls resulting in major injuries may increase.

Response: While we appreciate these comments and the importance of the role that sociodemographic status plays in the care of patients, we continue to have concerns about holding providers to different standards for the outcomes of their patients of low sociodemographic status because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We routinely monitor the impact of sociodemographic status on facilities' results on our measures.

NQF is currently undertaking a two-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate for each measure. For two-years, NQF will conduct a trial of a temporary policy change that will allow inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will determine whether to make this policy change permanent. Measure developers must submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model.

Furthermore, the ASPE is conducting research to examine the impact of socioeconomic status on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act. We will closely examine the findings of these

reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

Comment: One commenter believed that collecting data on falls would be burdensome for residents who are on the unit for only part of a day. Another commenter recommended shortening the discharge assessment to only include necessary information to decrease the data collection burden.

Response: We appreciate the commenter's position that tracking falls for residents who are on the unit for only part of a day could be burdensome. However, given that facilities are responsible for residents' safety regardless of location within the facility or duration of time spent in various units, if a resident experiences an injurious fall, no matter their location in the facility, that fall will need to be tracked and reported. Moreover, data on falls are already collected in the MDS, so the additional burden associated with this measure is minimal. We note that the SNF PPS Part A Discharge assessment is limited to just the items necessary to calculate the three SNF QRP measures proposed in this rule to minimize any additional burden.

Comment: Several commenters supported the measure's addition to the SNF QRP, but expressed concerns about the measure not having been adequately tested in the short-stay or SNF population. Additionally, several commenters expressed concerns regarding the lack of NQF endorsement for an application of the quality measure, the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) as a cross-setting measure for SNF, IRF and LTCH QRPs. Other commenters mentioned that the MAP conditionally supported this measure pending NQF endorsement.

Response: We thank the commenters for their support of the measure and suggested changes to the measure. We also appreciate the commenters' concerns pertaining to the adequacy of the measure's testing for use in the short-stay or SNF population, which we interpret to mean adequacy regarding the reliability and validity of the proposed application of the quality measure, the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) and the items used to calculate the measure in the SNF setting.

This proposed measure is a cross-setting measure that we believe satisfies the measure required under section 1899B(c)(1)(D) of the Act domain, Incidence of Major Falls. For the reasons

⁶⁵ Cameron ID, Gillespie LD, Robertson MC, Murray GR, Hill KD, Cumming RG, Kerse N. Interventions for preventing falls in older people in care facilities and hospitals. *Cochrane Database of Systematic Reviews* 2012, Issue 12. Art. No.: CD005465. DOI: 10.1002/14651858.CD005465.pub3.

provided previously, we proposed this measure under the exception authority provided in section 1899B(e)(2)(B) of the Act, which allows CMS to apply a measure to the SNF setting that is not NQF-endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization.

With regard to the adequacy of the measure's testing for use in the short-stay or SNF population, the item-level testing during the development of the MDS 3.0 showed near-perfect inter-rater reliability for the MDS item (J1900C) used to identify falls with major injury; therefore, we disagree with the commenter's suggestion as to the strength of the item-level testing.⁶⁶ The NQF measure evaluation criteria do not require measure level reliability if item reliability is high.⁶⁷ However, we believe that, given the overlap in the populations and item-level testing results, the application of this measure for SNF residents will be reliable. That said, we intend to continue to test the measure once data collection begins as part of ongoing maintenance of the measure. We also note that a TEP convened in 2009 supported measuring falls with major injury in PAC settings regardless of the length of stay of the resident. The TEP also concurred that facilities need to take responsibility to not only prevent falls but to ensure that if they do occur, protections are in place so that the fall does not result in injury.

Comment: One commenter urged CMS to provide clarification in the final rule about the use of current falls MDS 3.0 data items under the SNF QRP. Others requested clarification on the measure specifications, stating that the specifications for how this measure will be constructed using admission and discharge assessments are unclear. Two commenters requested clarification about whether the numerator includes falls with and without injury. Another commenter asked if OBRA assessments are considered in the look-back scan and whether both long-stay and short-stay residents are included in the measure. One commenter requested that CMS clarify how the addition of the

MDS discharge assessment will affect the measure specifications for the numerator and denominator of the falls measure. The commenter noted that CMS proposes modifying the MDS discharge assessment to collect information for Part A FFS Medicare beneficiaries who continue in the SNF after ending their SNF Part A covered stay, but does not clarify how this change will be implemented in the proposed falls measure. That commenter was concerned that if this new MDS discharge assessment is not included, the measure will exclude individuals who are admitted but not discharged from the SNF during their PAC stay and limit CMS' ability to provide meaningful information to both PAC providers and consumers.

Response: To clarify, the proposed quality measure will be calculated for the purposes of the SNF QRP on residents receiving services under a SNF Part A covered stay. To further clarify, although this measure is based on the data collection of two items, the numerator and denominator only use one item: the number of falls with major injury. The assessment instrument includes an item about whether any fall took place (J1800) as a gateway item. If there were any falls, the assessor then completes the next set of items (J1900) indicating the number of falls by injury status. Facilities must report the data associated with all these items in order to avoid issues with missing data and as a way to ensure accurate data collection, but only the data on falls with major injury are used in calculating the measure.

We also want to clarify that the items used to calculate the measure are already included on the existing MDS 3.0 item sets, for example, both OBRA and PPS assessments. The necessary falls items will also be added to the proposed SNF PPS Part A Discharge assessment to ensure the capture of falls with major injury at the end of the SNF Part A covered stay for residents who continue in the SNF after ending their SNF Part A covered stay.

Other than the proposed SNF PPS Part A Discharge assessment, the implementation of the proposed application of the quality measure, the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) does not represent new data collection for SNFs. SNFs have been submitting data for these items as part of the Nursing Home Quality Initiative since October 2010.

We note that specifications for the application of the quality measure, the Percent of Residents Experiencing One or More Falls with Major Injury (Long

Stay) (NQF #0674) for the SNF population are available on our SNF QRP measures and technical Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.html>. The specifications include information on how the SNF PPS Part A Discharge will be used in the measure, and specify that the measure will apply to both long- and short-stay Medicare FFS beneficiaries as long as they have had a SNF PPS Part A covered stay.

Comment: Several commenters expressed concerns about the falls measure not being standardized across PAC settings. One commenter stated that the measure should have the same wording, timeframe, and item set across all PAC settings, and that the denominator and exclusions should be the same; they also specifically noted differences in the payers that are required to report data for this measure. Two commenters objected to the exclusion of Medicare Advantage beneficiaries from the numerator and denominator for this measure. One commenter noted that measures based on only Medicare FFS beneficiaries may be incomplete, since, according to some estimates, only about half of SNF residents are covered by Medicare FFS.

Another commenter asked about the extent to which the time horizon (that is, the time period during which the measure will be calculated) will differ across settings, and another suggested that the exclusions listed in the specifications were different in different settings. One comment mistakenly asserted that the item used in the equivalent IRF specifications asks about the occurrence of two or more falls in the past year and whether a patient had major surgery, in contrast to the SNF specifications for the measure. Another commenter expressed concern regarding differences in the populations across quality measures in the SNF QRP. The commenters mentioned that the falls measure (NQF #0674) and function measure (NQF #2631) include only Medicare FFS residents, while the pressure ulcer measure (NQF #0678) includes all short-stay SNF residents. The commenter mentioned that this inconsistency could result in confusion for providers because of the varying denominators across measures.

Response: CMS appreciates the commenters' comments pertaining to the differences in the quality measure denominators by payer type across the IRF, SNF and LTCH settings. As previously stated, we believe that

⁶⁶ Saliba D. and Buchanan J. (2008). Development and Validation of a Revised Nursing Home Assessment Tool: MDS 3.0. Contract No. 500-00-0027/Task Order #2. Santa Monica, CA: Rand Corporation. Retrieved from <http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf>; http://www.geronet.med.ucla.edu/centers/borun/Appendix_A-G.pdf.

⁶⁷ NQF. Measure Evaluation Criteria and Guidance for Evaluating Measures for Endorsement. April 2015. Available online at: <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdIdentifier=id&ItemID=79434>.

quality care is best represented through the inclusion of all patient data regardless of payer source. We agree that consistency in the data would reduce confusion in data interpretation and enable a more comprehensive evaluation of quality and although we had not proposed all payer data collection through this current rulemaking, we will take into consideration the expansion of the SNF QRP to include all payer sources through future rulemaking.

We appreciate the comment pertaining to consistent data collection across the reporting programs. We believe that quality measures that include all residents in a facility are better able to capture the health outcomes of that facility's residents, and thus, including all residents in quality reporting is important. Regarding expansion of the population used to calculate this measure to include payer sources beyond Medicare Part A, we agree with the commenter's position and intend to take this under consideration through future measure development and rulemaking.

We wish to clarify that this falls measure is not currently used for the short-stay nursing home population as part of Nursing Home Compare and that this measure will be calculated using only Medicare Part A data collected by the SNF.

With regard to the use of standardized items for this measure, until now, the post-acute assessment instruments have not included standardized items for falls with major injury. Although the quality measure, an Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674), and the data collection items used to calculate this measure are harmonized across settings and assessment instruments, we believe that there are constraints in current data collection (that is, use of only admission and discharge assessments in IRFs and LTCHs vs. admission/re-entry, interim, and discharge assessments in SNFs.). For the purposes of measure calculation, we are able to compensate for this data collection approach to ensure a uniform application of the measure where currently practicable for providers and feasible for the measure so that we have harmonized the measure's calculation across all PAC settings. Although we believe that we have applied the measure consistently across the programs, to enable efficiencies in the measure's calculation, we intend to address any outstanding standardization issues through future rulemaking.

We would like to clarify that the occurrence of two or more falls in the

past year and major surgery prior to admission are risk-adjusters for the function outcomes measures proposed in the FY 2016 IRF PPS proposed rule and are not related to the cross-setting falls measure, and therefore, are not included in SNF QRP version of the falls measure. We also wish to clarify that as proposed, the application of this measure for the SNF QRP will include a look-back from the time of discharge from the SNF Part A covered stay to the time of admission, so that the measure's calculation and time frame used will be consistent with the other QRPs. We note that the assessment at discharge is an actual discharge from the facility or a discharge from the SNF Part A covered stay with a transition in place. We also disagree that the exclusions listed in the measure specification for each setting are not standardized. Specifically, all three settings only exclude cases due to missing data.

Comment: One commenter supported this measure, but expressed concerns about the accuracy of the data on which the fall measure is calculated, noting that a recent survey identified deficiencies in reporting by a small sample of SNFs. One commenter expressed concerns regarding the fact that CMS excludes residents for whom missing data precludes calculation of the measure from the measure calculations. The commenter expressed concerns that this exclusion may encourage gaming, because if a facility recognizes that a resident is declining, it can simply omit some data for that resident, ensuring that the resident is excluded from the measure calculation. The commenter referenced several different media reports, which highlight the seriousness of gaming of MDS 3.0 data.

Response: We have proposed and are finalizing a threshold for reporting of actual resident data for determinations. We also intend to carefully monitor rates of missing data across all facilities. Specifically, we have proposed and are now finalizing that for FY 2018 SNF QRP, any SNF that does not meet the requirement that 80 percent of all MDS assessments submitted contain 100 percent of all data items necessary to calculate the SNF QRP measures would be subject to a reduction of 2 percentage points to its FY 2018 market basket percentage. We hope this requirement will provide incentives to providers to submit complete MDS 3.0 assessments. Further, we intend to align with other QRPs and propose through future rulemaking to implement a data validation program. Historically, rates of missing data for the items used to calculate for the NHQI falls measure in

nursing homes have averaged less than 0.01 percent across all target assessments in a given quarter (for example, the rate of missing data in Q3 2014 was 0.004 percent), suggesting that missing data is minimal. Further, we intend to align with other QRPs and propose through future rulemaking a process and program surrounding data validation.

Comment: One commenter expressed concerns about providers being penalized for resident-centered care practices, such as allowing frail residents to ambulate without help.

Response: We fully support resident-centered care and enabling all residents to make informed decisions about their care. However, providers are responsible for resident safety, and falls with major injury are considered "never events." Thus, providers must balance the desire to allow residents full autonomy with the need to care for their well-being, including appropriate care planning and taking steps to reduce injurious falls.

Having carefully considered the comments we received on the application of the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) measure, we are finalizing the adoption of this measure for use in the SNF QRP.

(3) Quality Measure Addressing the Domain of Functional Status, Cognitive Function, and Changes in Function and Cognitive Function: Application of Percent of Long-Term Care Hospital Patients With an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; Endorsed on July 23, 2015)

We proposed to adopt, beginning with the FY 2018 SNF QRP, an application of the quality measure Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631; endorsed on July 23, 2015) as a cross-setting quality measure that satisfies the functional status, cognitive function, and changes in functional status and cognitive function domain. This quality measure reports the percent of patients or residents with both an admission and a discharge functional assessment and an activity (self-care or mobility) goal that addresses function. The new self-care and mobility items are included in a new section of the MDS titled, Section GG.

The National Committee on Vital and Health Statistics' Subcommittee on

Health,⁶⁸ noted that “[i]nformation on functional status is becoming increasingly essential for fostering healthy people and a healthy population. Achieving optimal health and well-being for Americans requires an understanding across the life span of the effects of people’s health conditions on their ability to do basic activities and participate in life situations in other words, their functional status.” This is supported by research showing that patient and resident functioning is associated with important outcomes such as discharge destination and length of stay in inpatient settings,⁶⁹ as well as the risk of nursing home placement and hospitalization of older adults living in the community.⁷⁰

The majority of individuals who receive PAC services, including care provided by SNFs, HHAs, IRFs, and LTCHs, have functional limitations and many of these individuals are at risk for further decline in function due to limited mobility and ambulation.⁷¹ The patient and resident populations treated by SNFs, HHAs, IRFs, and LTCHs vary in terms of their functional abilities at the time of the PAC admission and their goals of care. For IRF patients and many SNF residents, treatment goals may include fostering the person’s ability to manage his or her daily activities so that he or she can complete self-care and/or mobility activities as independently as possible, and if feasible, return to a safe, active, and productive life in a community-based setting. For home health patients, achieving independence within the home environment and promoting community mobility may be the goal of care. For other home care patients, the goal of care may be to slow the rate of functional decline in order to allow the person to remain at home and avoid institutionalization.⁷² Lastly, in addition to having complex medical care needs for an extended period of time, LTCH patients often have

limitations in functioning because of the nature of their conditions, as well as deconditioning due to prolonged bed rest and treatment requirements (for example, ventilator use). The clinical practice guideline *Assessment of Physical Function*⁷³ recommends that clinicians document functional status at baseline and over time to validate capacity, decline, or progress. Therefore, assessment of functional status at admission and discharge and establishing a functional goal for discharge as part of the care plan is an important aspect of patient or resident care in all of these PAC settings.

Given the variation in patient or resident populations across the PAC settings, the functional activities that are typically assessed by clinicians for each type of PAC provider may vary. For example, rolling left and right in bed is an example of a functional activity that may be most relevant for low-functioning patients or residents who are chronically critically ill. However, certain functional activities such as eating, oral hygiene, lying to sitting on the side of the bed, toilet transfers, and walking or wheelchair mobility are important activities for patients or residents in each PAC setting.

Although, functional assessment data are currently collected by all four PAC providers and in NFs, this data collection has employed different assessment instruments, scales, and item definitions. The data cover similar topics, but are not standardized across PAC settings. The different sets of functional assessment items coupled with different rating scales makes communication about patient and resident functioning challenging when patients and residents transition from one type of setting to another. Collection of standardized functional assessment data across SNFs, HHAs, IRFs, and LTCHs using common data items would establish a common language for patient and resident functioning, which may facilitate communication and care coordination as patients and residents transition from one type of provider to another. The collection of standardized functional status data may also help improve patient and resident functioning during an episode of care by ensuring that basic daily activities are assessed for all PAC residents at the start and end of care and that at least one functional goal is established.

The functional assessment items included in the proposed functional

status quality measure were originally developed and tested as part of the Post-Acute Care Payment Reform Demonstration version of the Continuity Assessment Record and Evaluation (CARE) Item Set, which was designed to standardize the assessment of a person’s status, including functional status, across acute and post-acute settings (SNFs, HHAs, IRFs, and LTCHs). The functional status items on the CARE Item Set are daily activities that clinicians typically assess at the time of admission and/or discharge in order to determine patient’s or resident’s needs, evaluate patient or resident progress, and prepare patients, residents, and their families for a transition to home or to another setting.

The development of the CARE Item Set and a description and rationale for each item is described in a report entitled “The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report on the Development of the CARE Item Set: Volume 1 of 3.”⁷⁴ Reliability and validity testing were conducted as part of CMS’s Post-Acute Care Payment Reform Demonstration, and we concluded that the functional status items have acceptable reliability and validity. A description of the testing methodology and results are available in several reports, including the report entitled “The Development and Testing of the Continuity Assessment Record And Evaluation (CARE) Item Set: Final Report On Reliability Testing: Volume 2 of 3”⁷⁵ and the report entitled “The Development and Testing of The Continuity Assessment Record And Evaluation (CARE) Item Set: Final Report on Care Item Set and Current Assessment Comparisons: Volume 3 of 3.”⁷⁶ These reports are available on our Post-Acute Care Quality Initiatives Web page at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/CARE-Item-Set-and-B-CARE.html>.

The functional status quality measure we proposed to adopt beginning with the FY 2018 SNF QRP is a process quality measure that is an application of the quality measure, Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631; endorsed on July 23, 2015). This quality

⁶⁸ Subcommittee on Health National Committee on Vital and Health Statistics, “Classifying and Reporting Functional Status” (2001).

⁶⁹ Reistetter TA, Graham JE, Granger CV, Deutsch A, Ottenbacher KJ. Utility of Functional Status for Classifying Community Versus Institutional Discharges after Inpatient Rehabilitation for Stroke. *Archives of Physical Medicine and Rehabilitation*, 2010; 91:345–350.

⁷⁰ Miller EA, Weissert WG. Predicting Elderly People’s Risk for Nursing Home Placement, Hospitalization, Functional Impairment, and Mortality: A Synthesis. *Medical Care Research and Review*, 57; 3: 259–297.

⁷¹ Kortebein P, Ferrando A, Lombebeida J, Wolfe R, Evans WJ. Effect of 10 days of bed rest on skeletal muscle in health adults. *JAMA*; 297(16):1772–4.

⁷² Ellenbecker CH, Samia L, Cushman MJ, Alster K. Patient safety and quality in home health care. *Patient Safety and Quality: An Evidence-Based Handbook for Nurses*. Vol 1.

⁷³ Kresevic DM. Assessment of physical function. In: Boltz M, Capezuti E, Fulmer T, Zwicker D, editor(s). *Evidence-based geriatric nursing protocols for best practice*. 4th ed. New York (NY): Springer Publishing Company; 2012. p. 89–103.

⁷⁴ Barbara Gage et al., “The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report on the Development of the CARE Item Set” (RTI International, 2012).

⁷⁵ Ibid.

⁷⁶ Ibid.

measure reports the percent of patients or residents with both an admission and a discharge functional assessment and a treatment goal that addresses function.

This process measure requires the collection of admission and discharge functional status data by clinicians using standardized clinical assessment items, or data elements, which assess specific functional activities, that is, self-care and mobility activities. The self-care and mobility function activities are coded using a 6-level rating scale that indicates the resident's level of independence with the activity at both admission and discharge. A higher score indicates more independence.

For this quality measure, there must be documentation at the time of admission that at least one activity (function) goal is recorded for at least one of the standardized self-care or mobility function items using the 6-level rating scale. This indicates that an activity goal(s) has been established. Following an initial assessment, the clinical best practice would be to ensure that the resident's care plan reflected and included a plan to achieve such an activity goal(s). At the time of discharge, function is reassessed using the same 6-level rating scale, enabling the ability to evaluate success in achieving the resident's activity performance goals.

To the extent that a resident has an unplanned discharge, for example, for the purpose of being admitted to an acute care facility, the collection of discharge functional status data might not be feasible. Therefore, for patients or residents with unplanned discharges, admission functional status data and at least one treatment goal must be reported, but discharge functional status data are not required to be reported.

A TEP convened by the measure development contractor for CMS provided input on the technical specifications of this quality measure, including the feasibility of implementing the measure across PAC settings. The TEP was supportive of the implementation of this measure across PAC settings and was also supportive of our efforts to standardize this measure for cross-setting use. Additionally, the MAP conditionally supported the use of an application of the Percent of Long-Term Care Hospital Patients With an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631; endorsed on July 23, 2015) for use in the SNF QRP as a cross-setting measure. The MAP noted that this functional status measure addresses an IMPACT Act domain and a MAP PAC/LTC core concept. The MAP conditionally supported this measure pending NQF-

endorsement and resolution of concerns about the use of two different functional status scales for quality reporting and payment purposes. Finally, the MAP reiterated its support for adding measures addressing function, noting the group's special interest in this PAC/LTC core concept. More information about the MAP's recommendations for this measure is available in the report entitled MAP Off-Cycle Deliberations 2015: Measures under Considerations to Implement Provisions of the IMPACT Act, is available at http://www.qualityforum.org/Project_Pages/MAP_Post-Acute_CareLong-Term_Care_Workgroup.aspx.

The proposed measure is derived from the Percent of Long-Term Care Hospital Patients With an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function quality measure, and we submitted the proposed measure to NQF for endorsement. The specifications are available for review at the SNF QRP measures and technical Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.html>.

We reviewed the NQF's endorsed measures and were unable to identify any NQF-endorsed cross-setting quality measures focused on assessment of function for PAC patients and residents. We are also unaware of any other cross-setting quality measures for functional assessment that have been endorsed or adopted by another consensus organization. Therefore, we proposed to adopt this function measure for use in the SNF QRP for the FY 2018 payment determination and subsequent years under the Secretary's authority under section 1899B(e)(2)(B) of the Act to select non-NQF-endorsed measures as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization.

We proposed that data for the proposed quality measure would be collected through the MDS 3.0, which SNFs currently submit through the QIES ASAP system. We refer readers to section V.C.7 of this final rule for more information on the proposed data collection and submission timeline for this proposed quality measure. The calculation algorithm of the proposed measure is described in the FY 2016 SNF PPS proposed rule (80 FR 22075).

For purposes of assessment data collection, we proposed to add new functional status items to the MDS 3.0. The items would assess specific self-care and mobility activities, and would

be based on functional items included in the Post-Acute Care Payment Reform Demonstration version of the CARE Item Set. The items have been developed and tested for reliability and validity in SNFs, HHAs, IRFs, and LTCHs. More information pertaining to item testing is available on our Post-Acute Care Quality Initiatives Web page at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/CARE-Item-Set-and-B-CARE.html>.

The proposed function items that we will add to the MDS for purposes of the calculation of this proposed quality measure do not duplicate existing items currently collected in that assessment instrument for other purposes. The currently used MDS function items evaluate a resident's most dependent episode that occurs three or more times, whereas the proposed functional items would evaluate an individual's usual performance at the time of admission and at the time of discharge. Additionally, there are several key differences between the existing and new proposed function items that may result in variation in the resident assessment results including: (1) The data collection and associated data collection instructions; (2) the rating scales used to score a resident's level of independence; and (3) the item definitions. A description of these differences is provided with the measure specifications on our SNF QRP measures and technical Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.html>.

Because of the differences between the current function assessment items (Section G of the MDS 3.0) and the proposed function assessment items that we would collect for purposes of calculating the proposed measure, we would require that SNFs submit data on both sets of items. Data collection for the new proposed function items do not substitute for the data collection under the current Section G.

We invited public comments on our proposal to adopt beginning with the FY 2018 SNF QRP an application of the quality measure Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631; endorsed on July 23, 2015). The following is a summary of the comments received and our responses.

Comment: MedPAC did not support the adoption of the function process measure in the SNF QRP, and urged CMS to adopt outcome measures focused on changes in resident physical and cognitive functioning while under a provider's care.

Response: We appreciate MedPAC's preference for moving toward the use of functional outcome measures in order to assess the resident's physical and cognitive functioning under a provider's care. We believe that the use of this process measure at this time will give us the data we need to develop a more robust outcome-based quality measure on this topic in the future. The proposed function quality measure, an Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631; endorsed on July 23, 2015), has attributes to enable outcomes-based evaluation by the provider. Such attributes include the assessment of functional status at two points in time, admission and discharge, enabling the provider to identify, in real time, changes, improvement or decline, as well as maintenance. Additionally, the proposed quality measure requires that the provider indicate at least one functional goal associated with a functional activity, and the provider can calculate the percent of patients who meet goals. Such real time use enables providers to engage in person-centered goal setting and the ability to use the data for quality improvement efforts. In particular, we are currently developing functional outcome measures, including self-care and mobility quality measures, for use in the SNF setting. These outcome function quality measures are intentionally being designed to use the same standardized functional assessment items that are included in the proposed function process measure, which will result in a limited additional reporting burden for SNFs.

Comment: One commenter supported the concept of measuring function and monitoring the percentage of residents with completed functional assessments. The commenter was pleased that the quality measure, an Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631, endorsed on July 23, 2015), was proposed for multiple PAC settings in accordance with the IMPACT Act. The commenter, as well as several other commenters, noted that the proposed quality measure is an application of the LTCH quality measure, and that fewer

functional assessment items are in the proposed measure when compared to the LTCH process quality measure, the Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631, endorsed on July 23, 2015). For example, one commenter noted that the Confusion Assessment Method (CAM[®]) items and the Bladder Continence items are not included in the proposed application of the quality measure.

Response: The proposed functional status process quality measure is specified as a cross setting quality measure and is standardized across multiple settings. However, to clarify which specific function items are included in each function measure for each QRP, we added a table to the document entitled, SNF QRP: Specifications of Quality Measures Adopted in the FY 2016 Final Rule, which identifies which functional assessment items are used in the cross-setting process measure as well as the setting-specific IRF and LTCH outcome quality measures. The document is available at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.html>.

We believe that standardization of assessment items across the spectrum of post-acute care is an important goal. In this cross-setting process quality measure, there is a common core subset of function items that will allow tracking of residents' functional status across settings. We recognize that there are some differences in residents' clinical characteristics, including medical acuity, across the LTCH, SNF and IRF settings, and that certain functional items may be more relevant for certain patients/residents. Decisions regarding item selection for each quality measure were based on our review of the literature, input from a TEP convened by our measure contractor, our experiences and review of data in each setting from the PAC PRD, and public comments.

Comment: Several commenters questioned why CARE function items on the proposed IRF-PAI, MDS 3.0 and LTCH CARE Data Set are not the same set of items and believed the measure, an Application of The Percent of Long-Term Care Hospital Patients With an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; endorsed on July 23, 2015), meant that

the items should be the same set of items.

Response: A core set of mobility and self-care items are proposed for IRFs, SNFs, and LTCHs, and are nested in the proposed section GG of the IRF-PAI, MDS 3.0 and LTCH CARE Data Set. Additional function items are included on the IRF-PAI and LTCH CARE Data Set due to the adoption of additional outcome-based quality measures in those specific settings. Therefore, a core set of items in the proposed section GG are standardized to one another by item and through the use of the standardized 6-level rating scale. We will work to harmonize the assessment instructions that better guide the coding of the assessment(s) as we believe that this will lead to accurate and reliable data, allowing us to compare the data within each setting.

Comment: Several commenters noted that the proposed function measure is a process measure and does not capture functional outcomes. One commenter did not believe that the measure would provide incentives to improve quality of care given that CMS will not determine if goals are achieved. The commenters expressed their preference for outcome measures. One commenter preferred an outcome measure, because they noted concerns about residents at risk for decline in function. Two commenters noted that functional outcome measures were under review at NQF, and two of these quality measures were developed for the SNF setting. Some of these commenters added that function outcome measures were proposed for IRFs, but no functional outcomes measures were proposed for LTCHs or SNFs. One commenter believed that CMS had a "few" years to implement the SNF QRP and, thus, has time to develop outcome measures. One commenter also noted that the name of the measure, which refers to Long-Term Care Hospital patients, is misleading. Several commenters expressed concern that the proposed function process measure does not meet the requirements of the IMPACT Act because measures must be outcome-based. One commenter stated that the proposed measure did not satisfy the specified IMPACT Act domain as the measure is not able to report on changes in function, and one other commenter claimed that the measure does not satisfy the reporting of data on functional status. Finally, a commenter stated that the measure does not have an appropriate numerator, denominator, or exclusions; lacks NQF endorsement; fails to be based on a common standardized assessment tool; and lacks evidence that associates the measure with improved outcomes. One

commenter claims that because the specifications for the proposed measure are inconsistent with the measure specifications posted by NQF for the measure that is under endorsement review, CMS failed to meet the requirements under the IMPACT Act to provide measure specifications to the public, and further asserted that one is not able to determine the specifications that are associated with the proposed measure, which is an application of the NQF version of the measure.

Response: We agree that the use of outcome measures is important and, as discussed above, we are currently developing functional outcome measures for the SNF setting. We appreciate the commenters concern about monitoring for decline in function and will take that into consideration as we develop the SNF outcome measures. With regard to the LTCH QRP, we adopted the quality measure Long-Term Care Hospital Functional Outcome Measure: Change in Mobility Among Patients Requiring Ventilator Support (NQF #2632; endorsed on July 23, 2015) in the FY 2015 Final Rule and data collection for this outcome measure begins in LTCHs on April 1, 2016.

The words "Long-Term Care Hospital Patients" are included in the title of the quality measure because it is an application to the SNF setting of the existing quality measure, Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF 2631; endorsed on July 23, 2015), which is a Long-Term Care Hospital quality measure.

We believe that the proposed function measure meets the requirements of the IMPACT Act. The statute requires, among other things, the submission of data on the quality measures specified in at least the domains identified in the Act, but does not require a particular type of measure (for example, outcome or process) for each measure domain. Further, as discussed in this section, the measure has attributes within the assessment and data collection that enables outcomes-based evaluation by the provider.

We also disagree with the comment that we failed to provide the specifications to the proposed measure. The proposed function process quality measure is an application of the measure, the Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631; endorsed on July 23, 2015). The now NQF-endorsed quality measure was proposed and finalized in the IPPS/

LTCH PPS final rule (FR 79 50291 through 50298) for adoption in the LTCH QRP. An application of this measure was proposed in the FY 2016 SNF QRP proposed rule, and similarly it was proposed in the FY 2016 IPPS/ LTCH PPS proposed rule and the FY 2016 IRF PPS proposed rule. We proposed the cross-setting version, an application of the LTCH QRP quality measure, based on guidance from multiple TEPs convened by our measure contractor, RTI International. The specifications for this quality measure, as well as all other proposed measures for the SNF, LTCH, and IRF QRPs were posted on the CMS Web site with the posting of the proposed rules to enable public comment. For the SNF QRP, please see the specifications at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.html>. These specifications were posted at the time we issued the proposed rule.

As discussed in the proposed rule under section V.C.5.c., prior to our consideration to propose this measure's use in the SNF QRP, we reviewed the NQF's endorsed measures and were unable to identify any NQF-endorsed, cross-setting or standardized quality measures focused on assessment of function for PAC patients/residents. We were also unaware of any other cross setting quality measures for functional assessment that have been endorsed or adopted by another consensus organization. Therefore, we proposed a modified version of the quality measure, the Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631; endorsed on July 23, 2015), with such modifications to allow for its cross-setting application in the SNF QRP for the FY 2018 payment determination and subsequent years under the Secretary's authority to select a non-NQF-endorsed measure. Since the cross-setting measure is not identical to the measure recommended for NQF-endorsement, it is considered an application of the measure.

Comment: One commenter suggested that CMS conduct additional testing of the CARE function items with specific patient/resident subpopulations. The commenter also suggested research studies that compare CARE items with other instruments across diverse PAC populations. They suggested this data be used to improve the CARE items or replace them with other items to address any potential floor or ceiling

effects. This commenter also suggested studies that compare models of care for subpopulations so as to elicit best practices related to complex conditions.

Response: We agree that adoption of the proposed quality measure, an application to of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF 2631; endorsed on July 23, 2015), would offer many opportunities to examine best practices for caring for SNF residents. Examining the data for any floor and ceiling effects in special populations is also a very worthy research idea. With regard to examining the CARE data against other functional assessment instrument data, as part of the PAC PRD analyses, we compared data from the existing items (that is, MDS, OASIS, and the FIM® instrument) with data from the analogous CARE items. More specifically, we ran cross tabulations of MDS function scores and CARE scores for the patients/residents in the PAC PRD to compare scores. A full description of the analyses and the results are provided in the report, The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report on the Development of the CARE Item Set and Current Assessment Comparisons Volume 3 of 3, and the report is available at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/CARE-Item-Set-and-B-CARE.html>. Finally, we agree that ongoing reliability and validity testing is critical for all items used to calculate quality measures.

Comment: One commenter recommended revising the definition of the item "eating" as it is a combination of multiple elements of self-feeding, swallowing ability, and diet texture modification.

Response: The item "eating" is classified as an activity, and is only scored when a resident eats by mouth. The "eating" score may reflect assistance needed due to various impairments such as hand/arm weakness or coordination issues or swallowing limitations. If a resident does not eat by mouth and relies on an alternative means of getting nutrition, "eating" is scored as "activity not attempted."

Comment: One commenter noted that proposed quality measures, such as the proposed function quality measure, should reflect several attributes, including low reporting burden, comprehensibility for beneficiaries, a

high level of significance to patients/residents, and data that is routinely captured.

Response: We believe that this proposed quality measure will have a high level of significance to residents and providers because it assesses resident functional status and goals, and that the measure will not impose a new, significant reporting burden on SNFs because many already assess these items as part of their standard care practices. Additionally, the NQF Person- and Family-Centered Care panel, which included several patient and patient advocates, indicated by preliminary vote that the measure meets the moderate level of evidence for "Use and Usability." "Use and Usability" refers to whether the measure is meaningful, understandable, and useful for the intended audiences for public reporting and quality improvement. These preliminary results and the description of, "Use and Usability" are described in the report entitled, Phase 2 Draft Report for Voting, which is available on the Person-and Family-Centered Project Web site at http://www.qualityforum.org/projects/person_family_centered_care/. Among the panel, two members voted that the measure met the criteria at a high level, 12 indicated it met the moderate level of evidence, and three indicated it was low. With regard to the importance of the measure to residents, and their families, the measure reviewed by the Person-and Family-Centered Care panel did meet the importance criteria with the majority of panel members finding moderate level for evidence, performance gap and high-priority. These preliminary results and the description of "Importance" are described in the Report entitled, Phase 2 Draft Report for Voting, which is available on the Person-and Family-Centered Project Web site at http://www.qualityforum.org/projects/person_family_centered_care/.

Comment: Several commenters indicated they support quality measures focused on function, but did not support the proposed cross-setting functional status measure for the SNF QRP. Several commenters noted their lack of support was due to burden related to reporting functional status information using two distinct but similar standards and scales, using different time frames. One commenter noted that section G and section GG have different measurement metrics, with section GG providing a more granular look at the components of section G. They noted that collection of function data using different and conflicting items presents significant operational challenges and would

undermine the accuracy of data collection. The commenters suggested that the adoption of the measure would also increase provider confusion because SNFs would need to be familiar with and apply different rules, definitions, and metrics when completing resident assessments. Commenters also suggested that the functional status measure increases the reporting burden on SNFs but will also lead to inaccurate coding of resident function for both measurement and payment. In addition, they noted providers would be required to spend significant time and resources providing training and oversight to ensure that each data set is completed accurately and at the right time in the resident's stay. Commenters also suggested that record keeping and reporting will be complicated, as electronic medical records will need to be updated to accommodate dual processes for recording similar clinical information leading to greater cost to providers and a decrease in the quality and accuracy of the data collected. Several commenters noted the significance of adequate training stressing the importance of appropriate coding of the new items used to calculate the proposed measures and one commenter specifically asked for clarification on which health care professional would be responsible for performing the assessment while another asked that the Minimum Data Set (MDS) Resident Assessment Instrument (RAI) Manual be provided with the necessary coding and assessment instructions for the provider's reference in a timely manner. One commenter suggested transparency with regard to how CMS will implement the new quality measures and stated that training for all providers, including instructions for the revised MDS RAI Manual, would be needed. The commenter suggested open door forums and training webinars for providers. One commenter specifically asked for clarification on which health care professional would be responsible for performing the assessment.

One commenter asked for clarification about the rationale for the short assessment period for section GG. In addition, a commenter noted that the coding of section GG, with the current look-back, will make coding of section G more complex and asked that a streamlined coding construct that is less complex be adopted. One commenter suggested that CMS develop a crosswalk to adapt the current items to create the standardization. One commenter suggested that CMS revise the MDS items to reduce burden and confusion

from the duplication of data, variation in item definitions, and the variation in the rating scales. One commenter encouraged CMS to remove items from the existing data sets where possible. One commenter encouraged CMS to keep the transition period, during which both section G and section GG would be collected, short, which would allow for better cross-setting comparisons and better quality measures, and which is more in line with the intent of the IMPACT Act. Another commenter cautioned CMS about removing MDS items that are used for payment, particularly as section G has become a "payment tool for Medicaid." Finally, a commenter suggested that CMS reach out to vendors to assure validity, timeliness, and accuracy when MDS changes occur.

Response: We appreciate the commenter's concerns related to the new requirements that SNFs will have to satisfy to report the proposed function measure. We agree with the importance of thorough and comprehensive training and we intend to provide such training in the near future for all updates to the MDS and assessment requirements. We also recognize that SNFs might need to conduct training to ensure that their staffs understand how to properly fill out both section G and section GG. We also intend to provide comprehensive training as we do each time the assessment items change.

In addition to the manual and training sessions, we will provide training materials through the CMS webinars, open door forums, and help desk support. We welcome ongoing input from stakeholders on key implementation and training considerations, which can be submitted via email: PACQualityInitiative@cms.hhs.gov.

We believe that the 6-level scale and additional items in section GG will allow us to better distinguish change at the highest and lowest levels of functioning by documenting minimal change from no change at the low end of the scale.⁷⁷ This is important for measuring progress in some of the most complex cases treated in PAC. The items in section GG were developed with input from the clinical therapy communities to better measure the change in function, regardless of the severity of the individual's functional limitations.

⁷⁷ Barbara Gage et al., "The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report on the Development of the CARE Item Set" (RTI International, 2012).

To reduce the potential burden associated with collecting additional items, we have included several mechanisms in the section GG to reduce the number of items that apply to any one resident. First, in section GG, there are gateway questions pertaining to walking and wheelchair mobility that allow the clinician to skip items that ask if the resident does not walk or does not use a wheelchair, respectively. For example, in section GG, there is an item that asks whether or not the resident walks. If the resident does not walk, three items in section GG related to walking ability are skipped. Second, section GG items will only be collected at admission and discharge. The gateway questions and skip patterns mean that only a subset of section GG items are needed for most residents. However, by including all of them in the form, the standardized versions are available when appropriate for an individual resident. With regard to the assessment time frames, for the MDS items located in section G, the assessment time frames take into consideration all episodes of the activity that occur over a 24-hour period during each day of the 7-day assessment period, as a resident's ADL self-performance and the support required may vary from day to day, shift to shift, or within shifts. As stated in the CMS MDS 3.0 Resident Assessment Instrument manual, "the responsibility of the person completing the assessment, therefore, is to capture the total picture of the resident's ADL self-performance over the 7-day period, 24 hours a day (that is, not only how the evaluating clinician sees the resident, but how the resident performs on other shifts as well)" (CMS, 2014, ch. 3, p. G-4). The CARE function items in the proposed functional quality measures, to be nested in the proposed Section GG, have a shorter assessment time frame (3 calendar days), which is standardized across the PAC settings, based on the need for data reflecting the resident's status at the time of admission and discharge. For admission, the CARE function items are to reflect the status of the person as the person is admitted to the SNF; in other words, self-care and mobility limitations present at the time of admission. We recognize that when residents are first admitted to a SNF, clinicians often determine the resident's clinical status based on several observations and often after a period of time in which the resident adjusts to the new environment. We also recognize that several clinicians from different disciplines are observing the resident's

status and this may not occur on the day of admission. Further, we are aware that residents who receive rehabilitation services may have improvement in function soon after admission to the SNF as therapy services may be provided on the day of admission or the next day. If the admission assessment is not completed early in the stay, the admission score may reflect improvement already achieved by the resident due to treatment provided. In other words, functional improvement would not be reflected in function scores if the admission assessment is conducted after therapy has started and impacted the resident's status or before therapy ends. Therefore, clinicians report resident's admission functional assessment for the CARE items based on 3 calendar days. This assessment time frame has been used in IRFs successfully and balances the need for data reflecting the resident's status at the time of admission and the interest in documenting changes in function between admission and discharge.

Finally, we thank the commenters for their comments pertaining to electronic medical records (EMRs). While we applaud the use of EMRs, CMS does not require that providers use EMRs to populate assessment data. It should be noted that with each assessment release, we provide free software to our providers that allows for the completion and submission of any required assessment data. The use of a vendor to design software that extracts data from a provider's EMR to populate CMS quality assessments, is a business decision that is made solely by the provider. We only require that assessment data be submitted via the QIES ASAP system in a specific compatible format. Providers can choose to use our free software, or the data submission specifications we provide that allow providers and their vendors to develop their own software, while ensuring compatibility with the QIES ASAP system.

Comment: Several commenters noted that the items included in the Section GG of the MDS differ from those tested during the PAC PRD and represented a limited set of items from the original CARE Tool. One of these commenters suggested that the contributions of occupational therapy may not be measureable with the limited set of items. Another commenter suggested that the assessment time frame differed from that used in the PAC PRD.

Response: The PAC PRD tested a range of items, some of which were duplicative, to identify the best performing items in each domain. Select items were removed from the item set

where testing results and clinician feedback suggested the need for fewer items to be included in a particular scale. We also received feedback on the items tested in the PAC PRD from a cross-setting TEP convened by our measure development contractor, RTI International. Other changes from the original PAC-PRD items included incorporating instructional detail from the manual and training materials directly into the data collection form and updating skip patterns to minimize burden. We agree that the contribution of occupational therapy as well as other clinical disciplines, should be reflected in all item and measure development. During the PAC-PRD, clinicians from many different disciplines collected CARE data, including occupational therapists (OTs). In addition, the items in section GG were developed with the input from clinicians would be performing the assessments, including OTs.

With regard to the assessment time frame for the CARE function items, we instructed clinicians to use a 2-day time frame if the patients/residents were admitted before 12 p.m. (noon) or 3 calendar days if the patients/residents were admitted after 12 p.m. Our exit interviews revealed that most patients/residents were admitted to the SNF after 12 p.m. and that clinicians used 3 calendar days. Therefore, we have used the assessment time frame that most clinicians used during the PAC-PRD.

Comment: One commenter expressed concern about the reliability testing results for licensed nurses in the PAC PRD, given that licensed nurses play a large role in documenting function.

Response: The reliability results mentioned by this commenter were only one of several reliability analyses conducted to support the development of this measure as part of the PAC PRD. The results of licensed nurses reflect the small sample. In addition to the inter-rater reliability study mentioned by these commenters, we also examined: (1) Inter-rater reliability of the CARE items using videotaped case studies, which included 550 assessments from 28 providers; and (2) internal consistency of the function data, which included more than 2,749 SNF residents. Overall, these results indicate moderate to substantial agreement on these items. The report describing these additional analyses and an interpretation of the Kappa statistics results is available at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/The-Development-and-Testing-of-the->

Continuity-Assessment-Record-and-Evaluation-CARE-Item-Set-Final-Reporton-Reliability-Testing-Volume-2-of-3.pdf.

Therefore, given the overall findings of these reliability analyses, we believe that the proposed function measure is sufficiently reliable for the SNF QRP.

Comment: One commenter was concerned that no data was provided clearly linking improved outcomes to this process measure.

Response: We believe that there is evidence that this is a best practice based on several clinical practice guidelines. The NQF requirement for endorsing process measures is that the process should be evidence-based, such as processes that are recommended in clinical practice guidelines. As part of the NQF process, CMS submitted several such clinical practice guidelines^{78 79 80} to support this measure, and referenced another cross-cutting clinical practice guideline in the proposed rule. The clinical practice guideline Assessment of Physical Function⁸¹ recommends that clinicians should document functional status at baseline and over time to validate capacity, decline, or progress. Therefore, assessment of functional status at admission and discharge and establishing a functional goal for discharge as part of the care plan (that is, treatment plan) is an important aspect of patient/resident care for all of these PAC providers.

Comment: Several commenters suggested that CMS develop a plan to revise the existing MDS function items to be more consistent with the data collected in the other PAC settings, noting this would lay the groundwork for a measure that is more “standardized” and “interoperable”

⁷⁸ Kresevic DM. Assessment of physical function. In: Boltz M., Capezuti E., Fulmer T., Zwicker D., editor(s). Evidence-based geriatric nursing protocols for best practice. 4th ed. New York (NY): Springer Publishing Company; 2012. p. 89–103. Retrieved from <http://www.guideline.gov/content.aspx?id=43918>.

⁷⁹ Centre for Clinical Practice at NICE (UK). (2009). Rehabilitation after critical illness (NICE Clinical Guidelines No. 83). Retrieved from <http://www.nice.org.uk/guidance/CG83>.

⁸⁰ Balas M.C., Casey C.M., Happ M.B. Comprehensive assessment and management of the critically ill. In: Boltz M., Capezuti E., Fulmer T., Zwicker D., editor(s). Evidence-based geriatric nursing protocols for best practice. 4th ed. New York (NY): Springer Publishing Company; 2012. p. 600–27. Retrieved from <http://www.guideline.gov/content.aspx?id=43919>.

⁸¹ Kresevic DM. Assessment of physical function. In: Boltz M., Capezuti E., Fulmer T., Zwicker D., editor(s). Evidence-based geriatric nursing protocols for best practice. 4th ed. New York (NY): Springer Publishing Company; 2012. p. 89–103. Retrieved from <http://www.guideline.gov/content.aspx?id=43918>.

across post-acute care settings. Some commenters noted that this transition would require considerable analysis to ensure there are not negative unintended consequences for SNF reimbursement, and testing in SNF facilities to ensure the revised instrument collects accurate, reliable and meaningful data.

Response: We have proposed to add a core set of CARE function items to the MDS for SNFs, the IRF–PAI for IRFs and the LTCH CARE Data Set. These standardized data will enable interoperability across these PAC settings. As noted above, the proposed IRF–PAI and proposed LTCH CARE Data Set include additional CARE function items, because those QRPs include additional functional outcome measures, and these measures require collection of more than just the core items included in the function process measure. The development of the entire original set of CARE function items, including the definitions for each activity, were selected based on a review of all existing items used by LTCHs, IRFs, SNFs and HHAs, a review of the literature, and input from stakeholders such as clinicians and researchers.

Comment: One commenter noted that the proposed function measure includes reporting of a goal as a way to document that residents have a care plan that addresses function, and that this reporting of function goals was not part of the original PAC PRD. The commenter further noted that reporting of only one goal was not ideal, because many residents have goals for multiple functional activities and the number of standardized functional assessment items is limited compared to the full set of function items tested as part of the PAC PRD. Finally, the commenter indicated that treatment goals may be to improve function, and therefore, are restorative in nature, while therapy may be necessary so to ensure the maintenance of a PAC resident’s function.

Response: The proposed function measure requires a minimum of one (1) goal per resident stay; however, clinicians can report goals for each self-care and mobility item included in the proposed section GG of the MDS. We believe that assessing resident function goals should be part of clinical care and builds upon the conditions of participation (CoPs) for SNF providers. The IMPACT Act also specifically mentions goals of care as an important aspect of the use of standardized assessment data, quality measures, and resource use to inform discharge planning and incorporate resident

preference. We agree that for many PAC patients/residents, the goal of therapy is to improve function and we also recognize that for some residents, delaying decline may be the goal. We believe that individual, person-centered goals exist in relation to individual preferences and needs. We will provide instructions pertaining to the reporting of goals in a training manual and in training sessions in order to better clarify that goals set at admission may be focused on improvement of function or maintenance of function.

Comment: Several commenters were concerned that the measure, an Application of the Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; endorsed on July 23, 2015) was not NQF endorsed. Some of these commenters noted that it was under review at NQF for the LTCH setting and not for the SNF setting.

Response: We agree that the NQF endorsement process is an important part of measure development. We have proposed an application of the quality measure, the Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function. This quality measure is now NQF endorsed. We have a rigorous process of construct testing and measure selection, guided by the TEPs, public comments from stakeholders, and recommendations by the PAC/LTC MAPs.

Comment: One commenter recognized the burden of changing assessment items, but noted the utilization of standardized assessment items is expected to improve transitions. The commenter indicated that proposal was an action of good intent toward the statutory standardization of assessment.

Response: We thank the commenter for their comment and support for the inclusion of the standardized (that is, CARE) functional assessment items. We agree that standardized assessment across PAC settings has the potential to improve care.

Comment: One commenter noted that one reason for standardized assessment items “would be to establish a common language for patient and resident functioning, which may facilitate communication and care coordination as patients and residents transition from one type of provider to another,” and asked CMS to provide data on the number or percent of patients/residents that transition from one type of provider to another. The commenter further requested information about why the

current measures fail to provide clinicians with the information needed.

Response: Several studies have documented patient/resident transition patterns following discharge from the hospital and continuing for 30, 60, or 90 days.^{82 83 84} While the exact proportions discharging to each type of care vary slightly across the years, the proportion of acute hospital admissions being discharged to PAC has grown from 35 percent in 2006 to 43 percent in more recent years (MedPAC, 2014). Among those discharged to PAC, the majority are discharged to SNF or HHA, and a much smaller proportion are discharged to IRFs and LTCHs. Further examination shows that among each of the four PAC admissions, many individuals continue to transition to subsequent sites of care. Common discharge patterns from the IRF, for example, include over 75 percent of cases continuing into HHA or outpatient therapy services. SNF cases are commonly discharged home with either outpatient therapy or home health services. One report outlining these issues is entitled, "Examining Post Acute Care Relationships in an Integrated Hospital System" (available at <http://aspe.hhs.gov/health/reports/09/pacihs/report.pdf>). This report includes a summary of the most common PAC transition patterns for Medicare FFS Beneficiaries in 2006.

Comment: One commenter encouraged CMS to risk adjust all outcome measures.

Response: The proposed function quality measure, an Application of the Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631, endorsed on July 23, 2015), is a process measure that focuses on the clinical process of completion of functional assessments and a care plan addressing function. Although the IMPACT Act requires that the cross-

setting quality measures be risk-adjusted as determined appropriate by the Secretary, it does not limit the Secretary to adopting outcome measures. Some process measures are risk adjusted,^{85 86} However, in the development of an application of the measure, the Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631; endorsed on July 23, 2015), the Technical Expert Panel considered, but did not recommend, the application of a risk adjustment model. We agree with that conclusion because the completion of a functional assessment, which includes the use of "activity not attempted" codes, is not affected by the medical and functional complexity of the resident. Therefore, we believe that risk adjustment of this quality measure is not warranted.

Comment: Several commenters noted additional areas of function that are key to residents, including cognition, communication, and swallowing. One commenter encouraged CMS to consider cognition and expressive and receptive language and swallowing as items of function and not exclusively as risk adjusters, and offered their expertise to CMS for discussions and to develop goals. Another commenter examined the SNF, IRF, HHA and LTCH assessment instruments and noted that cognitive function is measured differently across the settings in terms of content, scoring process, and intended calibration of each tool, and encouraged CMS to align items and quality measurement of cognition.

Response: We are working toward developing quality measures that assess areas of cognition and expression, recognizing that these quality topic domains are intrinsically linked or associated to the domain of function and cognitive function. We appreciate the commenter's offer for assistance and encourage the submission of comments and measure specification details to our comment email: PACQualityInitiative@cms.hhs.gov.

Comment: One commenter suggested that CMS remove some items from section G if section GG items are adopted. One commenter noted that the

four late-loss activities of daily living (ADL) items from Section G should be retained and this commenter recognized that some items were needed for payment. The commenter noted differences in the rating scales for the items in section G and the items in section GG.

Response: We recognize that the items in section G serve many purposes such as those items that are used for payment, and will continue to take into consideration all factors pertaining to payment and quality.

Comment: One commenter was concerned that residents with missing data in their assessment records would be excluded from this measure. This commenter was concerned that this could present SNFs with an opportunity to purposefully exclude data.

Response: We thank the commenter for their comments and appreciate the concerns pertaining to intentionally excluded data. We would like to clarify that there are no resident exclusions criteria for this measure. Therefore, this potential for "gaming" does not exist for this measure. Nonetheless, as part of our compliance analysis we intend to carefully monitor rates of missing data across all facilities. Specifically, we are finalizing that for FY 2018, any SNF that does not meet the proposed requirement that 80 percent of all MDS assessments submitted contain 100 percent of all data items necessary to calculate the SNF QRP measures would be subject to a reduction of two percentage points to its FY 2018 market basket percentage. We hope this requirement will incentivize providers to submit complete MDS 3.0 assessments.

Comment: A commenter was concerned about the use of a consistent definition of the short-stay population, the denominator, in this function measure, as well as the other proposed measures for use in the SNF QRP. The commenter was also concerned about the alignment of measures with major CMS initiatives.

Response: We appreciate the commenters' comments pertaining to the differences in the function quality measure denominators by payer type across the IRF, SNF and LTCH settings and we have addressed this comment previously. We believe that quality care is best represented through the inclusion of all patient data regardless of payer source. We agree that consistency in the data would reduce confusion in data interpretation and enable a more comprehensive evaluation of quality and although we had not proposed all payer data collection through this current rulemaking, we will take into

⁸² Gage, B., Morley, M., Ingber, M., & Smith, L. (2011). Post-Acute Care Episodes Expanded Analytic File: RTI International. Prepared for the Assistant Secretary for Planning and Evaluation. Retrieved from <http://aspe.hhs.gov/health/reports/09/pacihs/report.pdf>.

⁸³ Gage, B., Morley, M., Constantine, R., Spain, P., Allpress, J., Garrity, M., & Ingber, M. (2008). Examining Relationships in an Integrated Hospital System: RTI International. Prepared for the Assistant Secretary for Planning and Evaluation. Retrieved from <http://aspe.hhs.gov/health/reports/08/examine/report.html>.

⁸⁴ Gage, B., Pilkauskas, N., Dalton, K., Constantine, R., Leung, M., Hoover, S., & Green, J. (2007). Long-Term Care Hospital (LTCH) Payment System Monitoring and Evaluation Phase II Report RTI International. Prepared for the Centers for Medicare & Medicaid Services. Retrieved from http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/downloads/rti_ltchpps_final_rpt.pdf.

⁸⁵ For example, in the NQF-endorsed process measure Percent of Residents Who Have/ Had a Catheter Inserted and Left in Their Bladder (long stay) (NQF#0686) for which we are the steward, resident-level limited covariates (Frequent bowel incontinence, or always incontinent on prior assessment; and Pressure ulcers at stages II, III, or IV on prior assessment) are used in a logistic regression model to calculate a resident-level expected quality measure score.

⁸⁶ Peter C. Smith, Elias Mossialos, Irene Papanicolas and Sheila Leatherman. Performance Measurement for Health.

consideration the expansion of the SNF QRP to include all payer sources through future rulemaking.

Comment: Two commenters requested that CMS continue in its public engagement with stakeholders, and one requested increased engagement with regard to the IMPACT Act and measures it considers. Other commenters stated their appreciation for inclusion and opportunity to work with CMS during the implementation phases of the IMPACT Act. One commenter also recommended that CMS establish a more formal stakeholder group to include rehabilitation professionals who can provide expertise on the provision of rehabilitation therapy in NFs. This commenter noted that the more opportunities stakeholders have to engage in dialogue with and advise CMS on the quality measures, the greater the possibility that the measures will be accurate and helpful to determining care quality.

Response: We appreciate the continued involvement of stakeholders in all phases of measure development and implementation, as we see the value in strong public-private partnerships. We also believe that ongoing stakeholder input is important to the success of the IMPACT Act and look forward to continued and regular input from the provider communities as we continue to implement the IMPACT Act.

Comment: One commenter suggested that the PAC PRD data was collected only by therapists, and expressed concern that the items had not been tested using other care providers. In addition, this commenter had specific questions about scoring different assessments during the time window proposed. This commenter also had specific questions about which SNF clinicians will complete the functional assessment items for this measure.

Response: We wish to clarify that during the PAC PRD, data were collected by clinicians from many different disciplines, including OTs, PTs, SLPs and RNs. Reliability testing included testing by discipline as well as by setting. However, the items were developed with the input of various personnel who would be performing the assessments, which included OTs, PTs, SLPs, and RNs. Regarding the questions about scoring assessments and staff that will be trained to complete functional assessments, we have historically provided training for providers. As we prepare for this type of training, we will make sure to have this type of information available to the public to increase transparency and readiness.

Comment: A commenter urged CMS to develop function measures that take resident quality of life into account. The commenter noted that function measures are not “one size fits all.” Another commenter suggested CMS focus on key concerns of beneficiaries with disabilities and chronic conditions, including, where appropriate: The ability to live as independently as possible, to function at the maximum extent possible, to return to employment where appropriate, to engage in recreational and athletic pursuits, to engage in community activities, and to maintain the highest quality of life possible.

Response: We believe that this proposed quality measure will have a high level of significance to residents and providers. The proposed function quality measure is a person and family-centered process measure that reports standardized functional assessment data at admission and discharge, as well as at least one functional status discharge goal, demonstrating person and family-centered care. The IMPACT Act

specifically mentions goals of care as an important aspect of the use of standardized assessment data, quality measures, and resource use to inform discharge planning and incorporate resident preference. However, we are always open to stakeholder feedback on measure development and encourage everyone to submit comments to our comment email: PACQualityInitiative@cms.hhs.gov.

Comment: One commenter recommended that CMS exclude section GG data from all medical review organizations or processes for the first three years.

Response: The item sets included in section GG are being proposed to satisfy measure domains under the IMPACT Act and are not being proposed for use in making payment determinations. The primary purpose of medical review is to validate medical necessity and to identify coding discrepancies to determine whether payment is appropriate. The item sets in Section GG are not being used for this purpose and are therefore not subject to medical review. A provider’s failure to submit the data to complete section GG could result in a determination of noncompliance with the SNF QRP, resulting in a 2 percent reduction to the SNF’s market basked percentage for the applicable fiscal year.

Final Decision: Having carefully considered the comments we received on the application of the Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631; endorsed on July 23, 2015), we are finalizing the adoption of this measure for use in the SNF QRP.

f. SNF QRP Quality Measures Under Consideration for Future Years

TABLE 10—SNF QRP QUALITY MEASURES AND CONCEPTS UNDER CONSIDERATION FOR FUTURE YEARS

IMPACT Act Domain	Measures to reflect all-condition risk-adjusted potentially preventable hospital readmission rates.
Measures	(NQF #2510): <i>Skilled Nursing Facility 30-Day All-Cause Readmission Measure (SNFRM)</i> . (NQF #2512; NQF #2502): Application of the LTCH/IRF All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from LTCHs/IRFs.
IMPACT Act Domain	Resource Use, including total estimated Medicare spending per beneficiary.
Measure	(NQF #2158): Application of the Payment Standardized Medicare Spending Per Beneficiary (MSPB).
IMPACT Act Domain	Discharge to community.
Measure	Percentage residents/patients at discharge assessment, who are discharged to a higher level of care or to the community. Measure assesses if the patient/resident went to the community and whether they stayed there. Ideally, this measure would be paired with the 30-day all-cause readmission measure.

We invited comments on the measure domains and associated measures and measure concepts listed in Table 10. In addition, consistent with the requirements of the IMPACT Act to develop quality measures and

standardize data for comparative purposes, we believe that evaluating outcomes across the post-acute care settings using standardized data is an important priority. Therefore, in addition to adopting a process-based

measure for the IMPACT Act domain of “Functional status, cognitive function, and changes in function and cognitive function”, which is included in this year’s final rule, we also intend to develop outcomes-based quality

measures, including functional status and other quality outcome measures to further satisfy this domain. These measures will be proposed in future rulemaking in order to assess functional change for each care setting as well as across care settings. The comments we received on this topic, with their responses, appear below.

Comment: Several commenters urged CMS to consider future quality measures for the SNF QRP related to various topics including: Patient and family engagement; nutrition; key concerns related to a patient's quality of life following discharge from post-acute care; and workforce. One commenter requested that quality measures currently reported through Nursing Home Compare also be considered for future use in the SNF QRP.

Response: We agree that the suggested measure areas are important for quality of care in SNFs, and we would like to highlight that measures pertaining to nutrition, quality of life, patient and family engagement and person-centered care are known gaps in quality, and therefore, are among our priorities to address. Such measures align with our CMS Quality Strategy. We also agree with the importance of workforce related measures as we understand that quality outcomes are often directly linked with staffing and workforce. We agree that measures currently reported through Nursing Home Compare should also be considered for future use in the SNF QRP, and we are finalizing two measures currently reported through Nursing Home Compare (Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short Stay) (NQF #0678) and an application of the measure Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674)) for the FY 2018 SNF QRP. We will consider the commenters' recommendations in our measure development and testing efforts, as well as in our ongoing efforts to identify and propose appropriate measures for the SNF QRP in the future.

Comment: One commenter supported the IMPACT Act requirement to measure and report on rehospitalization and discharge to community measures. However, the commenter expressed several concerns regarding the potential future measures identified by CMS and recommended several considerations for future measure development. The commenter did not believe that three potential future rehospitalization measures (Skilled Nursing Facility 30-Day All-Cause Readmission Measure (NQF #2510), Application of the LTCH/IRF All-Cause Unplanned Readmission

Measure for 30 Days Post Discharge from LTCHs/IRFs (NQF #2512; NQF #2502)) comply with IMPACT Act requirements because the measures have different numerator and denominator definitions and exclusions. The commenter is also concerned that while the three measures are NQF-endorsed in each of their respective settings, they are not yet endorsed as cross-setting measures. Finally, the commenter states that these measures should not be restricted to Medicare FFS beneficiaries as this is inconsistent with the IMPACT Act. To comply with the IMPACT Act requirements, this commenter recommended that CMS develop an all-cause all payer rehospitalization measure that (a) is not restricted to Medicare FFS beneficiaries, and (b) has the same numerator and denominator definitions, but may use different risk adjustment variables, in each PAC setting. The commenter further suggests that pairing the proposed rehospitalization measure with the discharge to community measure would not be appropriate.

When developing the Discharge to Community measure, the commenter recommends that CMS consider differences across PAC providers, and the implications of those differences on measure specification. An additional commenter also supported the Discharge to Community measure, which is under consideration for future years.

The commenter also recommended that when developing a resource measure, CMS should collect information from NQF on prior work done to address challenges related to developing a reliable and valid resource measure that measures total Medicare spending per beneficiary. Finally, the commenter stated that CMS needs to begin working on a medication reconciliation measure as listed in the IMPACT Act.

Response: We believe that we have the discretion to implement either a within stay readmission measure, or a post-PAC discharge readmission measure in satisfaction of the IMPACT Act. Therefore, both measure concepts listed could be applicable. We appreciate the suggestion that such a measure not be paired with the discharge to community measure and will take this under consideration. With regard to the suggested development of an all-cause all payer rehospitalization measure that is not restricted to Medicare FFS beneficiaries, has uniform numerators and denominators and is appropriately risk adjusted in each PAC setting, we appreciate the commenter's suggestions and generally agree to the

importance of all payer data. That said, consistent with the other PAC settings' post-discharge hospital readmission measures, such a cross-setting measure for this setting is currently under development as a claims based measure thereby limiting its denominator to Medicare claims data and we intend to standardize denominator and numerator definitions. With regard to NQF endorsement as a cross-setting measure, as mentioned previously, when possible we will propose and adopt a measure that has been endorsed by the NQF. However, when this is not feasible, the IMPACT Act in section 1899B(e)(2)(B), permits the Secretary to adopt a measure for the QRPs that is not NQF-endorsed. We want to clarify that the IMPACT Act does allow for program-related risk adjustment, as appropriate, and we intend to risk adjust the readmission measure intended to satisfy the IMPACT Act domain, which is an all-condition risk-adjusted potentially preventable hospital readmission rate. We appreciate the commenter's concern that CMS ensure the development of a medication reconciliation measure and although the Medication Reconciliation domain of the IMPACT Act was not addressed in this year's SNF proposed rule, we are currently in the process of developing a cross-setting measure to address this domain of care.

Comment: One commenter made several suggestions regarding the process CMS should use when developing future measures. The commenter recommended that CMS seek additional stakeholder input as it develops more detailed specifications for the measures under consideration for future years and that CMS seek NQF endorsement for future measures prior to including them in rulemaking.

Response: We will take the recommendations into consideration in our measure development and testing efforts, as well as in our ongoing efforts to identify and propose appropriate measures for the SNF QRP in the future. We recognize the need for transparency as we move forward to implement the provisions of the IMPACT Act and plan to continue to engage stakeholders to ensure that our approach to implementation is communicated in an open and informative manner.

Comment: Two commenters requested that CMS consider the CARE-C and CARE-F items based on the National Outcomes Measurement System (NOMS) to capture communication, cognition, and swallowing as additional measures to be adopted in post-acute care settings for future measures. One commenter encourages CMS and other measure developers to consider

functional items such as velocity or gait speed which may provide a more meaningful picture of the quality of mobility performance versus ambulation distance.

Response: We note that comments on the addition of areas of function, including cognition, communication, and swallowing are addressed further in section III.D.3.e. iii., Quality Measure Addressing the Domain of Functional Status, Cognitive Function, and Changes in Function and Cognitive Function: Application of Percent of Long-Term Care Hospital Patients With an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631; endorsed on July 23, 2015). We appreciate the suggestion that we consider functional items such as velocity or gait speed which may provide a more meaningful picture of the quality of mobility performance versus ambulation distance. We will consider these recommendations in our item and measure development and testing efforts for both measure development as well as standardized assessment domain development.

g. Form, Manner, and Timing of Quality Data Submission

(1) Participation/Timing for New SNFs

Beginning with the submission of data required for the FY 2018 payment determination, we proposed that a new SNF would be required to begin reporting data on any quality measures finalized for that program year by no later than the first day of the calendar quarter subsequent to 30 days after the date on its CMS Certification Number (CCN) notification letter. For example, for FY 2018 payment determinations, if a SNF received its CCN on August 28, 2016, and 30 days are added (for example, August 28 + 30 days = September 27), the SNF would be required to submit data for residents who are admitted beginning on October 1, 2016.

We invited public comments on this proposed timing for new SNFs to begin reporting quality data under the SNF QRP. However we received no comments on this proposal.

Final Decision: We are finalizing our proposal pertaining to the Participation/Timing for New SNFs as proposed.

(2) Data Collection Timelines and Requirements for the FY 2018 Payment Determination and Subsequent Years

As discussed previously, we proposed that SNFs would submit data on the proposed functional status, skin integrity, and incidence of major falls

measures by completing items on the MDS and then submitting the MDS to CMS through the Quality Improvement and Evaluation System (QIES), Assessment Submission and Processing System (ASAP) system. We sought comment on the proposed method of data collection.

We received no comments on the use of the MDS as the proposed method for data collection and the QIES ASAP system for data submission. Therefore, we are finalizing this approach as proposed.

Currently, there is no discharge assessment required when a resident is discharged from the SNF Medicare Part A covered stay but does not leave the facility, and we are aware that this affects nearly 30 percent of all SNF residents. To collect the data at the time these beneficiaries are discharged from the SNF Part A covered stay, we proposed to add an item set in addition to the 5-Day PPS Assessment. Further, to collect the data elements required to calculate the function quality measure (an application of Percent of Long-Term Care Hospital Patients With an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function [NQF #2631; endorsed on July 23, 2015]) at the time of a residents admission, we also proposed to add the necessary items to the 5-day PPS Assessment.

A list of the data items that we are proposed to add to the SNF PPS Part A Discharge and the 5-Day PPS Assessments is available on our Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.html>. We recognize that there may be instances where SNFs want to combine the SNF PPS Part A Discharge Assessment with other required assessments, as happens with other PPS and OBRA assessments, or scenarios in which the end of the Part A covered stay occurs at the same time as a scheduled PPS assessment. Therefore, we invited public comment on any situations where assessments may be combined or interact, which should be considered in implementing the SNF PPS Part A Discharge Assessment with a view toward addressing any issues that we may identify through the public comment process as requiring additional clarification.

We invited public comments on our proposed SNF QRP Data Collection Requirements for the FY 2018 Payment Determination and Subsequent Years.

Comment: One commenter recommended that CMS shorten the MDS discharge assessment to only information needed to construct the measures since the information will not be used in patient care, suggesting that its use pertained to the IMPACT Act requirements for collecting information at admission and discharge for measurement purposes. The commenter also recommended that the OBRA Admission assessment should be completed as a dually coded assessment with the PPS 5-day assessments in order that admission assessments for measures are aligned for all Medicare and Non-Medicare beneficiaries, such as Medicare Advantage beneficiaries.

Response: The discharge assessment is intended to collect the standardized data used to calculate the measures. Therefore, the SNF PPS Part A Discharge includes only the discharge assessment data needed to inform current and future SNF QRP measures and the calculation of those measures. With regard to the commenter's recommendation that the OBRA Admission assessment be dually coded with the 5-day assessment, we note that this type of combination is possible under the current system, though not required.

Comment: Several commenters suggested that the MDS was designed as an assessment for adults and does not address the needs of individuals under 21 years of age, specifically children with complex medical needs like an intellectual or developmental disability. Though NFs that treat pediatric residents complete the MDS for those residents, it is not an appropriate tool to measure resident needs or to use as the basis of a comprehensive care plan for pediatric residents. Thus, the commenter requested that pediatric NFs be exempted from completing the MDS for their residents, and that data from the MDS not be utilized for the quality measures of pediatric NFs, or that CMS adopt an assessment instrument for pediatric SNFs that reflect the unique areas of focus.

In addition, one commenter suggests that residents of a sub-acute SNF unit are at elevated risk for medical complications due to their chronic, long-term, acute illnesses, when compared to residents of other SNF units. Due to the differences between residents of sub-acute SNF units and "regular" SNFs, the commenter requests that an additional field be added to the MDS to identify sub-acute SNF residents.

Response: The MDS was designed with numerous groups in mind, including pediatric nursing home

residents and their caregivers. In addition, data submission to CMS for the purposes of the SNF QRP requires the submission of such data while the resident is under a Part A covered stay. Regarding the comment on sub-acute units, we will take the recommendation into consideration.

Comment: One commenter expressed concerns about the accuracy of the MDS data that will be used to calculate the new quality measures. The commenter noted that the MDS 3.0 Focused Survey Pilot conducted by CMS found “room for improvement in MDS 3.0 assessment agreement with a resident’s medical record, especially in the reporting of the severity and frequency of falls, late loss ADL status, pressure ulcer status, restraint use, and coding of certain diagnoses including UTI.” The commenter suggested that additional steps are necessary to improve data accuracy, such as revising and testing revisions to the survey protocol, drafting additional guidance and requiring additional training for surveyors, conducting special surveys of resident assessments, reporting on Nursing Home Compare when data are invalid, and promulgating regulations to require penalties for violations of assessment requirements.

Response: We agree that training is critical to assure both provider accuracy and understanding of the assessment and data collection requirements. We appreciate the commenter’s suggestions pertaining to use of various means to ensure accuracy, such as surveyor-related protocols and activities as well as the use of Nursing Home Compare for the reporting of data and will take these into consideration. We discuss below our intention to develop a data validation program to ensure that SNF QRP data is accurately reported.

Comment: One commenter expressed that it is unclear about the timeframe in which additional items will be added to the MDS item sets. The commenter recommended that CMS standardize and align the PAC assessments (MDS, OASIS, IRF-PAI, and LTCH-CARE) prior to finalizing the proposed quality measures. The commenter suggested that after the PAC assessments are aligned, CMS should utilize a period of testing for the proposed measures. The commenter also suggested that the quarterly reporting of claims data requires that hospital claims and PAC provider claims be tracked simultaneously and will likely delay the production of data which can be reported to providers if provider claims are not submitted in a timely manner.

Response: We appreciate the commenter’s interest in clarification on

the timelines related to implementation of the assessment changes required for the submission of the standardized data for measures finalized in this rule. The implementation of the revised assessment instruments for data collection of the finalized measures is October 1, 2016. We appreciate the suggestion to standardize the post-acute assessment instruments prior to finalizing the measures; however, such an approach may not be feasible when, for example, the modification of the instruments is a result of a new measure using new items. In that instance, rulemaking is necessary to finalize such measures before subsequent assessment changes can be determined. That said, we will attempt to develop measures where appropriate from existing items. We agree that testing is imperative and through ongoing measure development and maintenance we apply such testing and intend to continue to do so. Additionally, we attempt to use endorsed measures where able, however, under certain circumstances, for reasons discussed earlier and under our authority to do so, we may elect to propose measures that are not endorsed. We appreciate the commenter’s concern regarding the quarterly reporting of claims data and potential delays, although we do not foresee such an issue. Nonetheless, we will monitor for this possibility.

Comment: Several commenters suggested that we had inaccurately estimated the economic impact associated with the burden of collection of the new assessment items used to calculate the proposed quality measures. Commenters suggested that the assessment of 0.5 minutes of nursing staff time per each new item was too low because it didn’t take into account the time for a beneficiary to complete tasks associated with self-care or mobility, or the time necessary to navigate through a data entry system. One commenter also noted that the function items take into account a person’s *usual* function, over the course of days 1 to 3 days, which they feel implies that activities need to be assessed multiple times, adding burden. Another commenter stated that the economic impact analysis did not account for staff training. Similarly, commenters stated that the economic analysis did not factor in the providers’ software and hardware costs. We also received a comment pertaining to changes in payer source during a resident’s stay, noting a concern that adding additional payer sources could also add additional burden. We also received a comment requesting that

CMS provide additional payment to the providers during the time that they implement the new assessment items.

Response: We appreciate the concerns related to the assessment of costs associated with the data collection for the SNF QRP. In response to commenters’ concerns regarding our estimate of nursing facility staff time per item, we would like to clarify that this is an estimate only of the time spent determining and documenting the score following the observation of the patient. The burden-related estimates used to evaluate the economic impact are based on assessment data coding and would not take into account computer system delays or other such features. In response to the comment regarding multiple assessments required to assess usual function by the new section GG function items, we would like to clarify that only one score is reported for each item in section GG, the resident’s usual performance. Clinicians assess the resident’s functional abilities once or several times during an assessment period as part of routine practice. Consistent with the current function items in the MDS (section G), section GG considers the resident’s ability to perform an activity across the entire assessment period. Such clinical assessment and data collection is based upon customary and best practices that we believe would be occurring. We also note that, to minimize burden on providers, these items are only required for data collection at the time of admission and discharge. Further, to ensure minimal burden the new items found in section GG, we include several gateway questions that allow the clinician to skip questions in the data set that are not appropriate for an individual patient in order to reduce burden. We have instituted skip options so that the final number of items assessed per patient is limited depending on their complexity and capabilities. Therefore, although all of the items are available for assessment, we have built in mechanism that enables the assessor to include assessment information as, and when, appropriate.

With regard to the commenter’s concerns surrounding training and software/hardware costs, we recognize that with item set changes, there are necessary training and software updates that may be needed. Although the burden estimate would not be a reflection of individual provider training needs, or those related to software and hardware, we do include in the cost estimates cost pertaining to overhead. That said, CMS provides free of charge the submission specifications,

as well as free, downloadable software to providers and we intend to provide provider based training that would be free of charge, as we have done in the past. With regard to increased costs associated with all payer data capture, there already exists administrative-related data capture in the MDS 3.0, and therefore, such data capture, should we require all payer data in the future, would not come with additional burden.

We believe that we have accounted for the costs of reporting data in our burden estimates, as they are doubled to provide for overhead and fringe benefits, which should include costs associated with any required staff training related to the collection of new items. However, additionally, we do not include in our burden estimates the time that it takes providers to enter the data into their systems, as this is a part of routine clinical care and medical charting, and the data we require providers to report is routine in this respect as well.

Having carefully considered the comments we received on our proposal

pertaining to the Data Collection Requirements for the FY 2018 Payment Determination and Subsequent Years, we are finalizing the policy as proposed.

For the FY 2018 payment determination, we proposed that SNFs submit data on the three proposed quality measures for residents who are admitted to the SNF on and after October 1, 2016, and discharged from the SNF up to and including December 31, 2016, using the data submission schedule that we proposed in this section.

We proposed to collect a single quarter of data for FY 2018 to remain consistent with the usual October release schedule for the MDS, to give SNFs a sufficient amount of time to update their systems so that they can comply with the new data reporting requirements, and to give CMS a sufficient amount of time to determine compliance for the FY 2018 program. The proposed use of one quarter of data for the initial year of quality reporting is consistent with the approach we used to implement a number of other QRPs,

including the LTCH, IRF, and Hospice QRPs.

We also proposed that following the close of the reporting quarter, October 1, 2016, through December 31, 2016, for the FY 2018 payment determination, SNFs would have an additional 5½ months to correct and/or submit their quality data. Consistent with the IRF QRP, we proposed that the final deadline for submitting data for the FY 2018 payment determination would be May 15, 2017. We further proposed that for the FY 2019 payment determination, we would collect data from the 2nd through 4th quarters of FY 2017 (that is, data for residents who are admitted from January 1st and discharged up to and including September 30th) to determine whether a SNF has met its quality reporting requirements for that FY. Beginning with the FY 2020 payment determination, we proposed to move to a full year of FY data collection. We intended to propose the FY 2019 payment determination quality reporting data submission deadlines in future rulemaking.

TABLE 11—PROPOSED MEASURES, DATA COLLECTION SOURCE, DATA COLLECTION PERIOD AND DATA SUBMISSION DEADLINES AFFECTING THE FY 2018 PAYMENT DETERMINATION

Quality measure	Data collection source	Proposed data collection period	Proposed data submission deadline for FY 2018 payment determination
NQF #0678: Percent of Patients or Residents with Pressure Ulcers that are New or Worsened.	MDS	10/01/16–12/31/16	May 15, 2017.
NQF #0674: Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay).	MDS	10/01/16–12/31/16	May 15, 2017.
NQF #2631:* Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function.	MDS	10/01/16–12/31/16	May 15, 2017.

* Status: NQF-endorsed on July 23, 2015, please see: <http://www.qualityforum.org/ProjectMeasures.aspx?projectId=73867>, see NQF #2631.

We invited public comment on Proposed Measures, Data Collection Source, Data Collection Period and Data Submission Deadlines Affecting the FY 2018 Payment Determination. The comments we received on this topic, with their responses, appear below.

Comment: One commenter expressed support for CMS’s proposed timing for new SNFs to begin reporting quality data. One commenter requested that data from the MDS be made publicly available sooner than 2 years after the specified application date for the measure. The commenter suggested that collecting only one quarter of data between October 1 and December 31, 2016 is not sufficient to establish data trending. The commenter requested that at least 2 quarters be used for FY 2018 payment determination, and by FY 2019 a full year’s worth of data should be

used. Another commenter expressed that facilities should not be given 5½ months to submit or correct their quarterly data.

Response: We appreciate the suggestion regarding extending the timing of data collection to establish sufficient data trending. We proposed to collect a single quarter of data for FY 2018 to remain consistent with the usual October release for the MDS, to give SNFs a sufficient amount of time to update their systems so that they can comply with the new data reporting requirements, and to give CMS a sufficient amount of time to determine compliance for the FY 2018 program. The proposed use of one quarter of data for the initial year of quality reporting is consistent with the approach we used to implement a number of other QRPs,

including the LTCH, IRF, and Hospice QRPs. With regard to the 5½ month post-data collection period, this Proposed Data Submission timeframe and final deadline for FY 2018 Payment Determination is to allow providers an opportunity to ensure that the data from the collection period has been submitted and is accurate and corrections, where necessary, have been made. We have aligned these timeframes with the LTCH, and IRF and other QRPs. We appreciate and will take into consideration the commenter’s suggestion to implement public reporting sooner.

Final Decision: Having carefully considered the comments we received on Proposed Measures, Data Collection Source, Data Collection Period and Data Submission Deadlines Affecting the FY 2018 Payment Determination we are finalizing the policy as proposed.

h. SNF QRP Data Completion Thresholds for the FY 2018 Payment Determination and Subsequent Years

We proposed that, beginning with the FY 2018 payment determination, SNFs must report all of the data necessary to calculate the proposed quality measures on at least 80 percent of the MDS assessments that they submit. We proposed that a SNF has reported all of the data necessary to calculate the measures if the data actually can be used for purposes of calculating the quality measures, as opposed to, for example, the use of a dash [-], to indicate that the SNF was unable to perform a pressure ulcer assessment.

We believe that because SNFs have long been required to submit MDS assessments for other purposes, SNFs should easily be able to meet this proposed requirement for the SNF QRP. Our proposal to set reporting thresholds is consistent with policies we have adopted for the Long-Term Care Hospital (79 FR 50314), Inpatient-Rehabilitation Hospital (79 FR 45923) and Home Health (79 FR 66079) QRPs.

Although we proposed to adopt an 80 percent threshold initially, we stated our intention to propose to raise the threshold level for subsequent program years through future rulemaking.

We also proposed that for the FY 2018 SNF QRP, any SNF that does not meet the proposed requirement that 80 percent of all MDS assessments submitted contain 100 percent of all data items necessary to calculate the SNF QRP measures would be subject to a reduction of 2 percentage points to its FY 2018 market basket percentage.

We invited comment on the proposed SNF QRP data completion requirements. The comments we received on this topic, with their responses, appear below.

Comment: One commenter expressed support for the application of a 2 percent penalty for incomplete reporting of the quality data necessary to calculate NQF endorsed measures. This commenter states that this support extends only to those measures with NQF endorsement as they believe that the 2 percent incentive would ensure that providers are collecting data necessary to implement the IMPACT Act.

Response: Section 1888(e)(6)(A)(i) of the Act requires that, for FYs beginning with FY 2018, if a SNF does not submit data, as applicable, on quality and resource use and other measures in accordance with section 1888(e)(6)(B)(i)(II) of the Act and standardized patient assessment in accordance with section

1888(e)(6)(B)(i)(III) of the Act for such FY, the Secretary must reduce the SNF's market basket percentage described in section 1888(e)(5)(B)(ii) of the Act by 2 percentage points. As we have discussed above, we are not limited to adopting for the SNF QRP only measures that have been endorsed by the NQF, and to the extent that a SNF fails to satisfactorily report one or more SNF QRP measures that are not NQF-endorsed, we would be statutorily obligated to reduce the SNF's market basket percentage for the applicable fiscal year by 2 percentage points.

Comment: One commenter does not support the proposed 80 percent threshold for completion of all of the data necessary to calculate the quality measure. This commenter expressed concern that data could be omitted resulting in negative quality measure results. Their recommendation is to increase the threshold to 90 percent. Another commenter recommended lowering the threshold from 80 percent to 40 percent during the first 2 years of data collection.

Response: Our proposal to set reporting thresholds is consistent with policies we have adopted for the Long-Term Care Hospital (79 FR 50314), Inpatient-Rehabilitation Hospital (79 FR 45923) and Home Health (79 FR 66079) QRPs. SNF providers have been submitting the MDS for many years and we disagree that we should lower the submission threshold as suggested. However, we intend to reevaluate our threshold over time and will propose to modify it, if warranted, based on our analysis.

Comment: One commenter requested clarification on what constitutes data that is "satisfactorily" submitted.

Response: We are finalizing that data will have been satisfactorily submitted for the FY 2018 SNF QRP if the SNF has reported all of the data necessary to calculate the finalized measures and that the data can actually be used for purposes of calculating the quality measures, as opposed to, for example, the use of a dash [-], to indicate that the SNF was unable to perform a pressure ulcer assessment.

After consideration of the public comments received, we are finalizing the adoption of the policy for SNF QRP Data Completion Thresholds for the FY 2018 Payment Determination and Subsequent Years as proposed.

i. SNF QRP Data Validation Requirements for the FY 2018 Payment Determination and Subsequent Years

To ensure the reliability and accuracy of the data submitted under the SNF QRP, we proposed to adopt policies and

processes for validating the data submitted under the SNF QRP in future rulemaking. We received the following comments on elements we should consider including in such a process:

Comment: One commenter expressed concern that CMS is not ensuring that the data submitted by SNFs is accurate. Specifically, the commenter suggested that self-reported MDS data are unreliable and are subject to gaming and that a variety of media outlets and CMS itself have reported on data accuracy concerns. The commenter suggested that facilities may electively omit data for residents whose health is deteriorating. The commenter supported CMS asking for the identification of elements to validate the data that SNFs submit and suggested several ways that CMS may validate the data. Another commenter recommended that CMS revisit the 2014 MDS-focused survey process assessing MDS Version 3.0 coding practices to help inform SNF QRP validation requirements.

Response: We appreciate the concerns pertaining to gaming and note that we will apply a threshold for reporting of complete resident data for the FY 2018 SNF QRP. As part of our compliance analysis, we intend to carefully monitor rates of missing data across all facilities. Further, we intend to align with other QRPs and propose through future rulemaking data validation policies.

Comment: One commenter suggested several recommendations for elements CMS should include to ensure the reliability and accuracy of data submitted for the SNF QRP. CMS should explore a combination of pure data checks to identify inconsistencies that exist between items relevant to the SNF QRP and other items reported in the MDS and audit suspicious data patterns. Another commenter suggested providing a list of validation checks that could be used by both providers and vendors to help improve the accuracy of data. Another commenter recommended public reporting on Nursing Home Compare when facilities submit invalid data and stricter regulations that require specific penalties for violations of resident assessment requirements.

Response: We appreciate the commenters' suggestions to ensure data accuracy such as a combination of pure data checks to identify inconsistencies. We agree with this approach and intend to perform such monitoring as part of overall programmatic monitoring and evaluation. We encourage providers to engage in available opportunities to improve the accuracy of their data. We appreciate the suggestion that we make public on Nursing Home Compare when facilities submit to CMS invalid data,

and will also take under consideration the suggestion that we implement additional regulatory requirements on this issue.

We thank the commenters for their input on policies that we should consider pertaining to data validation and accuracy analysis.

j. SNF QRP Submission Exception and Extension Requirements for the FY 2018 Payment Determination and Subsequent Years

Our experience with other QRPs has shown that there are times when providers are unable to submit quality data due to extraordinary circumstances beyond their control (for example, natural, or man-made disasters). Other extenuating circumstances are reviewed on a case-by-case basis. We have defined 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 and impact multiple structures or be isolated and impact a single site only.

In certain instances of either natural or man-made disasters, a SNF may have the ability to conduct a full resident assessment, and record and save the associated data either during or before the occurrence of the extraordinary event. In this case, the extraordinary event has not caused the facility’s data files to be destroyed, but it could hinder the SNF’s ability to meet the QRP’s data submission deadlines. In this scenario, the SNF would potentially have the ability to report the data at a later date, after the emergency has passed. In such cases, a temporary extension of the deadlines for reporting might be appropriate.

In other circumstances of natural or man-made disaster, a SNF may not have had the ability to conduct a full resident assessment, or to record and save the associated data before the occurrence of the extraordinary event. In such a scenario, the facility may not have complete data to submit to CMS. We believe that it may be appropriate, in these situations, to grant a full exception to the reporting requirements for a specific period of time.

We do not wish to penalize SNFs in these circumstances or to unduly

increase their burden during these times. Therefore, we proposed a process for SNFs to request and for us to grant exceptions and extensions with respect to the quality data reporting requirements of the SNF QRP for one or more quarters, beginning with the FY 2018 payment determination, when there are certain extraordinary circumstances beyond the control of the SNF. When an exception or extension is granted, we would not reduce the SNF’s PPS payment for failure to comply with the requirements of the SNF QRP.

We proposed that if a SNF seeks to request an exception or extension for the SNF QRP, the SNF should request an exception or extension within 90 days of the date that the extraordinary circumstances occurred. The SNF may request an exception or extension for one or more quarters by submitting a written request to CMS that contains the information noted below, via email to the SNF Exception and Extension mailbox at SNFQRPreconsiderations@cms.hhs.gov. Requests sent to CMS through any other channel will not be considered as valid requests for an exception or extension from the SNF QRP’s reporting requirements for any payment determination.

We note that the subject of the email must read “SNF QRP Exception or Extension Request” and the email must contain the following information:

- SNF CCN;
- SNF 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);
- SNF’s reason for requesting an exception or extension;
- Evidence of the impact of extraordinary circumstances, including but not limited to photographs, newspaper and other media articles; and
- A date when the SNF believes it will be able to again submit SNF QRP data and a justification for the proposed date.

We proposed that exception and extension requests be signed by the SNF’s CEO or CEO-designated personnel, and that if the CEO designates an individual to sign the request, the CEO-designated individual has the appropriate authority to submit such a request on behalf of the SNF. Following receipt of the email, we will: (1) Provide a written acknowledgement, using the contact information provided in the email, to the CEO or CEO-designated contact notifying them that the request has been received; and (2) provide a formal response to the CEO or any CEO-designated SNF personnel,

using the contact information provided in the email, indicating our decision.

This proposal does not preclude us from granting exceptions or extensions to SNFs 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 an exception or extension to all SNFs in a region or locale, we proposed to communicate this decision through routine communication channels to SNF’s and vendors, including, but not limited to, issuing memos, emails, and notices on our SNF QRP Web site once it is available at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/SNF-QR-Reconsideration-and-ExceptionExtension.html>.

We also proposed that we may grant an exception or extension to SNFs if we determine that a systemic problem with one of our data collection systems directly affected the ability of the SNF to submit data. Because we do not anticipate that these types of systemic errors will happen often, we do not anticipate granting an exception or extension on this basis frequently.

If a SNF is granted an exception, we will not require that the SNF submit any measure data for the period of time specified in the exception request decision. If we grant an extension to a SNF, the SNF will still remain responsible for submitting quality data collected during the timeframe in question, although we will specify a revised deadline by which the SNF must submit this quality data.

We also proposed that any exception or extension requests submitted for purposes of the SNF QRP will apply to that program only, and not to any other program we administer for SNFs such as survey and certification. MDS requirements, including electronic submission, during Declared Public Health Emergencies can be found at FAQs K–5, K–6, and K–9 on the following link: <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/downloads/AllHazardsFAQs.pdf>.

We intend to provide additional information pertaining to exceptions and extensions for the SNF QRP, including any additional guidance, on the SNFQRP Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/SNF-QR-Reconsideration-and-ExceptionExtension.html>. We invited public comment on these proposals for seeking and being granted exceptions

and extensions to the quality reporting requirements. The following is a summary of the comments received and our responses.

Comment: Many commenters expressed strong support for the creation of an exception and extension request process for SNFs that experience disasters or other extraordinary circumstances.

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

After consideration of the public comments received, we are finalizing the adoption of the policy for SNF QRP Submission Exception and Extension Requirements for the FY 2018 Payment Determination and Subsequent Years.

k. SNF QRP Reconsideration and Appeals Procedures for the FY 2018 Payment Determination and Subsequent Years

At the conclusion of the required quality data reporting and submission period, we will review the data received from each SNF during that reporting period to determine if the SNF met the quality data reporting requirements. SNFs that are found to be noncompliant with the reporting requirements for the applicable FY will receive a 2 percentage point reduction to their market basket percentage update for that FY.

We are aware that some of our other QRPs, such as the HIQR Program, the LTCHQR Program, and the IRF QRP include an opportunity for the providers to request a reconsideration of our initial non-compliance determination. Therefore, to be consistent with other established QRPs and to provide an opportunity for SNFs to seek reconsideration of our initial non-compliance decision, we proposed a process that will enable a SNF to request reconsideration of our initial non-compliance decision in the event that it believes that it was incorrectly identified as being non-compliant with the SNF QRP reporting requirements for a particular FY.

For the FY 2018 payment determination, and that of subsequent years, we proposed that a SNF would receive a notification of noncompliance if we determine that the SNF did not submit data in accordance with the data reporting requirements with respect to the applicable FY. The purpose of this notification is to put the SNF on notice of the following: (1) That the SNF has been identified as being non-compliant with the SNF QRP's reporting requirements for the applicable FY; (2) that the SNF will be scheduled to receive a reduction in the amount of two percentage points to its market basket

percentage update for the applicable FY; (3) that the SNF may file a request for reconsideration if it believes that the finding of noncompliance is erroneous, has submitted a request for an extension or exception that has not yet been decided, or has been granted an extension or exception; and (4) that the SNF must follow a defined process on how to file a request for reconsideration, which will be described in the notification. We would only consider requests for reconsideration after an SNF has been found to be noncompliant.

Notifications of noncompliance and any subsequent notifications from CMS would be sent via a traceable delivery method, such as certified U.S. mail or registered U.S. mail, or through other practicable notification processes, such as a report from CMS to the provider as a Certification and Survey Provider Enhanced Reports (CASPER) report, that will provide information pertaining to their compliance with the reporting requirements for the given reporting cycle. To obtain the CASPER report, providers should access the CASPER Reporting Application. Information on how to access the CASPER Reporting Application is available on the Quality Improvement Evaluation System (QIES) Technical Support Office Web site (direct link), <https://web.qiesnet.org/qiestosuccess/>. Once access is established providers can select "CASPER Reports" link. The "CASPER Reports" link will connect a SNF to the QIES National System Login page for CASPER Reporting.

We invited comments on the most preferable delivery method for the notice of non-compliance, such as U.S. Mail, email, CASPER, etc. The comments we received on this topic, with their responses, appear below.

Comment: One commenter suggested the use of QIES to communicate notices of non-compliance. Another commenter suggested that non-compliance notifications be sent via multiple mechanisms to ensure delivery, including CASPER reports and a traceable delivery method.

Response: We intend to provide further guidance regarding the delivery method for the notices of non-compliance in future rulemaking.

We proposed to disseminate communications regarding the availability of compliance reports in the CASPER reports through routine channels to SNFs and vendors, including, but not limited to issuing memos, emails, Medicare Learning Network (MLN) announcements, and notices on our SNF QRP Web site once it is available at <http://www.cms.gov/>

Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/SNF-QR-Reconsideration-and-ExceptionExtension.html.

A SNF would have 30 days from the date of the initial notification of noncompliance to submit to us a request for reconsideration. This proposed time frame allows us to balance our desire to ensure that SNFs have the opportunity to request reconsideration with our need to complete the process and provide SNFs with our reconsideration decision in a timely manner. We proposed that a SNF may withdraw its request at any time and may file an updated request within the proposed 30-day deadline. We also proposed that, in very limited circumstances, we may grant a request by a SNF to extend the proposed deadline for reconsideration requests. It would be the responsibility of a SNF to request an extension and demonstrate that extenuating circumstances existed that prevented the filing of the reconsideration request by the proposed deadline.

We also proposed that as part of the SNF's request for reconsideration, the SNF would be required to submit all supporting documentation and evidence demonstrating full compliance with all SNF QRP reporting requirements for the applicable FY, that the SNF has requested an extension or exception for which a decision has not yet been made, that the SNF has been granted an extension or exception, or has experienced an extenuating circumstance as defined in section III.D.3.j. of this rule but failed to file a timely request of exception. We proposed that we would not review any reconsideration request that fails to provide the necessary documentation and evidence along with the request.

The documentation and evidence may include copies of any communications that demonstrate the SNF's compliance with the SNF QRP, as well as any other records that support the SNF's rationale for seeking reconsideration, but should not include any protected health information (PHI). We intended to provide a sample list of acceptable supporting documentation and evidence, as well as instructions for SNFs on how to retrieve copies of the data submitted to CMS for the appropriate program year in the future on our SNF QRP Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/SNF-QR-Reconsideration-and-ExceptionExtension.html>.

We proposed that a SNF wishing to request a reconsideration of our initial

noncompliance determination would be required to do so by submitting an email to the following email address: SNFQRPreconsiderations@cms.hhs.gov. Any request for reconsideration submitted to us by a SNF would be required to follow the guidelines outlined on our SNF QRP Web site once it is available at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/SNF-QR-Reconsideration-and-ExceptionExtension.html>.

All emails must contain a subject line that reads "SNF QRP Reconsideration Request." Electronic email submission is the only form of reconsideration request submission that will be accepted by us. Any reconsideration requests communicated through another channel including, but not limited to, U.S. Postal Service or phone, will not be considered as a valid reconsideration request.

We proposed that a reconsideration request include the following information:

- SNF CMS Certification Number (CCN);

- SNF Business Name;
- SNF Business Address;
- The CEO contact information

including name, email address, telephone number and physical mailing address; or

The CEO-designated representative contact information including name, title, email address, telephone number and physical mailing address; and

- CMS identified reason(s) for non-compliance from the non-compliance notification; and

- The reason(s) for requesting reconsideration

The request for reconsideration must be accompanied by supporting documentation demonstrating compliance.

Following receipt of a request for reconsideration, we will provide an email acknowledgment, using the contact information provided in the reconsideration request, to the CEO or CEO-designated representative that the request has been received. Once we have reached a decision regarding the reconsideration request, an email will be sent to the SNF CEO or CEO-designated representative, using the contact information provided in the reconsideration request, notifying the SNF of our decision.

We also proposed that the notifications of our decision regarding reconsideration requests may be made available through the use of CASPER reports or through a traceable delivery method, such as certified U.S. mail or registered U.S. mail. If the SNF is

dissatisfied with the decision rendered at the reconsideration level, the SNF may appeal the decision to the PRRB under 42 CFR 405.1835. We believe this proposed process is more efficient and less costly for CMS and for SNFs because it decreases the number of PRRB appeals by resolving issues earlier in the process. Additional information about the reconsideration process including details for submitting a reconsideration request will be posted in the future to our SNF QRP Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/SNF-QR-Reconsideration-and-ExceptionExtension.html>. We invited public comment on the proposed procedures for reconsideration and appeals. The following is a summary of the comments received and our responses.

Comment: Many commenters supported the policy to allow SNFs an opportunity to submit reconsideration requests. One commenter recommended extending the appeal timeline from 30 to 45 days if CMS does not provide for a timely notification method.

Response: To remain consistent with our other QRPs which have successfully implemented a reconsideration process, we believe that 30 days is sufficient.

Final Decision: After consideration of the public comments received, we are finalizing the adoption of the policy for SNF QRP Reconsideration and Appeals Procedure for the FY 2018 Payment Determination and Subsequent Years.

l. Public Display of Quality Measure Data for the SNF QRP

Section 1899B(g)(1) of the Act requires the Secretary to provide for the public reporting of SNF provider performance on the quality measures specified under subsection (c)(1) and the resource use and other measures specified under subsection (d)(1) by establishing procedures for making available to the public data and information on the performance of individual SNFs with respect to the measures. Under section 1899B(g)(2) of the Act, such procedures must be consistent with those under section 1886(b)(3)(B)(viii)(VII) of the Act and also allow SNFs the opportunity to review and submit corrections to the data and other information before it is made public. Section 1899B(g)(3) of the Act requires that the data and information be made publicly available not later than 2 years after the specified application date applicable to such a measure and provider. Finally, section 1899B(g)(4)(B) of the Act requires such procedures be consistent with sections

1819(i) and 1919(i) of the Act. We stated our intention to propose details related to the public display of quality measures in the future. The following is a summary of the comments received and our responses.

Comment: One commenter suggested that CMS replace or add to the existing measures on Nursing Home Compare when measures that meet the IMPACT Act requirements are adopted. This commenter further suggested adjustment to the thresholds used in assigning Star Ratings to the quality measures, and cautioned CMS to compare SNFs against performance of meaningful scores on the quality measures rather than against their respective rankings. The commenter also suggested the formation of a TEP to develop a method on how to publicly report in a single cross-setting report that compares PAC performance across PAC providers, as well as assist in the development of meaningful targets on quality measures. One commenter stated that the imposition of a financial penalty should be publicly reported.

Response: We will take these recommendations into consideration as we develop the process for the public display of data and information on the performance of individual SNFs with respect to the measures.

m. Mechanism for Providing Feedback Reports to SNFs

Section 1899B(f) of the Act requires the Secretary to provide confidential feedback reports to post-acute care providers on their performance with respect to the measures specified under subsections (c)(1) and (d)(1), beginning 1 year after the specified application date that applies to such measures and PAC providers. We intended to provide detailed procedures to SNFs on how to obtain their confidential feedback reports on the SNF QRP Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/SNF-Quality-Reporting.html>. The following is a summary of the comments received and our responses.

Comment: One commenter recommended that CMS use the same mechanism currently used by SNFs for previewing Five Star data and allow SNFs to preview all of the quality measures on Nursing Home Compare. The commenter also suggested that CMS use the QIES system so that all SNFs can preview their individual reports on a weekly basis.

Response: We will take the suggestion into consideration as we develop the mechanism for providing feedback reports to SNFs.

4. Staffing Data Collection

a. Background and Statutory Authority

Section 1819(d)(1)(A) of the Act for SNFs and section 1919(d)(1)(A) of the Act for NFs each state that, in general, a facility must be administered in a manner that enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident. Sections 1819(d)(4)(B) and 1919(d)(4)(B) of the Act give the Secretary authority to issue rules, for SNFs and NFs respectively, relating to the health, safety and well-being of residents and relating to the physical facilities thereof.

The Affordable Care Act of 2010 (Pub. L. 111–148, March 23, 2010) added a new section 1128I to the Act to promote greater accountability for LTC facilities (defined under section 1128I(a) of the Act as SNFs and nursing facilities). As added by the Affordable Care Act, section 1128I(g) pertains to the submission of staffing data by LTC facilities, and specifies that the Secretary, after consulting with state long-term care ombudsman programs, consumer advocacy groups, provider stakeholder groups, employees and their representatives and other parties the Secretary deems appropriate, shall require a facility to electronically submit to the Secretary direct care staffing information, including information for agency and contract staff, based on payroll and other verifiable and auditable data in a uniform format according to specifications established by the Secretary in consultation with such programs, groups, and parties. The statute further requires that the specifications established by the Secretary specify the category of work a certified employee performs (such as whether the employee is a registered nurse, licensed practical nurse, licensed vocational nurse, certified nursing assistant, therapist, or other medical personnel), include resident census data and information on resident case mix, be reported on a regular schedule, and include information on employee turnover and tenure and on the hours of care provided by each category of certified employees per resident per day. Section 1128I(g) of the Act establishes that the Secretary may require submission of information for specific categories, such as nursing staff, before other categories of certified employees, and requires that information for agency and contract staff be kept separate from information on employee staffing.

b. Provisions of the Proposed Rule and Response to Comments

As part of the FY 2016 SNF PPS proposed rule, we proposed to implement the new statutory requirement in section 1128I(g) of the Act. Specifically, we proposed to modify current regulations applicable to LTC facilities that participate in Medicare and Medicaid by amending the requirements for the administration of a LTC facility at § 483.75 to add a new paragraph (u), Mandatory submission of staffing information based on payroll data in a uniform format.

During the 60-day comment period on the proposed rule, we received approximately 22 timely comments on the staffing data collection proposal from individuals, providers, national and regional health care professional associations and advocacy groups. Summaries of the proposed provisions, as well as the public comments and our responses, are set forth below.

(1) Consultation on Specifications

As discussed in the FY 2016 SNF PPS proposed rule, we adopted a multi-pronged strategy to comply with section 1128I(g) of the Act's consultation requirement that includes both soliciting input from all interested parties through the rulemaking process and ongoing consultation with the statutorily identified entities regarding the sub-regulatory reporting specifications that we will establish. We invited public comment on our proposed methods for consultation on the submission specifications. The comments we received on this topic, with their responses, appear below.

Comment: One commenter suggested that CMS convene a TEP to design a structure and to clearly articulate the goals and purpose of the collected information prior to mandated reporting. Another commenter asked where it indicated in the rule that the specifications of staffing data would be based upon “. . . consultation with long-term care ombudsman programs, consumer advocacy groups, provider stakeholder groups, employees and their representatives.” This commenter proposed that CMS provide the result of those consultations with the aforementioned groups. Commenters further stated that it would seem such information could be valuable in the formation of a rational implementation of this particular provision of the Affordable Care Act. Other commenters stated that the designing of the reporting process should take into account differences among LTC providers, such as variations in size, location,

management and operations, including differences among payroll and time and attendance systems. Those commenters urged CMS, when implementing this new requirement, to assure opportunity for feedback and provider representation and participation across the full spectrum of nursing home structures and organization types, such as large, small, urban, rural, freestanding and multiple-site facilities, as well as regional companies and large companies.

Response: We are committed to consulting with stakeholders, including LTC facilities, consumer advocates, and other related groups. Through this rulemaking, we solicited input from all of the statutorily identified entities and this final rule reflects the outcome of that consultation. We are continuing our consultation on the sub-regulatory specifications through a variety of mechanisms. We have a regular dialogue with stakeholders through individual and national calls. These stakeholders represent a wide range of facilities throughout the country, including large and small, rural and urban, independently-owned facilities and national chains, and we have consulted with facilities with varying types of payroll and time keeping systems. In addition, we published a Draft Policy Manual (“1.0”) for the electronic staffing data submission payroll-based journal (“Draft PBJ Policy Manual”) that offers more details of planned technical specifications and invited comments that we continue to take into account as we develop and refine the specifications to implement this final rule. This manual is available at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Staffing-Data-Submission-PBJ.html>. We encourage stakeholders to email comments and requests to NHStaffing@cms.hhs.gov as another opportunity for consultation. We appreciate the suggestions from commenters on other mechanisms for consultation with stakeholders on our subregulatory specifications and we will consider these options as we continue our dialogue and engagement efforts throughout implementation.

(2) Scope of Submission Requirements

As noted above, section 1128(g) of the Act mandates that the Secretary require LTC facilities “to “to electronically submit to the Secretary direct care staffing information, including information for agency and contract staff, based on payroll and other verifiable and auditable data in a uniform format.” The proposed rule

used the statutory term “direct care staffing information” without elaboration. We received a number of comments regarding the scope of this term. Those comments and our responses are set forth below.

Comment: Several commenters asked that CMS define “direct care staff” and clarify the types of staff in the nursing facilities that are included in this reporting. Several commenters recommended we use the following definition; “Direct care staff means those individuals who provide care and services enabling the resident to receive the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care, as specified in § 483.25.” A few commenters recommended using the definition from the preamble of the October 2005 *Final Rule on Posting of Nurse Staffing Information* (70 FR 62065 available at <http://www.gpo.gov/fdsys/pkg/FR-2005-10-28/pdf/05-21278.pdf>), which states that direct care means that an individual is directly responsible for resident care, which includes, but is not limited to, such activities as assisting with activities of daily living (ADLs), performing gastro-intestinal feeds, giving medications, supervising the care given by CNAs, and performing nursing assessments to admit residents or notify physicians about a change in condition. Another commenter recommended defining direct care staff as staff having “hands on” care of a patient.

Several commenters expressed concern that the Draft PBJ Policy Manual suggested CMS planned to interpret the proposed regulation to require reporting of information on non-direct care employees and opined that this interpretation would go beyond what Congress intended. One commenter stated that nowhere in the Affordable Care Act, or the proposed rule, is there mention of the non-direct patient care services as direct care staff. They opined that some of the employee categories listed in the Draft PBJ Policy Manual, such as housekeeping and dietary, are generally not considered to be individuals that perform direct care. Commenters stated that it was not the intent of Congress to require reporting for individuals providing non-direct care services and that CMS’s interpretation would increase the burden beyond what is necessary, while at the same time not adding information that is helpful to the overall goal of the program. They stated that the interpretation by CMS of definitions of direct care staff in the Draft PBJ Policy Manual broadens the scope and breadth

of data required, and does so to an unnecessary extent that exhibits overreach of the legislative directive. They urged CMS to maintain internal consistency with the definitions in section 6106 of the Affordable Care Act, the proposed rule, the Draft PBJ Policy Manual and ultimately the final rule, and limit this data collection to direct patient care staff information. Commenters stated that the final rule should clarify that direct care staffing excludes non-direct care services. In addition, they recommended that references to non-direct care services be removed from the Draft PBJ Policy Manual to avoid confusion and unnecessary administrative costs for providers. Some examples the commenters provided as extraneous to the direct care staff normally employed by nursing homes (and that they advise should be reevaluated with stakeholder consultation and input) are blood service workers and vocational service workers.

Another commenter urged that CMS only collect staffing data about direct care staff that are typically employed (or contracted by) in nursing centers, including trained medication aides (where permitted by state law), and not all types of staff that are currently reflected in the CMS Form 671 (for example, housekeeping staff, administration and storage of blood, vocational services). They also recommended that CMS collect staffing data about additional direct care staff such as Certified Respiratory Therapists, all therapy staff (Speech and Language Pathologists, Physical Therapists, Occupational Therapists, PT/OT Assistants and Aides) therapeutic recreation staff, medical social workers, physicians and non-physician practitioners (NPPs). Another commenter asked that CMS clearly delineate all staff categories, including physical therapist and physical therapist assistants. Additional comments request that CMS clarify what categories of employees are included in “therapist and other type of medical personnel”.

Response: We believe that the statutory term “direct care staffing information” as used in the proposed rule is self-explanatory. As noted in the preamble to the proposed rule, facilities have a statutory obligation to be administered in a manner that enables it to use its resources efficiently and effectively to attain or maintain the highest practicable physical, mental and psychosocial well-being of each resident. We also noted that the statutory requirement to report direct care staffing information was added to

promote greater accountability for LTC facilities in meeting this obligation. In addition, the Congress gave context for the term “direct care staffing information” by including a non-exclusive list of the categories of work that may be performed by individuals whose information would be reported. We incorporated this non-exclusive list into the proposed rule. Accordingly, we believe that it was clear from the proposed rule that the reporting requirement would apply to the subset of staff at a LTC facility whose work directly advances resident well-being. However, we appreciate commenters’ desire to have specificity in the regulation. Based on the comments received, in this final rule we add a definition of “Direct Care Staff” at § 483.75(u)(1). This definition is grounded in the statutory text cited in the proposed rule and incorporates specific text offered by commenters. “Direct Care Staff” is defined as those individuals who, through interpersonal contact with residents or resident care management, provide care and services to residents to allow them to attain or maintain the highest practicable physical, mental, and psychosocial well-being. Direct care staff does not include individuals whose primary duty is maintaining the physical environment of the long term care facility (for example, housekeeping). In this definition, we do not exclude individuals who spend time on duties that are not always “hands on,” such as supervising nurses or medication management, as these types of duties directly impact a resident’s care. Therefore, the definition focuses primarily on whether the staff person in question provides care or services either through “hands on” care or through resident care management, with the intention of benefiting the resident’s well-being. We further note that there can be significant variation in the level and type of direct care that many staff provide. For example, a certified nurse assistant may spend the bulk of their time delivering hands-on care directly at the bedside, while an activities director may spend less time delivering hands-on bedside care. As such, we intend to collect staffing data on any staff that provides any amount of direct care.

Although comments on the Draft PBJ Policy Manual are beyond the scope of this rulemaking, we appreciate commenters’ feedback on how this draft guidance would implement the regulatory obligations established under this rule. We agree with commenters who stated that the reporting obligation under this regulation should not extend

to non-direct care staff, as well as their assertion that individuals who provide housekeeping are not direct care staff. As explained above, we are following commenters' recommendation to add a definition of direct care staff. As commenters requested, the definition of direct care staff expressly excludes housekeeping staff as well as any other individuals whose services are primarily related to maintaining the physical environment of the long term care facility. We believe this definition clarifies how CMS intends to interpret the scope of the reporting requirement. We agree with commenters who observed the reporting requirement should be consistently interpreted from the statute to the regulation to the implementing guidance. We believe the regulation is fully consistent with the statute and we will revise our subregulatory guidance to align with provisions of this final regulation. Finally, we note that we will take into account commenters' feedback on the categories of direct care staff as we refine the Draft PBJ Policy Manual.

(3) Hours Worked and Hours of Care

We proposed language for the new § 483.75(u)(1)(iii) that would require facilities to submit information on staff turnover and tenure and on the hours of care provided by each category of staff per resident per day (including, but limited to start date, end date (as applicable) and hours worked for each individual.

We noted that section 1128I(g)(4) of the Act requires LTC facilities to report on the hours of care provided by each category of certified employees per resident per day. We expressed our belief that the obligation to submit information on "hours of care" is satisfied by requiring facilities to submit hours worked by staff. In addition, we noted that although section 1128I(g)(2) of the Act requires the submission of resident case mix information, the proposed rule did not include a provision to implement this requirement because existing regulations at § 483.20 require LTC facilities to meet this statutory requirement through the required submission of the Minimum Data Set (MDS). Details of the comments we received on submission requirements, with our responses, appear below.

Comment: One commenter urged CMS to be consistent with language in the preamble and in the federal law related to "hours worked" and to eliminate language requiring the reporting of hours of care provided. Another commenter stated that they believe that CMS must find a way to

better capture hours provided than to equate it to hours worked. This commenter suggested one approach might be to conduct time studies to estimate the average amount of time CNAs, LPNs and RNs spend on non-direct care tasks and subtract that time from their total hours worked. Two commenters stated that CMS should require submission of time employees are taking personal leave during the work day (for example, for meals, breaks), and stated that these should not be recorded as hours worked as they are not hours of care. They further stated that although the language of CMS's proposed rule either quotes or paraphrases the statutory language, proposed at § 483.75(u), the preamble suggests that "the obligation to submit information on 'hours of care' is satisfied by requiring facilities to submit hours worked by staff." (80 FR 22081). Those commenters strongly disagree with the approach to collect hours of care worked as equivalent to hours of care. They observed that there could be a considerable difference between hours of care actually provided and hours of care worked. They stated that all staff, as a matter of practice and by law, have time when they are paid but are not working—meal and other mandated breaks, mandatory in-service training, etc. They observed that in an eight-hour workday, some time is devoted to meal and other mandated breaks and although staff may be paid for this time, but they are not providing care to residents. The commenters opined that if CMS is unwilling to require facilities to submit hours of direct care actually provided, then it must delete at least one hour from total hours worked in order to reflect the time at work that is not dedicated to resident care. Another commenter stated that CMS should require submission of time employees are absent from the facility on work-related leave if they are unavailable to fulfill direct care responsibilities. The commenter stated that this should include time nurse aides spend transporting individual residents to medical appointments since they are unavailable to provide services to other residents during that time. Other commenters expressed support for the proposed reporting of hours worked, but questioned how the reporting will distinguish between direct care hours worked and hours worked on management and other responsibilities by a salaried employee, as might be the case for nurse managers who split their time between direct care and management functions. One commenter remarked that they support the many

job classifications for which the Draft PBJ Policy Manual proposes to collect staffing information, but for both nursing and non-nursing job classifications there needs to be more specification on how to distinguish hours of care versus mandatory breaks or other non-direct care duties.

Other commenters supported the reporting of hours worked, but stated that submission specifications should account for actual hours worked by salaried/exempt staff. They observed that exempt direct care employees can frequently work more than the salaried time period (for example, 40-hour basis) for which they are paid. While alternate compensation for any additional hours will not be evident in a payroll-based system, they suggested that the CMS staffing data collection process should account for this additional time to accurately reflect direct care staffing and coverage. Similarly, another commenter observed that there are data elements that are not captured in payroll data alone, such as time worked off of the clock for contract employees, or the actual hours worked by the salaried employee. The commenter stated that capturing data that includes productivity standards and time allocated for indirect patient care would further illuminate quality patient care that is not intuitive to payroll data alone. The commenter suggested that this can be calculated by collecting data for direct patient contact time, which is captured in the MDS and/or medical record. The commenter recommended the inclusion of direct patient contact time, as reported by speech language pathologists or derived from the billable minutes provided on the date of service.

Response: In our proposed approach, and in this final regulation, we give deference to the statutory requirement that the staffing data be reported "based on payroll and other verifiable and auditable data in a uniform format (according to specifications established by the Secretary . . .)." Payrolls represent the primary source of verifiable and auditable information, and are explicitly referenced in the statute as such. Payroll systems contain the key information organized as "hours worked," and provide the most effective foundation for electronic reporting. We have therefore maintained "hours worked".

We appreciate commenters' observation that payroll systems record vacation, sick time, and certain other absences that are time other than "hours worked." Therefore, when LTC facilities report total hours worked by direct care staff (based on payroll and other verifiable and auditable data as

specified by CMS), these data should not include paid time off (for example, vacation, sick leave, etc.).

At the same time, we recognize that nursing home staff engage in other non-care and direct care activities throughout their day, such as breaks. Although outside the scope of this rulemaking, we appreciate that in calculating quality measures we may need to adopt some statistical refinements that allow for reasonable estimates of such time in order to afford the public the information that will enable recognition of the time that staff are engaged in non-care or non-direct care activities. Also, as required in the statute, we require that the primary care area of each staff person (as well as each individual's hours) be reported. Such categorization will allow the public to identify which care areas are most important to them, as well as to focus on the types of staff who provide most of the hands-on care. We thank the commenters for identifying these issues, and will take this feedback into account when assessing future uses of the data, such as quality measures.

We further note that the regulation does not limit collection of information to payroll data exclusively. In fact, the regulation specifies that the information will be "based on payroll *and* other verifiable and auditable data" (emphasis added). Although beyond the scope of this rulemaking, we do not rule out the possibility that future implementation specifications could require submission of information from time studies or other methods, in addition to payroll data, if CMS determines that other data capture methods are auditable and verifiable. For example, if at a future date CMS concludes there are auditable and verifiable data regarding extra hours worked by salaried employees or hours worked that are extraneous to the care of residents, CMS may revise the implementation specifications to address the submission of these data that permit refinement of the payroll data. However, as indicated in the draft subregulatory guidance implementing this regulation, we anticipate that initial reporting will be limited to the payroll-reported data for each individual who meets the definition of direct care staff. We plan to continue to work with stakeholders to further develop the initial specifications to implement this final rule and to make any future refinements to this subregulatory guidance.

Comment: A few commenters recognized the value of collecting and reporting staffing information but were concerned about the administrative burden resulting from this new

reporting requirement, in particular for hospital-based skilled-nursing facilities, where many staff may work in both the SNF and other departments of the hospital and health system, and where payroll systems are integrated. They urged CMS to test the proposed data collection system specifically in SNFs operated as distinct parts of acute care hospitals to address any unique issues that might arise in that setting. Another commenter observed that in their facility, attached to a hospital, the housekeeping, laundry, maintenance, dietary, and administrative services are provided by staff that conduct hospital and nursing home services. The commenter explained that at their facility only the nursing time is directly allocated to the nursing home on a timesheet; the times worked in the other departments are allocated to their individual departments. The commenter observed that at the end of the year when the cost report is prepared, their time is separated out to the revenue producing departments (nursing home, medical/surgical, ER, lab, radiology, etc.) based on meals served, square footage, pounds of laundry, etc. The commenter stated that, currently, this information will not be able to be sent directly from their payroll system and that it will be extremely time consuming to figure out the percentage of time a support service department employee worked for the nursing home each day and manually enter it into the Payroll-Based Journal system. The commenter observed that the cost report already provides a summary of staffing salaries and hours, and suggested that the cost report could be modified to conform to all the Affordable Care Act requirements. Another commenter stated that to require distinct part SNFs to collect data on the services not related to direct patient care, duties which are shared with the institutions where they are housed, will create unnecessary administrative burden to separate data for services, which are by definition shared. This works against the entire principle behind distinct part SNFs, and is, in fact, impossible to accomplish without hours of manual labor. For example, the commenter observed that in their 125-bed facility they have a 38-bed ventilator assist unit, with approximately 140 direct care staff with a 10-hour per patient day ratio. They stated that the amount of time to submit staffing information on this unit alone would require an inordinate amount of resources. A hospital association stated they are concerned that the requirement will be administratively burdensome,

particularly in light of the challenges of attributing hours worked to the distinct part unit as opposed to the hospital generally. They opined that therapy staff hours are now kept by department and allocated retrospectively as part of the facility's cost report. The association stated that the payroll system for these hospitals does not support the automated submission of data as envisioned in this regulatory proposal. For these types of facilities, they encouraged CMS to consider alternative mechanisms—such as adaptations of the current cost reporting system—to demonstrate compliance with the requirements of the statute. Finally, a commenter stated that one of the issues involved in reporting hours worked for non-direct care staff involves SNFs that are hospital or retirement community based. The commenter stated that non-direct care staff provides services to the whole organization and there is no way to determine the number of hours specific to the SNF and indicated that Medicare cost report methodology allows reporting of these "overhead" areas based on various statistics that have no relationship to hours. The commenter opined that to attempt to determine the SNF related hours would result in inaccurate estimates that would not be meaningful and would be a cumbersome manual process.

Response: We are aware that hospital-based facilities and other facilities such as nursing homes adjacent to assisted living facilities or part of retirement communities have staff that work in multiple areas of the broader entity. In response to these and other comments, in this final rule we have added a definition of "direct care staff" that excludes certain facility support staff. We believe that this adjustment will help address a large portion of the staff issues that distinct part and other conjoined entities would otherwise face with staff who have duties in multiple entities. For the staff who do meet the new definition of direct care staff, facilities will still need to report the hours that are allocated to the SNF/NF residents only, and not include hours for staff allocated for providing services to residents in non-certified SNF/NF beds. Data reported should be auditable and able to be verified through either payroll, invoices, and/or tied back to a contract. Facilities must use a reasonable methodology for calculating and reporting the number of hours allocated to providing services on site to the SNF/NF residents, and exclude hours allocated for providing services to other individuals in other settings. These types of facilities are encouraged

to participate in the voluntary program beginning on October 1, 2015. Voluntary submission will allow facilities to work through their processes to submit the data in advance of the mandatory submission period. We also note that Medicare cost reports are not an appropriate means to comply with this staffing reporting requirement because, among other concerns, they do not contain all of the data needed to comply with the Act, such as information on turnover and tenure.

Comment: Several commenters opined on how the submission schedule should apply to resident census data. Several commenters recommended that CMS collect resident census data in a time frame consistent with collection of other staffing data under this requirement. That is, they recommended that if staffing data is collected quarterly, census data should be collected quarterly. Some commenters suggested that data regarding resident census should reflect shorter time periods than quarterly. For example, several commenters recommended that the resident census data submitted each quarter should include three data points that reflect each month's total patient days in order to accurately reflect the hours of direct care per patient per day. Another commenter urged CMS to require facilities to collect and submit daily resident census data to capture fluctuations around facilities' surveys when many facilities temporarily increase staff; to reflect reduced staffing hours caused by higher absenteeism during certain periods such as holidays; and to reflect periods when census unexpectedly increases, such as accommodation of residents displaced by a facility closure. Another commenter remarked that it is their understanding that based on the specifications contained in the Draft PBJ Policy Manual CMS intended to interpret the proposed regulation to require submission of census data based on the resident population as of the last date of each month of each quarter. The commenter expressed strong objection and concern with this approach as misrepresentative and unreliable in depicting the hours of direct care provided per resident per day. The commenter opined that that collection of census information must be compared to and consistent with the data collected for hours worked during the same submission period. The commenter expressed the view that calculation and use of the average daily census for each month in a quarterly submission period was strongly favored

over the current CMS proposal. Another commenter recommended that resident census also be submitted on a daily basis to capture fluctuations in staff-to-resident ratios that may occur during a 30-day period that would not be recorded if data were reported only on the last day of the month; for example, the period around the annual survey or during a ban on admissions or closure. One commenter stated that it is unclear how the number of days will be gathered from the submitted data for purposes of determining hours of care per resident day. Given the desired level of accuracy in reporting of hours worked, they advocated for an accurate and unobtrusive method for collecting information on the number of resident days provided in each reporting period. Finally, a commenter stated that CMS proposes that resident census data should be collected on the last day of each of the 3 months within a quarter. The commenter recommended staffing data should be collected on a daily basis, because the lack of daily resident census data could lead to inaccurate calculation of staffing levels, and potential inflation of staffing level averages. The commenter observed that resident census fluctuates continually throughout the month, and it would not be a burden for facilities to report this information since this information is readily available at SNFs. They stated that primary purpose of payroll-based staffing data collection is to provide as accurate as possible staffing level information for consumers, rather than the current system which is fairly unreliable for several facilities as facilities "staff-up" near their expected inspection survey.

Response: We recognize that a facility's census fluctuates throughout each month and appreciate suggestions intended to promote the utility of the census data submitted under this regulation. However, while the requirement to submit census information is within the scope of this rule, the specifications for this submission are not. Therefore, these comments will be taken into account as we revise the Draft PBJ Policy Manual and other subregulatory guidance. For example, we will analyze the average census of a facility based on the last day of each month as compared to the average census based on the daily census. We will ensure that any eventual quality measure will be statistically sound in representing a facility's census. This may involve altering the data we propose to collect (for example, from once a month, to daily) or collecting this information

through other means. We note that the method to submit census data described in the current draft guidance was recommended by stakeholders who participated in the pilot in 2012 and was structured to reduce provider burden as much as possible.

Comment: Two commenters strongly supported the submission of nurse staffing hours by shift to capture what they describe as the dangerous decline that occurs in many facilities on the afternoon and night shifts. They expressed that sufficient direct care nursing staff on one or two shifts averaged over three shifts may hide critically deficient nursing levels on the other(s), when residents are at increased risk of serious harm from missed care, falls, abuse, elopement, missed meals, and lack of assistance with toileting. They further commented that shift-level nurse staffing hours per resident day would yield far more important evidence of quality than minor variations in case mix in typical nursing homes. They also noted that the *Staffing Quality Measure (SQM)* project evaluated the feasibility of collecting shift level data, concluding that it could be done and would allow calculation of "more detailed staffing measures, such as shift-level staffing ratios or the proportion of shifts for which at least one registered nurse was present." One commenter additionally remarked that CMS should collect nurse staffing data by unit. They concluded from the SQM Final Report that researchers gave only cursory attention to requiring facilities to submit data by units. They asserted that at a time when the industry is creating special subacute care or rehab units to maximize Medicare census and reduce rehospitalization rates, adequate or exceptional staffing in a subacute unit can create a false picture of levels in other units whose residents have similar needs. They stated that without such data, case mix adjustment would be more likely to obscure staffing hours than to clarify them. Another commenter recommended that staffing data be collected by shift and unit, especially as more facilities are developing Medicare/rehabilitation units and subacute units.

Response: We agree that data regarding staffing patterns at the shift and/or unit level would be valuable when assessing how LTC facilities are administered; however, these implementation specifications are beyond the scope of this rulemaking. We will continue to look at this as we develop subregulatory guidance and will evaluate the feasibility of collecting these data elements in the future.

Comment: One commenter recommended that CMS reconsider case-mix adjustment of staffing hours. Another commenter expressed opposition to making any adjustment for case mix. The commenter suggested that, at a minimum, the non-adjusted staffing level data should be publicly available. The commenter stated that the case-mix of residents is changing constantly, and consumers want to know if facilities are truly staffing near the recommended level of 4.1 hours per resident day, or are they only near this standard due to the case-mix adjustment. One commenter strongly objected to any language in regulations that would require or imply that CMS will use MDS data to adjust staffing information that is reported on Nursing Home Compare. In passing legislation to replace inaccurate, self-reported staffing data with information from auditable payroll records, the commenter stated that Congress intended to ensure that the public has *accurate* information about staffing hours, and that the Congress did not intend to have information from the new system degraded by consolidation with data from another self-reported source that is frequently inaccurate and even fraudulent. The commenter acknowledged and welcomed the fact that CMS is implementing nationwide, focused MDS surveys in response to criticism of the use of MDS data to construct Quality Measures (that are displayed on the CMS *Nursing Home Compare* Web site), but noted that such focused surveys will not be conducted in all nursing homes, and that they will be subject to the same limitations as other surveys (such as surveyor turnover, pressure from supervisors not to cite deficiencies, and weak enforcement).

Response: We thank commenters for their suggestions but note that the use of case-mix or MDS data is outside the scope of this rule. We will work with stakeholders prior to formulating publicly posted quality measures. We will consider making both adjusted and unadjusted data available. However, we believe that case mix adjustments are important for the very reasons the commenters observe—that the risk profile of a nursing home’s resident population does change over time, and is also different from one facility to another. We would expect that a nursing home that has a population with a higher risk profile should generally have an overall higher staffing level, or a staffing complement that matches the risk profile (for example, higher RN levels for a nursing home with a

population that has a higher acuity level compared to other nursing homes). We appreciate that the MDS data have limitations but at this time we believe MDS reporting does meet the statutory requirement for LTC facilities to submit information on resident case-mix that are auditable and verifiable. We will also continue to monitor the results of the new nationwide sample of targeted MDS surveys to determine if additional actions are advisable.

Comment: One commenter stated that if the Congress’ intent was to ensure that payroll data and staffing quality measures would conform with the minimum staffing requirements of the Nursing Home Reform Law, which require care to be provided by Licensed Health Professionals and nurse aides who meet the law’s 75-hour training, competency evaluation, and registry requirements, then they recommend that CMS define “certified employees” as staff who are licensed health professionals and/or who meet the requirements for nurse aides, as defined in section 1819(b)(5) of the Act.

Response: The requirement for reporting staffing data is not limited to licensed health care professionals and nurse aides. Direct care staff includes other staff that meet the definition of direct care staff. That said, we will provide definitions for certain categories of staff, such as nurse aides, through implementing guidance.

(4) Distinguishing Employees From Agency and Contract Staff

Under section 1128I(g) of the Act’s requirement that information for agency and contract staff be kept separate from information on employee staffing, we proposed to add a new § 483.75(u)(2) to establish that, when reporting direct care staffing information for an individual, a facility must specify whether the individual is an employee of the facility or is engaged by the facility as contract or agency staff. We believe the statute’s intent is to require LTC facilities to submit staffing information in a manner that can enable us to distinguish those staff that are employed by the facility from those that are engaged by the facility under a contract or through an agency. We do not believe the statute requires such data to be submitted at separate times or through separate systems, which would merely engender unnecessary costs and burden, so we intend to collect all facility staffing information at the same time and through the same system, employing a mechanism by which LTC facilities will clearly specify whether staff members are employees of the

facility, or engaged under contract or through an agency.

The comments we received on this topic, with their responses, appear below.

Comment: One commenter requested that CMS further clarify in the Draft Payroll-Based Journal Policy Manual that “floaters” or other employees that work at multiple facilities for the same operator should be categorized as contract staff. Another commenter agreed that facilities must indicate whether an employee is a direct employee of the facility (exempt or non-exempt), or employed under contract paid by the facility or through an agency. The commenter stated that CMS should consider defining “floaters”—individuals employed by the corporation who may work for the same employer but in different facilities at different times—as agency employees. Another commenter asked what the applicable start and end dates would be that a facility would report for contract and agency staff, since these workers can be used intermittently over indeterminate time periods.

Response: We appreciate the commenter’s insights into these implementation issues. Although these details are beyond the scope of this regulation; we believe they are appropriate for implementation specifications. We will take these comments into account when issuing the revised Draft PBJ Policy Manual and other subregulatory guidance.

(5) Data Format

We proposed to add a new § 483.75(u)(3) to establish that a facility must submit direct care staffing information in the format specified by CMS. This provision would implement the requirement in section 1128I(g) of the Act that facilities submit direct care staffing information in a uniform format. As noted, we are consulting with stakeholders on potential format specifications. The data that we proposed for submission are similar to those already submitted by LTC facilities to CMS on the forms CMS–671 and CMS–672 (we intended for this proposed new information collection to eventually supplant the data collections via the CMS–671 and CMS–672). In advance of the proposed July 1, 2016 implementation date, we will publicize the established format specifications and will offer training to help facilities and other interested parties (for example, payroll vendors) prepare to meet the requirement.

The comments we received on this topic, with their responses, appear below.

Comment: One commenter stated that there should not be an unreasonable financial burden placed on the providers to report the information that would be required, since providers are already being negatively affected by the sequestration and the managed care plans. The commenter stated that even though it is a good thing to keep costs down for the federal budget and the taxpayers, it is only the adjustment for cost increases that has helped to minimize the negative impact for the providers. The commenter observed that many providers have multiple types of staff, which includes different types of payment types from paychecks to payables. The commenter explained that this means that for many it is not one combined system for all of the detail, since not all of this information had been required, so it will require either a lot of hours to prepare or a lot of hours to program or possibly both in order to provide the information. The commenter further stated that not all providers benefited from the incentives for moving to an electronic record. Many were excluded from participation, but had to bear the costs anyway due to the sharing of patients (also called residents, clients, etc.) and the requirement to provide the information electronically. The commenter opined that this placed an undue hardship on them. Another commenter remarked that CMS has not adequately considered and accounted for the costs to SNFs to comply with the proposed data collection. Several commenters recommended that CMS complete a regulatory analysis addressing these costs. The commenters stated that the interpretation of the legislation by CMS through the proposed rule would be overly burdensome, redundant, and would create unnecessary and costly expense to distinct part SNFs. They asserted that the steps required to supply the data outlined in the proposal requires technical expertise, labor, and payroll system vendors in order to meet expectations. Another commenter expressed concern regarding the time to comply with this system proposed by CMS. The commenter strongly encouraged CMS to solicit input from a broad variety of providers to develop an approach that meets the requirements of the Affordable Care Act and also is more reasonable to providers in terms of labor and cost. The commenter expressed concern that cost of the requirements would be obtained from the cost of direct patient care given, as that reimbursement would not likely be increased. The commenter stated that, if high costs were incurred, then it would

be highly unlikely that additional data requirements would have a positive effect on the quality of nursing home services but, instead, the potential to decrease quality is significant as more and more resources are directed to regulatory mandates that do not affect direct patient care. The commenter stated that they were unaware of any CMS research or data analysis that demonstrates a direct relationship between this level of data and quality outcomes. Finally, the commenter stated that required reporting of non-direct patient care staffing data reduces the ability to provide quality care, as resources are diverted to administrative reporting, away from direct patient care. Another commenter opined that the proposed rule and the inclusion of the additional staffing data required by the Draft PBJ Policy Manual extend beyond the intent and language of the Affordable Care Act and that this is an unreasonable and costly additional administrative burden which does not improve patient care at a time when delivering quality care at a reasonable cost is paramount public policy; adding undue hardship which does not improve quality will have a definite negative impact on care. One commenter recommended that CMS recognize that this new process is occurring at the same time as several other mandates that require significant resource investment, including the initiation of ICD-10 and the training and software preparation needed. The commenter identified other concurrent provider efforts including initiation of the collection of data for the Quality Reporting Program related to the IMPACT Act, the initiation of 30-day all-cause, all-condition rehospitalization reporting, ongoing transition to electronic health records at many facilities, and the initiation of computerized physician order entry (CPOE) at facilities and all while providers work to increased interoperability so that data can be exchanged. One commenter supported the electronic collection of staffing data by CMS but noted that the system for doing this should be reasonable and achievable and as simple as possible. Commenters were also concerned that payroll vendors were not yet prepared to accommodate the required reporting and that providers would incur compliance costs associated with modifying their own payroll systems or from vendors needing to make these modifications. One commenter stated that every employee will need to have a unique employee number assigned for tracking and reporting purposes that

may require payroll and other systems modifications. Another commenter suggested CMS delay the mandatory electronic submission of staffing data until CMS has adequately tested the submission system and determined the cost and burden to providers to comply with this proposed regulation. The commenter observed that only the volunteer facilities will have had an opportunity to test the new system prior to the mandatory report date of July 1, 2016 that applies to all facilities.

Response: We appreciate commenters concerns about the costs associated with submitting direct care staffing information but note that this reporting obligation mandated by section 1128I(g) of the Act. We believe this final rule is fully consistent with the intent and text of the statute and represents the best approach to minimize the burdens associated with implementing the statutory reporting requirement. Based on the comments received, we have included information on the estimated costs and burden of this regulation to facilities in section V. of this final rule. As noted above, we will continue our consultation with LTC facilities and other stakeholders as we revised the Draft PBJ Policy Manual and other implementation guidance to implement this regulation.

Comment: Several commenters suggested that CMS modify already-existing reports and/or reporting systems to develop the uniform format to be used for staff reporting submission under this new regulation. Many commenters suggested that their cost reports could be modified to conform to all the Affordable Care Act requirements. One commenter stated that CMS should consider using staffing data that is collected for other programs which could, with minor adjustments, be used to meet the requirements of the Affordable Care Act. The commenter suggested that Medicare Cost Reports collect similar data which is obtained on a regular basis and a modified format of this form would result in less burden for providers and fewer opportunities for discrepancies in information provided in multiple reporting forms. Two commenters stated that the requirements of section 6106 of the Affordable Care Act could be met, consistent with the intent of the Congress, through the existing resident case-mix report without creating an additional duplicative report. The commenters stated that the report could be expanded to include the other requirements of the Affordable Care Act: Aggregate nursing hours, number of patient days, and staff turnover to be reported quarterly. Another commenter

suggested CMS work with states already collecting this information to reduce the reporting burden for facilities.

Response: In order to comply with section 1128I(g) of the Act, the final rule mandates that there be a uniform national method of electronically collecting specific staffing data that can be applied for both Medicare SNFs and Medicaid nursing facilities. When implementing this regulation we will adopt a system that will accommodate this requirement. We do not agree that the Medicare cost reports or existing state-based systems will satisfy the requirements of the law. For example, Medicare cost reports do not contain the data needed to comply with the Act, such as information on turnover and tenure.

Comment: One commenter suggested in § 483.75(u)(3) after the heading adding “uniform” before “format” for consistency between the statutory and regulatory text and for clarity in the requirement for submission of data in a uniform format.

Response: We agree. For consistency purposes, we have added “uniform” before “format” in the text of § 483.75(u)(3)

(6) Effective Date for Submission Requirement

In the proposed rule, we indicated that the regulation would take effect on July 1, 2016. We explained that prior to this effective date, we would establish a voluntary submission period whereby facilities can submit staffing information on a voluntary basis to become familiar with the system and to provide feedback to CMS on systems issues in advance of the mandatory submission date.

Comment: We received several comments regarding a phase-in or postponement of the mandatory submission date. One commenter recommended calling for a wider-range testing and evaluation period and/or phase-in of the data collection system. The commenter stated that this testing period would not only allow a broader spectrum of providers to gain understanding and familiarity with the process prior to final implementation, but would add information regarding cost and burden associated with meeting the submission requirements. For example, information could be collected on the implementation of required, but unanticipated system modifications and the potential investment of additional staff and/or documentation time. Another commenter suggested CMS phase in the reporting process over time and to initially only require reporting of the nursing staff and to add other staff such

as therapists at a later time. Another commenter suggested that as part of CMS’s consultation on the submission specifications, they should include an informal period of “testing” that will allow all providers (not just those who may volunteer for a “pilot”) the opportunity to work within the system to determine how it interfaces with their center’s system or to learn how to confidently input the required data (for those centers unable to automatically upload their information). The commenter suggested this proposal to provide centers and CMS a clearer understanding of the burden associated with the submission requirements. Another commenter stated that contingent on the outcomes and/or results of the voluntary submission period, CMS should consider postponement or a phase-in of the intended July 1, 2016 mandatory submission date pending resolution of identified problems or glitches. The commenter believes that all providers should have the opportunity to test their respective payroll and time and attendance processes and gain familiarity with the CMS submission requirements. The commenter further stated that CMS should again consider a phase-in or “grace period” approach within the planned mandatory reporting implementation that includes deferral of 5-Star calculation and scoring for initial submissions. The commenter concluded that, at a minimum, given the limits of the currently planned data collection system trial, the allowance for post-submission review and opportunity for correction should continue for at least the first year of mandatory implementation.

Response: We are establishing a voluntary submission period beginning in October 2015. The voluntary submission period will include a phased approach to registration and training which will allow facilities to test their submission methods in advance of the July 1, 2016 effective date of the regulation. In order to meet the requirements of section 6106 of the Affordable Care Act as soon as possible, we believe that July 1, 2016 is an appropriate start date. However, we appreciate that in any new, large system of this nature, implementation challenges may arise and adjustments likely will need to be made in both the receiving and sending systems. Therefore, we do not plan to use the results of the reported data in the CMS *Five Star Quality Rating System* in CY 2016. During the implementation we plan to maintain a feedback loop with nursing homes regarding the data

submitted, issues identified, and adjustments made or needed to the implementation specifications. We also plan to maintain use of the existing CMS Form 671 annual paper-based form during the initial implementation so that the results of the traditional and the new system can inform the learning process.

(7) Submission Schedule

Section 1128I(g)(3) of the Act requires that facilities submit direct care staffing information on a regular reporting schedule. At § 483.75(u)(4) we proposed to establish that a facility must submit direct care staffing information on the schedule specified by CMS, but no less frequently than quarterly. Comments we received on this topic and our responses appear elsewhere in this preamble.

(8) Compliance and Enforcement

In the proposed rule we noted that § 483.75(u) would establish that these new reporting requirements would be conditions a LTC facility must meet to qualify to participate as a SNF in the Medicare program or a NF in the Medicaid program. As such, we explained that we planned to enforce the requirements under this new regulation through 42 CFR part 488 and non-compliance with the proposed § 483.75(u), could result in CMS or the state imposing one or more remedies available to address noncompliance with the requirements for LTC facilities.

The comments we received on this topic, with our responses, appear below.

Comments: One commenter proposed that if a SNF is found to be non-compliant with the reporting requirements, there should be an expedited appeals process afforded to the SNF prior to imposition of a civil monetary fine or exclusion from a federal healthcare program. Other commenters stated that it would be more fruitful to lay out specific sanctions that CMS will impose if a facility fails to comply with the new reporting requirement. One commenter suggested, for example, that if a facility fails to provide required staffing data within 30 days of the deadline, CMS would send a warning letter; if the facility did not provide the data within 20 days of the warning letter, CMS would levy daily civil monetary penalties of \$X,000 per day starting on the 21st day after the warning letter; if the facility continued to fail to provide staffing data at the 40th day following the warning letter, CMS would institute a hold on new admissions. The commenter stated that such a sanctioning approach would result in more immediate compliance and clearer

expectations for the providers. The commenter further noted that if CMS or the state determines that a facility has intentionally provided inaccurate staffing data, the non-compliance should be considered a material false claim to the government for which payment is sought and damages should be available under the False Claims Act. The commenters recommended internal audits conducted by CMS, with non-compliance remedies of a significant downgrading of Five Star Quality Ratings while the facility is out of compliance, a significant per day Civil Monetary Penalty, and denial of payment for new admissions until compliance is achieved. Another commenter noted that, given the importance of this data, penalties should be imposed when a provider fails to submit staffing data as required or submits inaccurate or false data. The commenters recommended a per day Civil Monetary Penalty at a significant enough level to result in compliance. The commenters further suggested, a facility's penalty should be posted under "Staffing" on Nursing Home Compare so it is easily visible to consumers and others researching the facility. Still another commenter stated that they were concerned about the lack of specificity with regard to remedies for noncompliance and the potential for flexibility, inconsistency, and lenience that are unfortunately common in enforcement of other requirements of participation. The commenter noted that the statement that CMS or the state *may* impose one or more remedies underscores our concern—sanctions should be certain. Moreover, the commenters believe the instructions are ambiguous about when a deficiency and remedy are triggered. Another commenter urged CMS to provide greater clarity about how compliance with the proposed regulation will be determined. One commenter suggested that CMS clarify the possible enforcement actions that may be considered for aberrant data.

Response: We appreciate commenters' interest in additional information regarding how the agency will assess compliance with this regulation and what specific enforcement actions the agency will pursue when it identifies noncompliance. Discussion of implementation specifications and how the agency will apply its enforcement are beyond the scope of this rulemaking. We will take these comments into account as we develop guidance at a later date. We note, however, that nothing in section 1128(g) of the Act or this final rule establishes that the staff

reporting requirement is a condition of payment.

Comment: One commenter opposed the data collection requirement's inclusion as a requirement for participation in Medicare, because the timeline for implementation does not afford all providers the opportunity to test the CMS system and identify problems that may occur when interfacing with the facility's software and systems. Additionally, the commenter noted that CMS has not clearly stated within the proposed rule how it will determine compliance with the proposed regulation. Another commenter urged CMS to eliminate the staffing data collection designation as a requirement of participation, since such a designation will make compliance subject to the full array of enforcement actions. The commenter stated that it is premature to make this collection a requirement of participation since the system for submission of the staffing data is new and not adequately tested.

Response: As we stated in the proposed rule, we believe that the inclusion of the staffing data collection as a requirement of participation is appropriate and desirable, to meet the legislative goal of greater accountability for LTC facilities, given the importance of staffing to the quality of care and safety of the nursing home residents. We further believe that the full array of remedies available to enforce compliance with other conditions of participation should be available to enforce this regulation and ensure that the Act's requirements are met. This regulation is necessary to carry out CMS's and the state's obligation to ensure compliance with other conditions of participation (COPs) as specified in the Act. For example, section 1819(b)(4) of the Act includes requirements for staff such as nursing services, pharmaceutical services, dietary services and other services facilities are required to provide, and collection of the staffing data helps verify compliance with these requirements. However, we appreciate there will be a learning curve as the new reporting system is implemented. We therefore plan to be careful when assessing compliance to distinguish between the effects of newness in the initial implementation and failure to implement the system and ensure accuracy and adequacy of reporting.

Comment: One commenter remarked that the proposed rule did not include provisions for adjustment and/or correction to submitted data. The commenter noted that electronic staffing data submission will serve to eliminate current inconsistencies and mistakes

common to manual completion of the 671 form, but cited examples of errors were still possible under an automated system. The commenter stated that automated payroll systems frequently "lock down" once a payroll period ends and have to be re-entered manually for changes or updates. The commenter further stated that there can also be occasional clock breakdowns or clocking oversights, for example, if an individual clocks out, is asked to stay, but fails to clock back in, all hours worked may not be captured in real time. The commenter explained that similarly, some providers have adopted universal worker practices, with those employees performing, for example, non-nursing or other functions at different points, again resulting in potential clocking oversights or omissions. The commenter stated that in any of these circumstances, hours worked would at least initially be documented somewhere other than the payroll system and, if identified after a payroll period has closed and/or data transmission to CMS, adjustment would be required to accurately reflect staffing and coverage. The commenter believes a defined process should be incorporated into the collection and reporting system to allow providers to make documented, verifiable, and auditable data-based adjustments/corrections to submitted staffing information. The commenter stated that these adjustments/corrections should be permitted within the respective quarter to assure accurate documentation and calculation of staff hours worked and direct care services provided.

Response: We appreciate the commenter's observations about areas of ongoing data vulnerability and providers' interest in making corrections when they identify errors with previously submitted data. We anticipate that our reporting system when fully implemented will include functionality to submit data corrections. We will address this issue in further detail through guidance.

(9) Other Comments

Comment: Several commenters requested that CMS provide a written report on the results of the 2012 Staffing Data Collection Pilot to providers in advance of finalizing this rule. The commenters stated that CMS references the 6-month staffing data collection pilot conducted in 2012 as a strategy component in engaging in ongoing consultation with all relevant parties and stakeholders; however, no report regarding the results and outcomes of this pilot has ever been released for review and feedback by these entities.

The commenters believe that knowledge of the challenges and successes that were determined based on this pilot would be very beneficial in terms of “lessons learned”, enabling greater understanding of the requirements being proposed and final implementation of the currently drafted “Electronic Staffing Data Submission Payroll-based Journal” (PBJ) system.

Response: As part of our on-going consultation with stakeholders, we will make information from this project available on the CMS Staffing Data Submission Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Staffing-Data-Submission-PBJ.html>. However, it is important to note that this information relates to the implementation specifications, not the regulatory requirement, and therefore CMS is proceeding with finalization of the rule at this time but hopes the data from the project will facilitate dialogue as the agency develops implementation guidance.

Comment: One commenter stated that further clarification is needed regarding the voluntary submission process referenced in the preamble of the proposed rule to be conducted beginning in October 2015. The commenter stated that it is not clear whether these submissions will be instead of, or in addition to, the CMS 671 form, and or whether the information collected during this period will be data of record, thereby subject to 5-Star Nursing Home Rating System calculations and potential remedies if noncompliance is determined. The commenter stated that modifications will have to be made to virtually all homes’ payroll and time and attendance processes to accommodate the provisions of this rule, and not all homes will be able to begin submission during the voluntary period to test their own systems against the CMS data collection process. The commenter noted that again, with the variation in current payroll and time and attendance systems in nursing homes, providers must have some margin and flexibility to allow for unanticipated interface-related problems and need for further modifications that may occur with the junction of the PBJ and their respective processes. The commenter stated that the voluntary period will be the first wide-range, and to their understanding, the only testing opportunity for the CMS staffing data collection process. The commenter stated that the goal should be true evaluation and assessment, with the participating nursing homes not subject to Five-Star scoring or survey

and enforcement actions based only on these initial preliminary submissions. The commenter stated that if voluntary submissions are to be considered data of record, at minimum there should be an accompanying allowance for post submission review as needed, with opportunity to rectify identified errors, misinterpretations, or omissions prior to final determinations.

Response: As stated in the preamble of the proposed rule, we intend to eventually supplant the form CMS-671 and CMS-672, however, facilities will still be required to complete these until further notice. Data submitted through the PBJ system during the voluntary submission period will not have any impact on a facility’s Five-Star rating, or result in any enforcement remedies. Facilities will be provided with information about their voluntary submissions so they can make adjustments and be better prepared for the mandatory submission period. We do not plan on using the results of the reported data in the Five-Star Quality Rating System calculations in either CY 2015 or CY 2016 in order to accommodate both the voluntary phase and the initial months of mandatory reporting.

Comment: Several commenters expressed that manually uploaded data should not be permitted on an ongoing basis. The commenters noted that CMS should require facilities that want to submit some or all data manually to request a waiver documenting that they do not have the capability to report using an automated payroll system. The commenter stated that CMS should establish a deadline for facilities to have fully automated data reporting ability to meet the requirements of the law, after which manual submission would be noncompliant. The commenter recommended that waiver requests should be time-limited and require an annual re-application process in which the provider must document the steps taken to automate its system. Another commenter stated that CMS must ensure that staffing data come from verifiable, auditable sources and not self-reporting by facilities.

Response: The requirement in this regulation is for facilities to submit the data electronically, which facilities will do through the system we will provide. We note that regardless of whether a facility uploads their data from a payroll system, or enters it manually, all facilities are held to the same reporting requirements and standards.

Comment: One commenter remarked that data should be collected in an all-inclusive and meticulous manner that represents the complete assessment of

care furnished in the SNF setting. The commenter strongly urged CMS to adhere to the following: (1) Only count staffing data that represent a complete episode of care from admission to discharge; (2) CMS should distinguish those cases in which an unexpected readmission or inpatient hospital stay occurred; and (3) provide feedback reports to all applicable facilities prior to public reporting and provide an appropriate timeframe for facilities to dispute any information they believe is inaccurate. Another commenter requested that CMS clarify how the data will be analyzed, the benchmark that will be used to define quality, and the additional uses or actions CMS anticipates as a result of collecting this data.

Response: We are not entirely clear on some of the commenter’s suggestions and note that some issues raised by this commenter are outside of the scope of this rulemaking. The data collected under this regulation will not count episodes of care, but will reflect the staff in the facility and related average census. Although outside the scope of this rulemaking, we plan to provide feedback reports to providers and allow facilities to dispute information they believe to be inaccurate. In addition, we plan to discuss the uses of the data, including quality measures, with stakeholders prior to public posting.

Comment: One commenter requested that we eliminate the part-time/full-time distinction that appears in the Draft PBJ Policy Manual. The commenter stated that organizations vary in their definitions of part-time and full-time. The commenter believes in collecting staff hours worked for the purpose of interpreting staffing levels based on payroll and related auditable and verifiable data, it is irrelevant whether coverage is being provided by full or part-time employees.

Response: While this comment is directed at an issue outside the scope of this regulation, we agree. In response to feedback received, we have eliminated the part-time/full-time distinction described in the Draft PBJ Policy Manual.

Comment: One commenter requests that base hourly wage information be collected as part of this process, which can be used to develop a SNF-specific wage index.

Response: We believe this request is outside of the scope of the rulemaking. Further, we do not believe that section 1128I(g) of the Act authorizes us to require the reporting of base hourly wages.

Comment: One commenter stated that in light of the importance of MDS

assessment accuracy for QM reporting, payment, and coordination of the resident care plan across the care continuum, we recommend that duties related to completion of the RAI be separated out in statistical reporting job category (RN, LPN, etc.). Licensed staff performing RAI work cannot be accurately identified in the current proposed structure. The commenter stated that it is very important that the nurse staffing data enable consumers and researchers to know who is actually conducting the RAI. The commenter noted that while the LVN/LPN is authorized to perform the RAI process and certify its accuracy, an RN is required to coordinate the RAI process and verify completion (F-278, § 483.20(h), Coordination: A registered nurse must conduct or coordinate each assessment with the appropriate participation of health professionals).

Response: This request relates to the implementation specifications and is beyond the scope of this rulemaking. As we develop subregulatory guidance, we will work with stakeholders to consider any additional types of staff that should be reported separately, including RAI or MDS Coordinators.

Comment: One commenter strongly recommended against conducting audits for compliance with this staffing reporting requirement as part of the survey process, either as regular or focused surveys.

Response: The operations of audits are outside the scope of this regulation. As a general matter, CMS seeks to ensure that the audits to assess compliance with reporting requirements are conducted in a manner that directly addresses the need to verify the data submitted by facilities. This includes having the audits conducted by individuals or entities who are subject matter experts in this area.

Comment: One commenter remarked that it is not clear when the payroll submissions are due (for example, how much time providers will be given after the end of the quarter to make their submission).

Response: We will communicate information on submission requirements through guidance. For example, the Draft PBJ Policy Manual states that providers have 45 days from the end of the quarter to submit their data. Please see the following Web site for more information: <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Staffing-Data-Submission-PBJ.html>.

Comment: One commenter stated that reports must include the number and types of nursing staff on each shift,

including mutually exclusive staff categories, in particular RNs versus LPNs. For example, in reporting staffing, LPNs with administrative duties are not to be combined with RNs with administrative duties.

Response: The reporting of data is outside the scope of this regulation. We will work with stakeholders prior to posting information or formulating quality measures.

Comment: One commenter cautioned that if a facility has low staffing levels, it would not necessarily equate to poor quality of care.

Response: While this comment is discussing proposed uses of the collected data which is outside the scope of this regulation, we agree that there are many factors that contribute to good quality of care. Families and residents should not only use a variety of information in making judgments about a facility (such as the various types of information available on the CMS Nursing Home Compare Web site), but above all should visit facilities, talk to residents and staff, and consult with other knowledgeable parties in the community (such as the State Survey Agency and the local Nursing Home Ombudsman Program).

Comment: Several commenters expressed support for the implementation of this rule and CMS' intent to ensure that accurate staffing data was being reported by LTC facilities.

Response: We thank these commenters for their support.

c. Provisions of the Final Rule

We are adopting the provisions of this final rule as proposed, with the following changes:

- In consideration of public comments, we added a definition of "direct care staff" at § 483.75(u)(1). We renumbered the subsections within § 483.75(u) accordingly. In addition, we made conforming changes to utilize the defined term in the provisions regarding the submission requirements at § 483.75(u)(2)(i) and (iii) in the final rule and the provision regarding distinguishing employee from agency and contract staff at § 483.75(u)(3) of this final rule.
- Finally, in consideration of public comment, we added the adjective "uniform" to describe the format requirement in the provision regarding data format in § 483.75(u)(4) of the final rule.

IV. Collection of Information Requirements

In the FY 2016 SNF PPS proposed rule (80 FR 22082), we solicited public

comment on that rule's information collection requirements as they relate to the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*). However, of all of the comments received on the proposed rule, only one was related to our position that all of the proposed information collection requirements were exempt from the PRA. A summary of the comment and our response follows.

Consistent with the proposed rule, this final rule maintains that the information collection requirements are exempt from the PRA. We refer readers to the FY 2016 SNF PPS proposed rule for details.

Comment: One commenter disagreed with CMS's assertion that the PRA does not apply to the proposed staff reporting requirements. The commenter further stated that because the Affordable Care Act, not OBRA 1987, was the statute that established the staff reporting requirements, the requirements would likely not fall within the scope of OBRA 1987's PRA waivers.

Response: We respectfully disagree with the commenter's analysis. The staff reporting requirements are exempt from PRA because section 6106 of the Affordable Care Act (which added 1128I(g) of the Act) is related to the information required for the purposes of carrying out relevant sections of OBRA 1987's nursing home reform requirements. For example, section 1819(b)(4) of the Act includes requirements for staff such as nursing services, pharmaceutical services, dietary services, and other services facilities are required to provide, and the collection of the staffing data helps verify compliance with these requirements.

V. Economic Analyses

A. Regulatory Impact Analysis

1. Introduction

We have examined the impacts of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA, September 19, 1980, Pub. L. 96-354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA, March 22, 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. This rule has been designated an economically significant rule, under section 3(f)(1) of Executive Order 12866. Accordingly, we have prepared a regulatory impact analysis (RIA) as further discussed below. Also, the rule has been reviewed by OMB.

2. Statement of Need

This final rule would update the SNF prospective payment rates for FY 2015 as required under section 1888(e)(4)(E) of the Act. It also responds to section 1888(e)(4)(H) of the Act, which requires the Secretary to provide for publication in the **Federal Register** before the August 1 that precedes the start of each FY, the unadjusted federal per diem rates, the case-mix classification system, and the factors to be applied in making the area wage adjustment. As these statutory provisions prescribe a detailed methodology for calculating and disseminating payment rates under the SNF PPS, we do not have the discretion to adopt an alternative approach. In addition, this final rule specifies a SNF all-cause all-condition hospital readmission measure, as well as adopts that measure for a new SNF VBP Program, and includes a discussion of SNF VBP Program policies we are considering for future rulemaking to promote higher quality and more efficient health care for Medicare beneficiaries. This final rule also implements a new quality reporting program for SNFs, as specified in the IMPACT Act. Finally, through this final rule, we are implementing section 1128I(g) of the Act, which requires the electronic submission of staffing information based on payroll and other verifiable and auditable data.

3. Overall Impacts

This final rule sets forth updates of the SNF PPS rates contained in the SNF PPS final rule for FY 2015 (79 FR 45628). Based on the above, we estimate that the aggregate impact would be an increase of \$430 million in payments to SNFs, resulting from the SNF market basket update to the payment rates, as adjusted by the applicable forecast error adjustment and by the MFP adjustment. The impact analysis of this final rule represents the projected effects of the changes in the SNF PPS from FY 2015

to FY 2016. Although the best data available are utilized, there is no attempt to predict behavioral responses to these changes, or to make adjustments for future changes in such variables as days or case-mix.

Certain events may occur to limit the scope or accuracy of our impact analysis, as this analysis is future-oriented and, thus, very susceptible to forecasting errors due to certain events that may occur within the assessed impact time period. Some examples of possible events may include newly-legislated general Medicare program funding changes by the Congress, or changes specifically related to SNFs. In addition, changes to the Medicare program may continue to be made as a result of previously-enacted legislation, or new statutory provisions. Although these changes may not be specific to the SNF PPS, the nature of the Medicare program is such that the changes may interact and, thus, the complexity of the interaction of these changes could make it difficult to predict accurately the full scope of the impact upon SNFs.

In accordance with sections 1888(e)(4)(E) and 1888(e)(5) of the Act, we update the FY 2015 payment rates by a factor equal to the market basket index percentage change adjusted by the FY 2014 forecast error and the MFP adjustment to determine the payment rates for FY 2016. As discussed previously, for FY 2012 and each subsequent FY, as required by section 1888(e)(5)(B) of the Act as amended by section 3401(b) of the Affordable Care Act, the market basket percentage is reduced by the MFP adjustment. The special AIDS add-on established by section 511 of the MMA remains in effect until such date as the Secretary certifies that there is an appropriate adjustment in the case mix. We have not provided a separate impact analysis for the MMA provision. Our latest estimates indicate that there are fewer than 4,800 beneficiaries who qualify for the add-on payment for residents with AIDS. The impact to Medicare is included in the total column of Table 12. In updating the SNF PPS rates for FY 2016, we made a number of standard annual revisions and clarifications mentioned elsewhere in this final rule (for example, the update to the wage and market basket indexes used for adjusting the federal rates).

The annual update set forth in this final rule applies to SNF PPS payments in FY 2016. Accordingly, the analysis that follows only describes the impact of this single year. In accordance with the requirements of the Act, we will publish a notice or rule for each subsequent FY that will provide for an update to the

SNF PPS payment rates and include an associated impact analysis.

In accordance with sections 1888(g) and (h)(2)(A) of the Act, we are finalizing the adoption of a SNF 30-Day All-Cause Readmission Measure (SNFRM) for the SNF VBP Program. Because this measure is claims-based, its adoption under the SNF VBP Program would not result in any increased costs to SNFs.

However, we do not yet have preliminary data with which we could project economic impacts associated with the measure. We intend to make additional proposals for the SNF VBP Program in future rulemaking, and we will assess the impacts of the SNFRM and any associated SNF VBP Program proposals at that time.

The burden associated with the SNF QRP is the time and effort associated with data collection and reporting. In this final rule, we are finalizing three quality measures that meet the requirements of section 1888(e)(6)(B)(II) of the Act.

Our burden calculations take into account all “new” items required on the MDS 3.0 to support data collection and reporting for these three finalized measures. New items will be included on the following assessments: SNF PPS 5-Day, Swing Bed PPS 5-Day, OMRA—Start of Therapy Discharge, OMRA—Other Discharge, OBRA Discharge, Swing Bed OMRA—Start of Therapy Discharge, Swing Bed OMRA—Other Discharge, and Swing Bed Discharge on the MDS 3.0. The SNF QRP also requires the addition of a SNF PPS Part A Discharge Assessment, which will also include new items. New items include data elements required to identify whether pressure ulcers were present on admission, to inform future development of the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), as well as changes in function and occurrence of falls with major injury. To the extent applicable, we will use standardized items to collect data for the three measures. For a copy of the data collection instrument, please visit: <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.html>.

We estimate a total additional burden of \$30.00 per Medicare-covered SNF stay, based on the most recent data available, in this case FY 2014, that 15,421 SNFs had a total of 2,599,656 Medicare-covered stays for fee-for-service beneficiaries. This would equate

to 1,112,002.85 total added hours or 72.11 hours per SNF annually.

We anticipate that the additional MDS items we finalized will be completed by Registered Nurses (RN), Occupational Therapists (OT), and/or Physical Therapists (PT), depending on the item. We identified the staff type per item based on past LTCH and IRF burden calculations in conjunction with expert opinion. Our assumptions for staff type were based on the categories generally necessary to perform assessment: Registered Nurse (RN), Occupational Therapy (OT), and Physical Therapy (PT). Individual providers determine the staffing resources necessary, therefore, we averaged the national average for these labor types and established a composite cost estimate. We obtained mean hourly wages for these staff from the U.S. Bureau of Labor Statistics' May 2013 National Occupational Employment and Wage Estimates (http://www.bls.gov/oes/current/oes_nat.htm), and to account for overhead and fringe benefits, we have doubled the mean hourly wage. The mean hourly wage for an RN is \$33.13, doubled to \$66.26 to account for overhead and fringe benefits. The mean hourly wage for an OT is \$37.45, doubled to \$74.90 to account for overhead and fringe benefits. The mean hourly wage for a PT is \$39.51, doubled to \$79.02 to account for overhead and fringe benefits.

To calculate the added burden, we first identified the total number of new items to be added into assessment instruments. We assume that each new item accounts for 0.5 minutes of nursing facility staff time. This assumption is consistent with burden calculations in past IRF and LTCH federal regulations. For each staff type, we then multiply the added burden in minutes with the number of times we believe that each item will be completed annually. To identify the number of times an item would be completed annually, we noted the number of total SNF FFS Medicare-covered stays in FY 2014, the most recent data available to us. We assume that if an item were added to all discharge assessments, then that item would be completed at least one time

per SNF FFS Medicare-covered stay. For example, the time it takes to complete an item added to all discharge assessments (0.5 minutes) would be multiplied by the number of SNF FFS Medicare-covered stays in FY 2014 to identify the total added burden in minutes associated with that item. Items added only to the SNF PPS Part A Discharge were weighted to reflect the proportion of SNF stays for residents who switch payers, but are not physically discharged from the facility. Added burden in minutes per staff type was then converted to hours and multiplied by the doubled hourly wage to identify the annual cost per staff type. Given these wages and time estimates, the total cost related to the SNF PPS Part A Discharge Assessment and SNF QRP measures is estimated at \$5,057.45 per SNF annually, or \$78,011,166.25 for all SNFs annually. We received comments regarding the burden related to the SNF QRP, which we addressed in section III.D.3.g.(2). of this final rule.

We have also conducted an impact analysis with regard to the electronic submission of staffing information, which will be required under 42 CFR 483.75(u). While facilities have been reporting their staffing data for many years via an annual, paper-based system, we appreciate that the electronic submission of staffing data is something that facilities have not been required to do and that this new requirement will have financial and/or staff time implications. Like the implementation of many new programs, the level of effort will be higher upfront, but decline throughout subsequent years.

4. Detailed Economic Analysis

The FY 2016 SNF PPS payment impacts appear in Table 12. Using the most recently available data, in this case FY 2014, we apply the current FY 2015 wage index and labor-related share value to the number of payment days to simulate FY 2015 payments. Then, using the same FY 2014 data, we apply the FY 2016 wage index and labor-related share value to simulate FY 2016 payments. We tabulate the resulting

payments according to the classifications in Table 12 (for example, facility type, geographic region, facility ownership), and compare the simulated FY 2015 payments to the simulated FY 2016 payments to determine the overall impact. The breakdown of the various categories of data in the table follows.

The first column shows the breakdown of all SNFs by urban or rural status, hospital-based or freestanding status, census region, and ownership.

The first row of figures describes the estimated effects of the various changes on all facilities. The next six rows show the effects on facilities split by hospital-based, freestanding, urban, and rural categories. The next nineteen rows show the effects on facilities by urban versus rural status by census region. The last three rows show the effects on facilities by ownership (that is, government, profit, and non-profit status).

The second column shows the number of facilities in the impact database.

The third column shows the effect of the annual update to the wage index. This represents the effect of using the most recent wage data available. The total impact of this change is zero percent; however, there are distributional effects of the change.

The fourth column shows the effect of all of the changes on the FY 2016 payments. The update of 1.2 percent (consisting of the market basket increase of 2.3 percentage points, reduced by the 0.6 percentage point forecast error adjustment and further reduced by the 0.5 percentage point MFP adjustment) is constant for all providers and, though not shown individually, is included in the total column. It is projected that aggregate payments will increase by 1.2 percent, assuming facilities do not change their care delivery and billing practices in response.

As illustrated in Table 12, the combined effects of all of the changes vary by specific types of providers and by location. For example, due to changes finalized in this rule, providers in the rural Pacific region would experience a 1.4 percent increase in FY 2016 total payments.

TABLE 12—PROJECTED IMPACT TO THE SNF PPS FOR FY 2016

	Number of facilities FY 2016	Update wage data (%)	Total change (%)
Group:			
Total	15,425	0.0	1.2
Urban	10,888	0.1	1.3
Rural	4,537	-0.6	0.6
Hospital based urban	546	0.2	1.4
Freestanding urban	10,342	0.1	1.3

TABLE 12—PROJECTED IMPACT TO THE SNF PPS FOR FY 2016—Continued

	Number of facilities FY 2016	Update wage data (%)	Total change (%)
Hospital based rural	627	-0.6	0.6
Freestanding rural	3,910	-0.6	0.6
Urban by region:			
New England	801	0.5	1.7
Middle Atlantic	1,485	0.6	1.8
South Atlantic	1,853	-0.2	1.0
East North Central	2,068	-0.1	1.1
East South Central	544	0.0	1.2
West North Central	899	-0.5	0.6
West South Central	1,310	-0.1	1.1
Mountain	501	-0.4	0.8
Pacific	1,420	0.6	1.8
Outlying	7	-1.1	0.1
Rural by region:			
New England	142	-0.9	0.3
Middle Atlantic	222	-1.4	-0.3
South Atlantic	511	-0.1	1.1
East North Central	937	-0.1	1.1
East South Central	535	-0.5	0.7
West North Central	1,089	-0.9	0.3
West South Central	765	-1.3	-0.1
Mountain	233	-0.8	0.4
Pacific	103	0.2	1.4
Ownership:			
Government	882	0.0	1.2
Profit	10,862	0.0	1.2
Non-profit	3,681	-0.1	1.1

Note: The Total column includes the 2.3 percent market basket increase, reduced by the 0.6 percentage point forecast error adjustment and further reduced by the 0.5 percentage point MFP adjustment. Additionally, we found no SNFs in rural outlying areas.

We have also conducted an economic analysis with regard impact of the electronic submission of staffing information, which is required under 42 CFR 483.75(u). Factors affecting a facility's cost include the size of the facility, the number of employees of a facility, and the type of system a facility uses to report and submit data. To calculate the cost, we analyzed information from a staffing pilot conducted in 2012, including evaluating the type (for example, hours per day) and frequency (for example, quarterly) of the information to be submitted. For example, we estimate that a facility using a complex, automated payroll or time-keeping system would require some upfront and ongoing costs to configure their system to provide the data. We estimate these costs to be approximately \$500 to \$1,500 upfront, with an additional \$500 to \$1,500 in maintenance costs each year. Additionally, we estimate this type of facility would require an estimated 1 hour of in-house staff time per week, to oversee the process. Conversely, a facility without an automated time-keeping system would not have the upfront and ongoing costs associated with purchasing or configuring a system. However, this facility would require more time from in-house staff to

enter and submit the data. We estimate this time to be approximately 4 hours per week. To help mitigate potential cost for facilities, we will be providing a system for facilities to enter and submit data manually and at no cost. Using the 2013 hourly wage estimate of \$18.71 per hour for payroll and timekeeping employees in Skilled Nursing Facilities from the Bureau of Labor Statistics, we believe that the cost to facilities will range between \$4,100 and \$6,800 per facility for the first year of implementation. This includes one-time costs associated with configuring payroll or time-keeping systems to produce and submit the required data. Subsequent years would have lower costs ranging from \$2,700 to \$4,200 per facility per year. These estimates also include up to 16 hours per year for training staff on the submission of data.

5. Alternatives Considered

As described in this section, we estimate that the aggregate impact for FY 2016 would be an increase of \$430 million in payments to SNFs, resulting from the SNF market basket update to the payment rates, as adjusted by the applicable forecast error adjustment and by the MFP adjustment.

Section 1888(e) of the Act establishes the SNF PPS for the payment of Medicare SNF services for cost reporting

periods beginning on or after July 1, 1998. This section of the statute prescribes a detailed formula for calculating payment rates under the SNF PPS, and does not provide for the use of any alternative methodology. It specifies that the base year cost data to be used for computing the SNF PPS payment rates must be from FY 1995 (October 1, 1994, through September 30, 1995). In accordance with the statute, we also incorporated a number of elements into the SNF PPS (for example, case-mix classification methodology, a market basket index, a wage index, and the urban and rural distinction used in the development or adjustment of the federal rates). Further, section 1888(e)(4)(H) of the Act specifically requires us to disseminate the payment rates for each new FY through the **Federal Register**, and to do so before the August 1 that precedes the start of the new FY. Accordingly, we are not pursuing alternatives for the payment methodology as discussed previously.

Section 1128I(g) of the Act establishes requirement for LTC facilities to submit direct care staffing information. This section of the statute specifically prescribes the data to be submitted. Accordingly we are not pursuing alternatives to the reporting requirement as discussed previously.

6. Accounting Statement

As required by OMB Circular A-4 (available online at www.whitehouse.gov/sites/default/files/omb/assets/regulatory_matters_pdf/a-4.pdf), in Table 13, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final rule. Table 13 provides our best estimate of the possible changes in Medicare payments under the SNF PPS as a result of the policies in this final rule, based on the data for 15,425 SNFs in our database. All expenditures are classified as transfers to Medicare providers (that is, SNFs).

TABLE 13—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES, FROM THE 2015 SNF PPS FY TO THE 2016 SNF PPS FY

Category	Transfers
Annualized Monetized Transfers. From Whom To Whom?	\$430 million. * Federal Government to SNF Medicare Providers.

* The net increase of \$430 million in transfer payments is a result of the forecast error and MFP adjusted market basket increase of \$430 million.

7. Conclusion

This final rule sets forth updates of the SNF PPS rates contained in the SNF PPS final rule for FY 2015 (79 FR 45628). Based on the above, we estimate the overall estimated payments for SNFs in FY 2016 are projected to increase by \$430 million, or 1.2 percent, compared with those in FY 2015. We estimate that in FY 2016 under RUG-IV, SNFs in urban and rural areas would experience, on average, a 1.3 and 0.6 percent increase, respectively, in estimated payments compared with FY 2015. Providers in the urban Pacific and Middle Atlantic regions would experience the largest estimated increase in payments of approximately 1.8 percent. Providers in the rural Middle Atlantic region would experience a small decrease in payments of 0.3 percent.

B. Regulatory Flexibility Act Analysis

The 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, non-profit organizations, and small governmental jurisdictions. Most SNFs and most other providers and suppliers

are small entities, either by reason of their non-profit status or by having revenues of \$27.5 million or less in any 1 year. We utilized the revenues of individual SNF providers (from recent Medicare Cost Reports) to classify a small business, and not the revenue of a larger firm with which they may be affiliated. As a result, we estimate approximately 91 percent of SNFs are considered small businesses according to the Small Business Administration's latest size standards (NAICS 623110), with total revenues of \$27.5 million or less in any 1 year. (For details, see the Small Business Administration's Web site at <http://www.sba.gov/category/navigation-structure/contracting/contracting-officials/eligibility-size-standards>). In addition, approximately 25 percent of SNFs classified as small entities are non-profit organizations. Finally, individuals and states are not included in the definition of a small entity.

This final rule sets forth updates of the SNF PPS rates contained in the SNF PPS final rule for FY 2015 (79 FR 45628). Based on the above, we estimate that the aggregate impact would be an increase of \$430 million in payments to SNFs, resulting from the SNF market basket update to the payment rates, as adjusted by the MFP adjustment and forecast error adjustment. While it is projected in Table 12 that most providers would experience a net increase in payments, we note that some individual providers within the same region or group may experience different impacts on payments than others due to the distributional impact of the FY 2016 wage indexes and the degree of Medicare utilization.

Guidance issued by the Department of Health and Human Services on the proper assessment of the impact on small entities in rulemakings, utilizes a cost or revenue impact of 3 to 5 percent as a significance threshold under the RFA. According to MedPAC, Medicare covers approximately 12 percent of total patient days in freestanding facilities and 22 percent of facility revenue (Report to the Congress: Medicare Payment Policy, March 2015, available at [http://medpac.gov/documents/reports/chapter-8-skilled-nursing-facility-services-\(march-2015-report\).pdf](http://medpac.gov/documents/reports/chapter-8-skilled-nursing-facility-services-(march-2015-report).pdf)). However, it is worth noting that the distribution of days and payments is highly variable. That is, the majority of SNFs have significantly lower Medicare utilization (Report to the Congress: Medicare Payment Policy, March 2015, available at [http://medpac.gov/documents/reports/chapter-8-skilled-nursing-facility-services-\(march-2015-report\).pdf](http://medpac.gov/documents/reports/chapter-8-skilled-nursing-facility-services-(march-2015-report).pdf)). As a

result, for most facilities, when all payers are included in the revenue stream, the overall impact on total revenues should be substantially less than those impacts presented in Table 12. As indicated in Table 12, the effect on facilities is projected to be an aggregate positive impact of 1.2 percent. As the overall impact on the industry as a whole, and thus on small entities specifically, is less than the 3 to 5 percent threshold discussed previously, the Secretary has determined that this final rule will not have a significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. This final rule will affect small rural hospitals that (1) furnish SNF services under a swing-bed agreement or (2) have a hospital-based SNF. We anticipate that the impact on small rural hospitals would be similar to the impact on SNF providers overall. Moreover, as noted in previous SNF PPS final rules (most recently the one for FY 2015 (79 FR 45658)), the category of small rural hospitals would be included within the analysis of the impact of this final rule on small entities in general. As indicated in Table 12, the effect on facilities is projected to be an aggregate positive impact of 1.2 percent. As the overall impact on the industry as a whole is less than the 3 to 5 percent threshold discussed above, the Secretary has determined that this final rule will not have a significant impact on a substantial number of small rural hospitals.

C. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2015, that threshold is approximately \$144 million. This final rule would not impose spending costs on state, local, or tribal governments in the aggregate, or by the private sector, of \$144 million.

D. Federalism Analysis

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. This final rule will have no substantial direct effect on state and local governments, preempt state law, or otherwise have federalism implications.

E. Congressional Review Act

This final regulation is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and has been transmitted to the Congress and the Comptroller General for review.

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

List of Subjects in 42 CFR Part 483

Grant programs-health, Health facilities, Health professions, Health records, Medicaid, Medicare, Nursing homes, Nutrition, Reporting and recordkeeping requirements, Safety.

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

PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

■ 1. The authority citation for part 483 is revised to read as follows:

Authority: Secs. 1102, 1128I, 1819, 1871 and 1919 of the Social Security Act (42 U.S.C. 1302, 1320a-7, 1395i, 1395hh and 1396r).

■ 2. Section 483.75 is amended by adding paragraph (u) to read as follows:

§ 483.75 Administration.

* * * * *

(u) *Mandatory submission of staffing information based on payroll data in a uniform format.* Long-term care facilities must electronically submit to CMS complete and accurate direct care staffing information, including information for agency and contract staff, based on payroll and other verifiable and auditable data in a uniform format according to specifications established by CMS.

(1) *Direct Care Staff.* Direct Care Staff are those individuals who, through interpersonal contact with residents or resident care management, provide care and services to allow residents to attain or maintain the highest practicable physical, mental, and psychosocial well-being. Direct care staff does not include individuals whose primary duty is maintaining the physical environment of the long term care facility (for example, housekeeping).

(2) *Submission requirements.* The facility must electronically submit to CMS complete and accurate direct care staffing information, including the following:

(i) The category of work for each person on direct care staff (including, but not limited to, whether the individual is a registered nurse, licensed practical nurse, licensed vocational nurse, certified nursing assistant, therapist, or other type of medical personnel as specified by CMS);

(ii) Resident census data; and

(iii) Information on direct care staff turnover and tenure, and on the hours of care provided by each category of staff per resident per day (including, but not limited to, start date, end date (as applicable), and hours worked for each individual).

(3) *Distinguishing employee from agency and contract staff.* When reporting information about direct care staff, the facility must specify whether the individual is an employee of the facility, or is engaged by the facility under contract or through an agency.

(4) *Data format.* The facility must submit direct care staffing information in the uniform format specified by CMS.

(5) *Submission schedule.* The facility must submit direct care staffing information on the schedule specified by CMS, but no less frequently than quarterly.

Dated: July 27, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: July 28, 2015.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

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