



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 409 and 413

[CMS-1718-P]

RIN 0938-AT75

Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities; Updates to the Quality Reporting Program and Value-Based Purchasing Program for Federal Fiscal Year 2020

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would update the payment rates used under the prospective payment system (PPS) for skilled nursing facilities (SNFs) for fiscal year (FY) 2020. We also propose minor revisions to the regulation text to reflect the revised assessment schedule under Patient Driven Payment Model (PDPM). Additionally, we propose to revise the definition of group therapy under the SNF PPS, and to implement a subregulatory process for updating the code lists (International Classification of Diseases, Tenth Version (ICD-10) codes) used under PDPM. We are also soliciting comments on stakeholder concerns regarding the appropriateness of the wage index used to adjust SNF payments. In addition, the proposed rule includes proposals for the SNF Quality Reporting Program (QRP) and the SNF Value-Based Purchasing (VBP) Program that will affect Medicare payment to SNFs.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on June 18, 2019.

ADDRESSES: In commenting, please refer to file code CMS-1718-P. Because of staff and

resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to **<http://www.regulations.gov>**. Follow the "Submit a comment" instructions.
2. By regular mail. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-1718-P,

P.O. Box 8016,

Baltimore, MD 21244-8016.

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

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-1718-P,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

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

FOR FURTHER INFORMATION CONTACT: Penny Gershman, (410) 786-6643, for

information related to SNF PPS clinical issues.

Anthony Hodge, (410) 786-6645, for information related to payment for SNF-level swing-bed services.

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

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 and consolidated billing.

Casey Freeman, (410) 786-4354, for information related to skilled nursing facility quality reporting program.

James Poyer, (410) 786-2261, for information related to the skilled nursing facility value-based purchasing program.

SUPPLEMENTARY INFORMATION:

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

Availability of Certain Tables Exclusively Through the Internet on the CMS

Website

As discussed in the FY 2014 SNF PPS final rule (78 FR 47936), 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 website. The wage index tables for this proposed rule can be accessed on the SNF PPS Wage Index home page, at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/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.

To assist readers in referencing sections contained in this document, we are providing the following Table of Contents.

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Regulations Text

I. Executive Summary

A. Purpose

This proposed rule would update the SNF prospective payment rates for fiscal year (FY) 2020 as required under section 1888(e)(4)(E) of the Social Security Act (the Act). It would also respond 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, certain specified information relating to the payment update (see section II.C. of this proposed

rule). This proposed rule also proposes to revise the definition of group therapy under the SNF PPS and to implement a subregulatory process for updating ICD-10 code lists used under the PDPM. Finally, this proposed rule would also update the Skilled Nursing Facility Quality Reporting Program (SNF QRP) and Skilled Nursing Facility Value-Based Purchasing Program (SNF VBP).

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 proposed rule would reflect an update to the rates that we published in the SNF PPS final rule for FY 2019 (83 FR 39162), as corrected in the FY 2019 SNF PPS correction notice (83 FR 49832), which reflects the SNF market basket update, as adjusted by the multifactor productivity (MFP) adjustment, for FY 2020. In addition, we are proposing to revise the definition of group therapy under the SNF PPS and to implement a subregulatory process for updating ICD-10 code lists used under the PDPM.

This proposed rule proposes to update requirements for the SNF QRP, including the proposal of two Transfer of Health Information quality measures as well as standardized patient assessment data elements to begin collection on October 1, 2020 in satisfaction of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (Pub. L. 113-185, enacted October 6, 2014). We are also proposing to exclude baseline nursing home residents from the Discharge to Community Measure. In addition, we are proposing to expand data collection for SNF QRP quality measures to all skilled nursing facility residents, regardless of their payer. Further, we are also proposing the public display of the quality measure, Drug Regimen Review Conducted With Follow-Up for Identified Issues- Post Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP). We are also proposing to revise references in regulation text to reflect enhancements to the system used for the submission

of data. Finally, we are requesting information on quality measures and standardized resident assessment data elements under consideration for future years.

In accordance with section 1888(h) of the Act, this proposed rule would update certain policies for the SNF VBP.

C. Summary of Cost and Benefits

TABLE 1: Cost and Benefits

Provision Description	Total Transfers
FY 2020 SNF PPS payment rate update.	The overall economic impact of this proposed rule is an estimated increase of \$887 million in aggregate payments to SNFs during FY 2020.
FY 2020 SNF VBP changes.	The overall economic impact of the SNF VBP Program is an estimated reduction of \$213.6 million in aggregate payments to SNFs during FY 2020.

D. Advancing Health Information Exchange

The Department of Health and Human Services (HHS) has a number of initiatives designed to encourage and support the adoption of interoperable health information technology and to promote nationwide health information exchange to improve health care. The Office of the National Coordinator for Health Information Technology (ONC) and CMS work collaboratively to advance interoperability across settings of care, including post-acute care.

To further interoperability in post-acute care, we developed a Data Element Library (DEL) to serve as a publicly available centralized, authoritative resource for standardized data elements and their associated mappings to health IT standards. The DEL furthers CMS' goal of data standardization and interoperability, which is also a goal of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act). These interoperable data elements can reduce provider burden by allowing the use and exchange of healthcare data, support provider exchange of electronic health information for care coordination, person-centered care, and support real-time, data driven, clinical decision making. Standards in the Data Element Library (<https://del.cms.gov/>) can be referenced on the CMS website and in the ONC Interoperability Standards Advisory (ISA). The 2019 ISA is available at <https://www.healthit.gov/isa>.

The 21st Century Cures Act (the Cures Act) (Pub. L. 114-255, enacted December 13, 2016) requires HHS to take new steps to enable the electronic sharing of health information ensuring interoperability for providers and settings across the care continuum. In another important provision, Congress defined “information blocking” as practices likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information, and established new authority for HHS to discourage these practices. In March 2019, ONC and CMS published the proposed rules, “21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program,” (84 FR 7424) and “Interoperability and Patient Access” (84 FR 7610) to promote secure and more immediate access to health information for patients and healthcare providers through the implementation of information blocking provisions of the Cures Act and the use of standardized application programming interfaces (APIs) that enable easier access to electronic health information. These two proposed rules are open for public comment at www.regulations.gov. We invite providers to learn more about these important developments and how they are likely to affect SNFs.

II. Background on SNF PPS

A. Statutory Basis and Scope

As amended by section 4432 of the Balanced Budget Act of 1997 (BBA 1997) (Pub. L. 105-33, enacted on August 5, 1997), 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 physicians' 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 https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/Downloads/Legislative_History_2018-10-01.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 an all-cause all-condition hospital readmission measure and an all-condition risk-adjusted potentially preventable hospital readmission measure 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(c)(4) of the IMPACT Act amended section 1888(e)(6) to the Act, which requires the Secretary to implement a quality reporting program for SNFs under which SNFs report data on measures and resident assessment data.

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 3 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 2019 (83 FR 39162), as corrected in the FY 2019 SNF PPS correction notice (83 FR 49832).

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 proposed rule will provide the required annual updates to the per diem payment rates for SNFs for FY 2020.

III. Proposed SNF PPS Rate Setting Methodology and FY 2020 Update

A. 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 be 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 1997 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.

B. SNF Market Basket Update

1. 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. In the SNF PPS final rule for FY 2018 (82 FR 36548 through 36566), we revised and rebased the market basket index, which included updating the base year from FY 2010 to 2014.

The SNF market basket index is used to compute the market basket percentage change

that is used to update the SNF federal rates on an annual basis, as required by section 1888(e)(4)(E)(ii)(IV) of the Act. This market basket percentage update is adjusted by a forecast error correction, if applicable, and then further adjusted by the application of a productivity adjustment as required by section 1888(e)(5)(B)(ii) of the Act and described in section III.B.4. of this proposed rule. For FY 2020, the growth rate of the 2014-based SNF market basket is estimated to be 3.0 percent, based on the IHS Global Insight, Inc. (IGI) first quarter 2019 forecast with historical data through fourth quarter 2018, before the multifactor productivity adjustment is applied.

In section III.B.5. of this proposed rule, we discuss the 2 percent reduction applied to the market basket update for those SNFs that fail to submit measures data as required by section 1888(e)(6)(A) of the Act.

2. 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 proposed rule, we use the percentage change in the SNF market basket index to compute the update factor for FY 2020. This factor is based on the FY 2020 percentage increase in the 2014-based SNF market basket index reflecting routine, ancillary, and capital-related expenses. In this proposed rule, the SNF market basket percentage is estimated to be 3.0 percent for FY 2020 based on IGI's first quarter 2019 forecast (with historical data through fourth quarter 2018). Finally, as discussed in section II.B. of this proposed 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.

3. 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), § 413.337(d)(2) provides 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 2018 (the most recently available FY for which there is final data), the estimated increase in the market basket index was 2.6 percentage points, and the actual increase for FY 2018 is 2.6 percentage points, resulting in the actual increase being the same as the estimated increase. Accordingly, as the difference between the estimated and actual amount of change in the market basket index does not exceed the 0.5 percentage point threshold, the FY 2020 market basket percentage change of 3.0 percent would not be adjusted to account for the forecast error correction. Table 2 shows the forecasted and actual market basket amounts for FY 2018.

TABLE 2: Difference Between the Forecasted and Actual Market Basket Increases for FY 2018

Index	Forecasted FY 2018 Increase*	Actual FY 2018 Increase**	FY 2018 Difference
SNF	2.6	2.6	0.0

*Published in **Federal Register**; based on second quarter 2017 IGI forecast (2010-based index).

**Based on the first quarter 2019 IGI forecast, with historical data through the fourth quarter 2018 (2010-based index).

4. Multifactor Productivity Adjustment

Section 1888(e)(5)(B)(ii) of the Act, as added by section 3401(b) of the Patient Protection and Affordable Care Act (Affordable Care Act) (Pub. L. 111-148, enacted on March 23, 2010) 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 multifactor productivity (MFP) adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1886(b)(3)(B)(xi)(II) of the Act, in turn, defines the MFP adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor 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 Bureau of Labor Statistics (BLS) is the agency that publishes the official measure of private nonfarm business MFP. We refer readers to the BLS website at <http://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. For a discussion of the MFP projection methodology, we refer readers to the FY 2012 SNF PPS final rule (76 FR 48527 through 48529) and the FY 2016 SNF PPS

final rule (80 FR 46395). A complete description of the MFP projection methodology is available on our website at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html>.

a. Incorporating the MFP Adjustment into the Market Basket Update

Per 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) of the Act (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 being less than such payment rates for the preceding fiscal year. 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.

The MFP adjustment, calculated as the 10-year moving average of changes in MFP for the period ending September 30, 2020, is estimated to be 0.5 percent based on IGI's first quarter 2019 forecast. Also, consistent with section 1888(e)(5)(B)(i) of the Act and § 413.337(d)(2), the market basket percentage for FY 2020 for the SNF PPS is based on IGI's first quarter 2019 forecast of the SNF market basket percentage, which is estimated to be 3.0 percent. In

accordance with section 1888(e)(5)(B)(ii) of the Act and § 413.337(d)(3), this market basket percentage is then reduced by the MFP adjustment of 0.5 percent. The resulting MFP-adjusted SNF market basket update would be equal to 2.5 percent, or 3.0 percent less 0.5 percentage point.

5. Market Basket Update Factor for FY 2020

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 2020 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, 2018, through September 30, 2019 to the average market basket level for the period of October 1, 2019, through September 30, 2020. This process yields a percentage change in the 2014-based SNF market basket of 3.0 percent. As further explained in section III.B.3. of this proposed 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 difference between the forecasted FY 2018 SNF market basket percentage change and the actual FY 2018 SNF market basket percentage change (FY 2018 is the most recently available FY for which there is historical data) did not exceed the 0.5 percentage point threshold, the FY 2020 market basket percentage change of 3.0 percent would not be adjusted by the forecast error correction.

Section 1888(e)(5)(B)(ii) of the Act requires us to reduce the market basket percentage change by the MFP adjustment (10-year moving average of changes in MFP for the period ending September 30, 2020) of 0.5 percent, as described in section III.B.4 of this proposed rule. The resulting net SNF market basket update would equal 2.5 percent, or 3.0 percent less the 0.5

percentage point MFP adjustment. We note that our policy has been that, if more recent data become available (for example, a more recent estimate of the SNF market basket and/or MFP adjustment), we would use such data, if appropriate, to determine the SNF market basket percentage change, labor-related share relative importance, forecast error adjustment, and MFP adjustment in the SNF PPS final rule.

We also note that section 1888(e)(6)(A)(i) of the Act provides that, beginning with FY 2018, SNFs that fail to submit data, as applicable, in accordance with sections 1888(e)(6)(B)(i)(II) and (III) of the Act for a fiscal year will receive a 2.0 percentage point reduction to their market basket update for the fiscal year involved, after application of section 1888(e)(5)(B)(ii) of the Act (the MFP adjustment) and section 1888(e)(5)(B)(iii) of the Act (the 1 percent market basket increase for FY 2018). In addition, section 1888(e)(6)(A)(ii) of the Act states that application of the 2.0 percentage point reduction (after application of section 1888(e)(5)(B)(ii) and (iii) of the Act) may result in the market basket index percentage change being less than 0.0 for a fiscal year, and may result in payment rates for a fiscal year being less than such payment rates for the preceding fiscal year. Section 1888(e)(6)(A)(iii) of the Act further specifies that the 2.0 percentage point reduction is applied in a noncumulative manner, so that any reduction made under section 1888(e)(6)(A)(i) of the Act applies only with respect to the fiscal year involved, and that the reduction cannot be taken into account in computing the payment amount for a subsequent fiscal year.

Accordingly, for the reasons specified in this proposed rule, we are proposing to apply the FY 2020 SNF market basket increase factor of 2.5 percent in our determination of the FY 2020 SNF PPS unadjusted federal per diem rates, which reflects a market basket increase factor of 3.0 percent, less the 0.5 percentage point MFP-adjustment.

6. Unadjusted Federal per Diem Rates for FY 2020

As discussed in the FY 2019 SNF PPS final rule (83 FR 39162), we are implementing a new case-mix classification system to classify SNF patients under the SNF PPS, beginning in FY 2020, called the Patient Driven Payment Model (PDPM). As discussed in section V.B of that final rule, under PDPM, the unadjusted Federal per diem rates are divided into six components, five of which are case-mix adjusted components (Physical Therapy (PT), Occupational Therapy (OT), Speech-Language Pathology (SLP), Nursing, and Non-Therapy Ancillaries (NTA)), and one of which is a non-case-mix component, as exists under RUG-IV. In calculating the FY 2020 unadjusted Federal per diem rates that would be used under PDPM in FY 2020, we applied the FY 2020 MFP-adjusted market basket increase factor to the unadjusted Federal per diem rates provided in Tables 4 and 5 of the FY 2019 SNF PPS final rule (83 FR 39169) and then applied the methodology for separating the RUG-IV base rates into the PDPM base rates, as discussed and finalized in section V.B.3 of the FY 2019 SNF PPS final rule (83 FR 39191 through 39194).

Tables 3 and 4 reflect the proposed updated unadjusted federal rates for FY 2020, prior to adjustment for case-mix.

TABLE 3: FY 2020 Unadjusted Federal Rate Per Diem--URBAN

Rate Component	PT	OT	SLP	Nursing	NTA	Non-Case-Mix
Per Diem Amount	\$61.16	\$56.93	\$22.83	\$106.64	\$80.45	\$95.48

TABLE 4: FY 2020 Unadjusted Federal Rate Per Diem—RURAL

Rate Component	PT	OT	SLP	Nursing	NTA	Non-Case-Mix
Per Diem Amount	\$69.72	\$64.03	\$28.76	\$101.88	\$76.86	\$97.25

C. 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 FY 2019 final rule (83 FR 39162, August 8, 2018), we finalized a new case-mix classification model, the PDPM, to take effect beginning October 1, 2019. The RUG-IV model classifies most patients into a therapy payment group and primarily uses the volume of therapy services provided to the patient as the basis for payment classification, thus inadvertently creating an incentive for SNFs to furnish therapy regardless of the individual patient's unique characteristics, goals, or needs. PDPM eliminates this incentive and improves the overall accuracy and appropriateness of SNF payments by classifying patients into payment groups based on specific, data-driven patient characteristics, while simultaneously reducing the administrative burden on SNFs.

The PDPM (like the RUG-IV) uses clinical data from the MDS to assign case-mix classifiers to each patient that are then used to calculate a per diem payment under the SNF PPS. As discussed in section IV.A. of this proposed 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 timeframes 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 website at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/MDS30RAIManual.html>.

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 FY 2020 payment rates set forth in this proposed rule reflect the use of the PDPM case-mix classification system from October 1, 2019, through September 30, 2020. We list the proposed case-mix adjusted PDPM payment rates for FY 2020, provided separately for urban and rural SNFs, in Tables 6 and 7 with corresponding case-mix values.

As discussed in the FY 2019 SNF PPS final rule (83 FR 39255 through 39256), we finalized the implementation of PDPM in a budget neutral manner. To accomplish this, as discussed in the FY 2019 SNF PPS final rule (83 FR 39256), the unadjusted PDPM case mix indexes (CMIs) were multiplied by 1.46 so that the total estimated payments under the PDPM would be equal to the total actual payments under RUG-IV. Further, section 3.11.2 of the PDPM technical report, available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/Downloads/PDPM_Technical_Report_508.pdf, provided additional detail on the calculation of the PDPM CMIs in order to achieve budget neutrality. In that section, it states that “to align the distribution of resources across components with the statutory base rates, Acumen set CMIs such that the average product of the CMI and the variable per diem adjustment factor for a day of care is the same (set to 1) for each of the five case-mix-adjusted components in PDPM. To do this, Acumen first calculated the product of the CMI and the adjustment factor for every utilization day for each component. Then, we calculated the average of this product for each component. Finally, Acumen calculated the ratio of 1 divided by the average product for each component. This ratio is the standardization multiplier, shown in Table 65 for each component.” As discussed in section 3.11.2 of the PDPM Technical Report, the standardization multiplier is used to align the distribution of resources across components with the statutory base rates by setting the CMIs such that the average product of the component CMI and the variable

per diem adjustment factor for that component for a day of care is the same. Effectively, the standardization multiplier is used to mitigate the effect of the variable per diem adjustment when calculating budget neutrality. The CMIs were adjusted such that total payments under PDPM, if it had been in effect in FY 2017, equal total actual payments made under RUG-IV in FY 2017.

In this proposed rule, we propose to update the payment year used as the basis for the calculation of the standardization multiplier and budget neutrality multiplier, in order to best ensure that PDPM will be implemented in a budget neutral manner, as finalized in the FY 2019 SNF PPS final rule. The only difference in methodology between that used to calculate these multipliers and CMIs in the FY 2019 SNF PPS final rule and that used to calculate the multipliers and CMIs in this proposed rule is that, in this proposed rule, we are updating the data used from FY 2017 data to FY 2018 data. The impact of using the updated FY 2018 data and the proposed updated adjustment multipliers for standardization and budget neutrality, is provided in Table 5. We would note that while the multipliers discussed in the FY 2019 SNF PPS final rule and in the PDPM Technical Report are given to the hundredths place, in order to make clear the effect of this change in data, the multipliers in Table 5 are shown to the thousandths place. The CMIs provided in Tables 6 and 7 reflect the use of the proposed multipliers in Table 5, based on the update to FY 2018 data.

TABLE 5: Proposed PDPM Standardization and Budget Neutrality Multipliers

Component	FY 2017 Data		FY 2018 Data	
	Standardization Multiplier	Budget Neutrality Multiplier	Standardization Multiplier	Budget Neutrality Multiplier
PT	1.031	1.458	1.028	1.463
OT	1.030	1.458	1.028	1.463
SLP	0.995	1.458	0.996	1.463
Nursing	0.995	1.458	0.996	1.463
NTA	0.817	1.458	0.811	1.463

Given the differences between RUG-IV and PDPM in terms of patient classification and billing, it is important that the format of Tables 6 and 7 reflect these differences. More

specifically, under both RUG-IV and PDPM, providers use a Health Insurance Prospective Payment System (HIPPS) code on a claim in order to bill for covered SNF services. Under RUG-IV, the HIPPS code includes the three character RUG-IV group into which the patient classifies as well as a two character assessment indicator code that represents the assessment used to generate this code. Under PDPM, while providers would still use a HIPPS code, the characters in that code represent different things. For example, the first character represents the PT and OT group into which the patient classifies. If the patient is classified into the PT and OT group “TA”, then the first character in the patient’s HIPPS code would be an A. Similarly, if the patient is classified into the SLP group “SB”, then the second character in the patient’s HIPPS code would be a B. The third character represents the Nursing group into which the patient classifies. The fourth character represents the NTA group into which the patient classifies. Finally, the fifth character represents the assessment used to generate the HIPPS code.

Therefore, we have modified the format of Tables 6 and 7 from what we have used for similar tables in prior SNF PPS rulemaking, such as Tables 6 and 7 of the FY 2019 SNF PPS final rule (83 FR 39170 through 39172). Column 1 of Tables 6 and 7 represents the character in the HIPPS code associated with a given PDPM component. Columns 2 and 3 provide the case-mix index and associated case-mix adjusted component rate, respectively, for the relevant PT group. Columns 4 and 5 provide the case-mix index and associated case-mix adjusted component rate, respectively, for the relevant OT group. Columns 6 and 7 provide the case-mix index and associated case-mix adjusted component rate, respectively, for the relevant SLP group. Column 8 provides the nursing case-mix group (CMG) that is connected with a given PDPM HIPPS character. For example, if the patient qualified for the nursing group CBC1, then the third character in the patient’s HIPPS code would be a “P.” Columns 9 and 10 provide the case-mix index and associated case-mix adjusted component rate, respectively, for the relevant nursing

group. Finally, columns 11 and 12 provide the case-mix index and associated case-mix adjusted component rate, respectively, for the relevant NTA group. Tables 6 and 7 do not reflect adjustments which may be made to the SNF PPS rates as a result of either the SNF QRP, discussed in section VI.B. of this proposed rule, or the SNF VBP program, discussed in sections III.B.5. and VI.C. of this proposed rule, or other adjustments, such as the variable per diem adjustment. Further, we use the revised OMB delineations adopted in the FY 2015 SNF PPS final rule (79 FR 45632, 45634), with updates as reflected in OMB Bulletin Nos, 15-01 and 17-01, to identify a facility's urban or rural status for the purpose of determining which set of rate tables would apply to the facility.

TABLE 6: PDPM Case-Mix Adjusted Federal Rates and Associated Indexes--URBAN

PDPM Group	PT CMI	PT Rate	OT CMI	OT Rate	SLP CMI	SLP Rate	Nursing CMG	Nursing CMI	Nursing Rate	NTA CMI	NTA Rate
A	1.53	\$93.57	1.49	\$84.83	0.68	\$15.52	ES3	4.06	\$432.96	3.24	\$260.66
B	1.70	\$103.97	1.63	\$92.80	1.82	\$41.55	ES2	3.07	\$327.38	2.53	\$203.54
C	1.88	\$114.98	1.69	\$96.21	2.67	\$60.96	ES1	2.93	\$312.46	1.84	\$148.03
D	1.92	\$117.43	1.53	\$87.10	1.46	\$33.33	HDE2	2.40	\$255.94	1.33	\$107.00
E	1.42	\$86.85	1.41	\$80.27	2.34	\$53.42	HDE1	1.99	\$212.21	0.96	\$77.23
F	1.61	\$98.47	1.60	\$91.09	2.98	\$68.03	HBC2	2.24	\$238.87	0.72	\$57.92
G	1.67	\$102.14	1.64	\$93.37	2.04	\$46.57	HBC1	1.86	\$198.35	-	-
H	1.16	\$70.95	1.15	\$65.47	2.86	\$65.29	LDE2	2.08	\$221.81	-	-
I	1.13	\$69.11	1.18	\$67.18	3.53	\$80.59	LDE1	1.73	\$184.49	-	-
J	1.42	\$86.85	1.45	\$82.55	2.99	\$68.26	LBC2	1.72	\$183.42	-	-
K	1.52	\$92.96	1.54	\$87.67	3.70	\$84.47	LBC1	1.43	\$152.50	-	-
L	1.09	\$66.66	1.11	\$63.19	4.21	\$96.11	CDE2	1.87	\$199.42	-	-
M	1.27	\$77.67	1.30	\$74.01	-	-	CDE1	1.62	\$172.76	-	-
N	1.48	\$90.52	1.50	\$85.40	-	-	CBC2	1.55	\$165.29	-	-
O	1.55	\$94.80	1.55	\$88.24	-	-	CA2	1.09	\$116.24	-	-
P	1.08	\$66.05	1.09	\$62.05	-	-	CBC1	1.34	\$142.90	-	-
Q	-	-	-	-	-	-	CA1	0.94	\$100.24	-	-
R	-	-	-	-	-	-	BAB2	1.04	\$110.91	-	-
S	-	-	-	-	-	-	BAB1	0.99	\$105.57	-	-
T	-	-	-	-	-	-	PDE2	1.57	\$167.42	-	-
U	-	-	-	-	-	-	PDE1	1.47	\$156.76	-	-
V	-	-	-	-	-	-	PBC2	1.22	\$130.10	-	-
W	-	-	-	-	-	-	PA2	0.71	\$75.71	-	-
X	-	-	-	-	-	-	PBC1	1.13	\$120.50	-	-
Y	-	-	-	-	-	-	PA1	0.66	\$70.38	-	-

TABLE 7: RUG-IV Case-Mix Adjusted Federal Rates and Associated Indexes—RURAL

PDPM Group	PT CMI	PT Rate	OT CMI	OT Rate	SLP CMI	SLP Rate	Nursing CMG	Nursing CMI	Nursing Rate	NTA CMI	NTA Rate
A	1.53	\$106.67	1.49	\$95.40	0.68	\$19.56	ES3	4.06	\$413.63	3.24	\$249.03
B	1.70	\$118.52	1.63	\$104.37	1.82	\$52.34	ES2	3.07	\$312.77	2.53	\$194.46
C	1.88	\$131.07	1.69	\$108.21	2.67	\$76.79	ES1	2.93	\$298.51	1.84	\$141.42
D	1.92	\$133.86	1.53	\$97.97	1.46	\$41.99	HDE2	2.40	\$244.51	1.33	\$102.22
E	1.42	\$99.00	1.41	\$90.28	2.34	\$67.30	HDE1	1.99	\$202.74	0.96	\$73.79
F	1.61	\$112.25	1.60	\$102.45	2.98	\$85.70	HBC2	2.24	\$228.21	0.72	\$55.34
G	1.67	\$116.43	1.64	\$105.01	2.04	\$58.67	HBC1	1.86	\$189.50	-	-
H	1.16	\$80.88	1.15	\$73.63	2.86	\$82.25	LDE2	2.08	\$211.91	-	-
I	1.13	\$78.78	1.18	\$75.56	3.53	\$101.52	LDE1	1.73	\$176.25	-	-
J	1.42	\$99.00	1.45	\$92.84	2.99	\$85.99	LBC2	1.72	\$175.23	-	-
K	1.52	\$105.97	1.54	\$98.61	3.70	\$106.41	LBC1	1.43	\$145.69	-	-
L	1.09	\$75.99	1.11	\$71.07	4.21	\$121.08	CDE2	1.87	\$190.52	-	-
M	1.27	\$88.54	1.30	\$83.24	-	-	CDE1	1.62	\$165.05	-	-
N	1.48	\$103.19	1.50	\$96.05	-	-	CBC2	1.55	\$157.91	-	-
O	1.55	\$108.07	1.55	\$99.25	-	-	CA2	1.09	\$111.05	-	-
P	1.08	\$75.30	1.09	\$69.79	-	-	CBC1	1.34	\$136.52	-	-
Q	-	-	-	-	-	-	CA1	0.94	\$95.77	-	-
R	-	-	-	-	-	-	BAB2	1.04	\$105.96	-	-
S	-	-	-	-	-	-	BAB1	0.99	\$100.86	-	-
T	-	-	-	-	-	-	PDE2	1.57	\$159.95	-	-
U	-	-	-	-	-	-	PDE1	1.47	\$149.76	-	-
V	-	-	-	-	-	-	PBC2	1.22	\$124.29	-	-
W	-	-	-	-	-	-	PA2	0.71	\$72.33	-	-
X	-	-	-	-	-	-	PBC1	1.13	\$115.12	-	-
Y	-	-	-	-	-	-	PA1	0.66	\$67.24	-	-

D. 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 propose to continue this practice for FY 2020, 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. As in previous years, we would continue to use the pre-reclassified IPPS hospital wage data, unadjusted for occupational mix and the rural floor, as the basis for the SNF PPS wage index. For FY 2020, the updated wage data are for hospital cost reporting periods beginning on or after October 1, 2015 and before October 1, 2016 (FY 2016 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, enacted on December 21, 2000) authorized us to establish a geographic reclassification procedure that is specific to SNFs, but only after collecting the data necessary to establish a SNF PPS 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. More specifically, auditing all SNF cost reports, similar to the process used to audit inpatient hospital cost reports for purposes of the Inpatient Prospective Payment System (IPPS) wage index, would place a burden on providers in terms of recordkeeping and completion of the cost report worksheet. As discussed in greater detail later in this section, adopting such an approach would require a significant commitment of resources by CMS and the Medicare Administrative Contractors, potentially far in excess of those required under the IPPS given that there are nearly five times as many SNFs as there are inpatient hospitals. Therefore, while we continue to believe that the development of such an audit process could improve SNF cost reports in such a manner as to permit us to establish a SNF-specific wage index, we do not regard an undertaking of this magnitude as being feasible within the current level of programmatic resources.

In addition, we propose 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 2019 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 2020, there are no rural geographic areas that do not have hospitals, and thus, this methodology would not be applied. For rural Puerto Rico, we would 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 would continue to use the most recent wage index previously available for that area. For urban areas without specific hospital wage index data, we would 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 2020, the only urban area without wage index data available is CBSA 25980, Hinesville-Fort Stewart, GA. The final wage index applicable to FY 2020 is set forth in Tables A and B available on the CMS website at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPSP/WageIndex.html>.

In the SNF PPS final rule for FY 2006 (70 FR 45026, August 4, 2005), we adopted the changes discussed in OMB Bulletin No. 03-04 (June 6, 2003), 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.

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. OMB Bulletin No. 13-01 established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas in the United States and Puerto Rico based on the 2010 Census, and provided guidance on the use of the delineations of these statistical areas using standards published on June 28, 2010 in the **Federal Register** (75 FR 37246 through 37252). Subsequently, on July 15, 2015, OMB issued OMB Bulletin No. 15-01, which provides minor updates to and supersedes OMB Bulletin No. 13-01 that was issued on February 28, 2013. The attachment to OMB Bulletin No. 15-01 provides detailed information on the update to statistical areas since February 28, 2013. The updates provided in OMB Bulletin No. 15-01 are based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2012 and July 1, 2013. In addition, on August 15, 2017, OMB issued Bulletin No. 17-01 which announced a new urban CBSA, Twin Falls, Idaho (CBSA 46300). As we previously stated in the FY 2008 SNF PPS proposed and final rules (72 FR 25538 through 25539, and 72 FR 43423), we wish to note that this and all subsequent SNF PPS rules and notices are considered to incorporate any updates and revisions set forth in the most recent OMB bulletin that applies to the hospital wage data used to determine the current SNF PPS wage index.

Once calculated, we would 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 2018 (82 FR 36548 through 36566), we finalized a proposal to revise the labor-related share to reflect the relative importance of the 2014-based SNF market basket cost weights for the following cost categories: Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-Related Services; and a 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 2020. 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 2020 than the base year weights from the SNF market basket.

We calculate the labor-related relative importance for FY 2020 in four steps. First, we compute the FY 2020 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 2020 price index level for that cost category by the total market basket price index level. Third, we determine the FY 2020 relative importance for each cost category by multiplying this ratio by the base year (2014) weight. Finally, we add the FY 2020 relative importance for each of the labor-related cost categories (Wages and Salaries, Employee Benefits, Professional Fees: Labor-Related, Administrative and Facilities Support Services, Installation, Maintenance, and Repair

Services, All Other: Labor-related services, and a portion of Capital-Related expenses) to produce the FY 2020 labor-related relative importance. Table 8 summarizes the proposed labor-related share for FY 2020, based on IGI’s first quarter 2019 forecast with historical data through fourth quarter 2018, compared to the labor-related share that was used for the FY 2019 SNF PPS final rule.

TABLE 8: Labor-Related Relative Importance, FY 2019 and FY 2020

	Relative importance, labor-related, FY 2019 18:2 forecast¹	Relative importance, labor-related, FY 2020 19:1 forecast²
Wages and salaries	50.2	50.6
Employee benefits	10.1	10.0
Professional Fees: Labor-Related	3.7	3.7
Administrative and facilities support services	0.5	0.5
Installation, Maintenance and Repair Services	0.6	0.6
All Other: Labor Related Services	2.5	2.5
Capital-related (.391)	2.9	2.9
Total	70.5	70.8

¹ Published in the **Federal Register**; based on second quarter 2018 IGI forecast

² Based on first quarter 2019 IGI forecast, with historical data through fourth quarter 2018.

In order to calculate the labor portion of the case-mix adjusted per diem rate, one would multiply the total case-mix adjusted per diem rate, which is the sum of all five case-mix adjusted components into which a patient classifies, and the non-case-mix component rate, by the FY 2020 labor-related share percentage provided in Table 8. The remaining portion of the rate would be the non-labor portion. In prior years, we have included tables which provide the case-mix adjusted RUG-IV rates, by RUG-IV group, broken out by total rate, labor portion and non-labor portion, such as Table 9 of the FY 2019 SNF PPS final rule (83 FR 39175). However, under PDPM, as the total rate is calculated as a combination of six different component rates, five of which are case-mix adjusted, and given the sheer volume of possible combinations of these five case-mix adjusted components, it is not feasible to provide tables similar to those that

have existed in prior rulemaking.

Therefore, to aid stakeholders in understanding the effect of the wage index on the calculation of the SNF per diem rate, we have included a revised hypothetical rate calculation in Table 9.

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 2020 (federal rates effective October 1, 2019), we would apply an adjustment to fulfill the budget neutrality requirement. We would 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 2019 to the weighted average wage adjustment factor for FY 2020. For this calculation, we would use the same FY 2018 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 proposed budget neutrality factor for FY 2020 would be 1.0060.

E. Wage Index Comment Solicitation

As discussed above, historically, we have calculated the SNF PPS wage index values using unadjusted wage index values from another provider setting. Stakeholders have frequently commented on certain aspects of the SNF PPS wage index values and their impact on payments. We are soliciting comments on concerns stakeholders may have regarding the wage index used to adjust SNF PPS payments and suggestions for possible updates and improvements to the geographic adjustment of SNF PPS payments.

F. SNF Value-Based Purchasing Program

Beginning with payment for services furnished on October 1, 2018, section 1888(h) of the Act requires the Secretary to reduce the adjusted Federal per diem rate determined under section 1888(e)(4)(G) of the Act otherwise applicable to a SNF for services furnished during a fiscal year by 2 percent, and to adjust the resulting rate for a SNF by the value-based incentive payment amount earned by the SNF based on the SNF's performance score for that fiscal year under the SNF VBP Program. To implement these requirements, we finalized in the FY 2019 SNF PPS final rule the addition of § 413.337(f) to our regulations (83 FR 39178).

Please see section VI.B. of this proposed rule for a discussion of our proposals for the SNF VBP Program.

G. Adjusted Rate Computation Example

The following series of tables provides an example of how payment would be calculated during FY 2020 under PDPM for a hypothetical 30 day SNF stay, involving the hypothetical SNF XYZ, located in Frederick, MD (Urban CBSA 43524), for a hypothetical patient who is classified into such groups that the patient's HIPPS code is NHNC1. Table 9 shows the adjustments made to the federal per diem rates (prior to application of any adjustments under the SNF QRP and SNF VBP programs as discussed above) to compute the provider's case-mix adjusted per diem rate for FY 2020, based on the patient's PDPM classification, as well as how the VPD adjustment factor affects calculation of the per diem rate for a given day of the stay. Table 10 shows the adjustments made to the case-mix adjusted per diem rate from Table 9 to account for the provider's wage index. The wage index used in this example is based on the FY 2020 SNF PPS wage index that appears in Table A available on the CMS website at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPSP/WageIndex.html>. Finally, Table 11 provides the case-mix and wage index adjusted per-diem rate for this patient for each day of the 30-day stay, as well as the total payment for this stay. Table 11 also includes

the variable per diem (VPD) adjustment factors for each day of the patient’s stay, to clarify why the patient’s per diem rate changes for certain days of the stay. As illustrated in Table 11, SNF XYZ’s total PPS payment for this particular patient’s stay would equal \$19,992.80.

TABLE 9: PDPM Case-Mix Adjusted Rate Computation Example

Per Diem Rate Calculation				
Component	Component Group	Component Rate	VPD Adjustment Factor	VPD Adj. Rate
PT	TN	\$90.52	1.00	\$90.52
OT	TN	\$85.40	1.00	\$85.40
SLP	SH	\$65.29	-	\$65.29
Nursing	CBC2	\$165.29	-	\$165.29
NTA	NC	\$148.03	3.00	\$444.09
Non-Case-Mix	-	\$95.48	-	\$95.48
Total PDPM Case-Mix Adj. Per Diem				\$946.07

TABLE 10: Wage Index Adjusted Rate Computation Example

PDPM Wage Index Adjustment Calculation						
HIPPS Code	PDPM Case-Mix Adjusted Per Diem	Labor Portion	Wage Index	Wage Index Adjusted Rate	Non-Labor Portion	Total Case Mix and Wage Index Adj. Rate
NHNC1	\$946.07	\$669.82	0.9757	\$653.54	\$276.25	\$929.79

TABLE 11: Adjusted Rate Computation Example

Day of Stay	NTA VPD Adjustment Factor	PT/OT VPD Adjustment Factor	Case Mix and Wage Index Adjusted Per Diem Rate
1	3.0	1.0	\$929.79
2	3.0	1.0	\$929.79
3	3.0	1.0	\$929.79
4	1.0	1.0	\$638.83
5	1.0	1.0	\$638.83
6	1.0	1.0	\$638.83
7	1.0	1.0	\$638.83
8	1.0	1.0	\$638.83
9	1.0	1.0	\$638.83
10	1.0	1.0	\$638.83
11	1.0	1.0	\$638.83
12	1.0	1.0	\$638.83
13	1.0	1.0	\$638.83
14	1.0	1.0	\$638.83
15	1.0	1.0	\$638.83
16	1.0	1.0	\$638.83
17	1.0	1.0	\$638.83
18	1.0	1.0	\$638.83
19	1.0	1.0	\$638.83
20	1.0	1.0	\$638.83
21	1.0	0.98	\$635.37
22	1.0	0.98	\$635.37
23	1.0	0.98	\$635.37
24	1.0	0.98	\$635.37
25	1.0	0.98	\$635.37
26	1.0	0.98	\$635.37
27	1.0	0.98	\$635.37
28	1.0	0.96	\$631.91
29	1.0	0.96	\$631.91
30	1.0	0.96	\$631.91
Total Payment			\$19,992.80

IV. Additional Aspects of the SNF PPS

A. 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.C. of this proposed rule. This approach includes an administrative presumption that utilizes a beneficiary's correct assignment, at the outset of the

SNF stay, to one of the case-mix classifiers designated for this purpose to assist in making certain SNF level of care determinations.

In accordance with the regulations at § 413.345, we include in each update of the federal payment rates in the **Federal Register** a discussion of the resident classification system that provides the basis for case-mix adjustment. Under that discussion, we designate those specific classifiers under the case-mix classification system that represent the required SNF level of care, as provided in § 409.30. This designation reflects an administrative presumption that those beneficiaries who are correctly assigned one of the designated case-mix classifiers on the 5-day Medicare-required assessment are automatically classified as meeting the SNF level of care definition up to and including the assessment reference date (ARD) for that assessment.

A beneficiary who does not qualify for the presumption is not automatically classified as either meeting or not meeting the level of care definition, but instead receives an individual determination on this point using the existing administrative criteria. This presumption recognizes the strong likelihood that those beneficiaries who are assigned one of the designated case-mix classifiers during the immediate post-hospital period would require a covered level of care, which would be less likely for other beneficiaries.

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. The FY 2018 final rule (82 FR 36544) further specified that we would henceforth disseminate the standard description of the administrative presumption's designated groups via the SNF PPS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/index.html> (where such designations appear in the paragraph entitled "Case Mix Adjustment"), and would publish such designations in rulemaking only to the extent that we actually intend to make changes in

them. Under that approach, the set of case-mix classifiers designated for this purpose under PDPM was finalized in the FY 2019 SNF PPS final rule (83 FR 39253) and is posted on the SNF PPS website (<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/index.html>), in the paragraph entitled “Case Mix Adjustment.”

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 any services prompting the assignment of one of the designated case-mix classifiers (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 where the sole classifier that triggers the presumption is itself assigned through 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 ARD of the 5-day assessment. Finally, regarding the new set of case-mix classifiers designated under the PDPM for this purpose, we noted in the FY 2019 SNF PPS final rule (83 FR 39253, August 8, 2018) our intent “...to review the new designations going forward and make further adjustments over time as we gain actual operating experience under the new classification model.” Accordingly, to the extent that it may become evident in actual practice that these new criteria are not accurately performing their intended role (for example, by capturing cases that do not actually require an SNF level of care), we would propose appropriate adjustments to correct them.

B. Consolidated Billing

Sections 1842(b)(6)(E) and 1862(a)(18) of the Act (as added by section 4432(b) of the BBA 1997) require a SNF to submit consolidated Medicare bills to its Medicare Administrative Contractor (MAC) 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 website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/Downloads/Legislative_History_2018-10-01.pdf. In particular, section 103 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA, Pub. L. 106-113, enacted on November 29, 1999) 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 discuss 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 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 PPS. 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, the amendments enacted in section 103 of the BBRA do not 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 is consistent with 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). In this proposed rule, we specifically invite 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. We may consider excluding a particular service if it meets our criteria for exclusion as specified above. Commenters should 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.

We note that the original BBRA amendment (as well as the implementing regulations) identified a set of excluded services by means of specifying HCPCS codes that were in effect as of a particular date (in that case, as of July 1, 1999). Identifying the excluded services in this manner made it possible for us to utilize program issuances as the vehicle for accomplishing routine updates of the excluded codes, to reflect any minor revisions that might subsequently occur in the coding system itself (for example, the assignment of a different code number to the same service). Accordingly, in the event that we identify through the current rulemaking cycle any new services that would actually represent a substantive change in the scope of the exclusions from SNF consolidated billing, we would identify these additional excluded services by means of the HCPCS codes that are in effect as of a specific date (in this case, as of October 1, 2019). By making any new exclusions in this manner, we could similarly accomplish routine future updates of these additional codes through the issuance of program instructions.

C. 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, SNF-level 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. 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. As discussed in the FY 2019 SNF PPS final rule (83 FR 39235), revisions were made to the swing bed assessment in order to support implementation of PDPM, effective October 1, 2019. A discussion of the assessment schedule and the MDS effective beginning FY 2020 appears in the FY 2019 SNF PPS final rule (83 FR 39229 through 39237). The latest changes in the MDS for swing-bed rural hospitals appear on the SNF PPS website at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/index.html>.

V. Issues Relating to PDPM Implementation

A. Revised Group Therapy Definition

As set forth in the FY 2019 SNF PPS final rule (83 FR 39162), effective October 1, 2019 under the PDPM, patients will be classified into case-mix groups under each therapy component based on patient characteristics rather than using the volume of therapy services furnished to the patient as the basis for classification. Additionally, as discussed in the FY 2019 SNF PPS final rule (83 FR 39237 through 39243), we finalized a combined limit on concurrent and group therapy furnished to a patient, specifically that, for each therapy discipline, no more than 25 percent of the therapy services furnished to a patient in a covered Medicare Part A stay may be in a group or concurrent setting. Given these policy changes relating to therapy classification and therapy provision under the PDPM, as well as recent efforts to increase standardization across PAC settings, we believed it was appropriate to evaluate other policies associated with therapy under PDPM to determine if other policies should be revised as well.

In the FY 2012 SNF PPS final rule (76 FR 48511 through 48517), we finalized changes relating to the definition of group therapy and payment of group therapy services, specifically to define group therapy as the practice of one therapist or therapy assistant treating four patients at the same time while the patients are performing either the same or similar activities. In the FY 2012 SNF PPS final rule (76 FR 48511), we noted that, using our STRIVE data as a baseline, we identified under RUG-IV two significant changes in provider behavior related to the provision of therapy services to Medicare beneficiaries in SNFs. First, we saw a major decrease in the amount of concurrent therapy (that is therapy provided to two patients by one therapist or therapy assistant doing *different* activities) performed in SNFs, the minutes for which are divided between the two concurrent therapy participants when determining the patient's appropriate RUG classification. At the same time, we found a significant increase in the amount of group therapy services, which were not subject to the allocation requirement. Given this increase in group therapy services, we expressed concern that the method for reporting group therapy on the

MDS created an inappropriate payment incentive to perform the group therapy in place of individual therapy, because the method of reporting group therapy time did not require allocation among patients.

As we stated in the FY 2012 SNF PPS final rule (76 FR 48511), because in group therapy, patients are performing similar activities, in contrast to concurrent therapy, group therapy gives patients the opportunity to benefit from each other's therapy regimen by observing and interacting with one another and applying the lessons learned from others to one's own therapy program in order to progress. At that time, we stated that large groups, such as those of five or more participants, can make it difficult for the participants to engage with one another over the course of the session. In addition, we have long believed that individual therapists could not adequately supervise large groups, and since the inception of the SNF PPS in July 1998, we have capped the number of residents at four. Furthermore, we believed that groups of fewer than four participants did not maximize the group therapy benefit for the participants. As we stated in the FY 2012 final rule (76 FR 48511), we believed that in groups of two or three participants, the opportunities for patients in the group to interact and learn from each other are significantly diminished given the small size of the group. Thus, we revised the definition of group therapy to require a group size for the SNF setting of exactly four patients, which we believed was the size that permits the therapy participants to derive the maximum benefit from the group therapy setting.

Since that time, we have monitored group therapy utilization and found that, as discussed in the FY 2019 SNF PPS final rule (83 FR 39237 through 39238), group therapy represents a very small proportion of therapy provided to SNF patients. Further, as discussed in the FY 2019 SNF PPS final rule (83 FR 39240 through 39241), some commenters suggested that we revise the definition of group therapy to include two to six participants doing the same or similar

activities, as this would better align with the Inpatient Rehabilitation Facility (IRF) setting and allow increased flexibility so that patients in smaller SNFs, presumably where a group of exactly four patients may be difficult to attain, could utilize and benefit from group therapy. In our response to these comments, in the FY 2019 SNF PPS final rule (83 FR 39241), we stated that we may consider changing the definition of group therapy in future rulemaking. In the past we stated our concern that a group that consisted of more than 4 participants would not allow for adequate supervision of each participant as well as cause difficulty for participants to engage with one another in the most effective way. Conversely, we maintained that a group of fewer than 4 participants would not allow for effective interaction to best achieve the goals of a group. For these reasons, we defined group therapy as exactly 4 participants. However, based on our review of the use of group therapy in the IRF and outpatient settings where the definition of group therapy is less restrictive than the current definition under the SNF PPS, we have found that therapists do seem capable of managing groups of various sizes. Based on this review, we believe therapists have the clinical judgment to determine whether groups of different sizes would clinically benefit their patients, which they should be able to demonstrate with adequate documentation. Patients can often benefit from the psycho-social aspect of groups, and in some situations, a group of six participants is not too large to provide that benefit to participants. For example, a cooking activity which will provide very functional therapy for patients planning to return home can be done in a group of six that will enhance the patient's psycho-social experience in the SNF. Alternatively, a group of 2-3 patients can be clinically useful for certain patients as well. For example, a group of 2-3 patients who have pragmatic language difficulties following a stroke or head injury could very well benefit from a small communication group to work on the social aspects of language together without the concern of distraction that a larger group might cause. Thus, while we continue to maintain minimal concerns that some groups

may be either too small or too large to allow for effective interaction, we believe that the potential clinical benefits of various size groups outweigh our concerns, and that it would be appropriate to allow therapists greater flexibility to perform therapy in groups of different sizes.

In light of our discussion above and the comments in the FY 2019 SNF PPS final rule, and to align the SNF PPS more closely with other settings, in this proposed rule, we propose to adopt a new definition of group therapy for use under PDPM, effective October 1, 2019, as further discussed below.

In an effort to support CMS' cross-setting initiatives under the IMPACT Act and Meaningful Measures Initiative, we have looked at ways to align the definition of group therapy used under the SNF PPS more closely with the definitions used within the outpatient setting covered under Medicare Part B and under the IRF PPS, as this type of standardization would reduce administrative burden on providers by utilizing the same or similar definitions across settings. For group therapy in the outpatient setting, the Medicare Benefit Policy Manual, Chapter 15, Section 230 states that contractors pay for outpatient physical therapy services (which includes outpatient speech-language pathology services) and outpatient occupational therapy services provided simultaneously to two or more individuals by a practitioner as group therapy services (CPT code 97150). This manual section further states that the individuals can be, but need not be, performing the same activity. In addition, this section states that the physician or therapist involved in group therapy services must be in constant attendance, but one-on-one patient contact is not required. Under the IRF PPS, the definition of group therapy (found in Section 2 of the IRF PAI Training Manual, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Downloads/IRFPAI-1_5-2_0.zip) is the provision of therapy services by one licensed or certified therapist (or licensed therapy assistant,

under the appropriate direction of a licensed or certified therapist) treating two to six patients at the same time who are performing the same or similar activities.

We considered using the same definition as used in the outpatient setting covered under Medicare Part B, which is two or more patients performing either the same or different activity, as opposed to the IRF definition of two to six patients performing the same or similar activities. However, given the greater degree of similarity between the IRF and SNF settings in terms of the intensity of therapy and patient acuity, we believe that the IRF PPS definition would be more appropriate in the SNF setting.

Accordingly, for the reasons discussed previously, we are proposing to define group therapy in the SNF Part A setting as a qualified rehabilitation therapist or therapy assistant treating two to six patients at the same time who are performing the same or similar activities. We believe this definition would offer therapists more clinical flexibility when determining the appropriate number for a group, without compromising the therapist's ability to manage the group and the patient's ability to interact effectively and benefit from group therapy.

We continue to believe that individual therapy is the preferred mode of therapy provision and offers the most tailored service for patients. As we stated in the FY 2012 proposed rule (76 FR 26387), while group therapy can play an important role in SNF patient care, group therapy is not appropriate for either all patients or for all conditions, and is primarily effective as a supplement to individual therapy, which we maintain should be considered the primary therapy mode and standard of care in therapy services provided to SNF residents.

Additionally, we continue to maintain that when group therapy is used in a SNF, therapists must document its use in order to demonstrate why it is the most appropriate mode of therapy for the patient who is receiving it. As stated in the FY 2012 proposed rule (76 FR 26388) regarding group therapy documentation, because group therapy is not appropriate for

either all patients or all conditions, and in order to verify that group therapy is medically necessary and appropriate to the needs of each beneficiary, SNFs should include in the patient's plan of care an explicit justification for the use of group, rather than individual or concurrent, therapy. This description should include, but need not be limited to, the specific benefits to that particular patient of including the documented type and amount of group therapy; that is, how the prescribed type and amount of group therapy will meet the patient's needs and assist the patient in reaching the documented goals. In addition, we believe that the above documentation is necessary to demonstrate that the SNF is providing services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident in accordance with section 1819(b)(2) of the Act.

B. Updating ICD-10 Code Mappings and Lists

In the FY 2019 SNF PPS final rule (83 FR 39162), we finalized the implementation of PDPM, effective October 1, 2019. The PDPM utilizes ICD-10 codes in several ways, including to assign patients to clinical categories used for categorization in the PT, OT, and SLP components, as well as identifying certain comorbidities relevant for classification under the SLP and NTA components. The ICD-10 mappings and lists that would be used under PDPM, once implemented, are available on the PDPM website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/PDPM.html>.

Each year, the ICD-10 Coordination and Maintenance Committee, a federal interdepartmental committee that is chaired by representatives from the National Center for Health Statistics (NCHS) and by representatives from CMS, meets biannually and publishes updates to the ICD-10 medical code data sets in June of each year. These changes become effective October 1 of the year in which these updates are issued by the committee. The ICD-10

Coordination and Maintenance Committee also has the ability to make changes to the ICD–10 medical code data sets effective on April 1, but has not yet done so.

As providers are required to follow the most up to date coding guidance issued by this committee in accordance with 45 CFR part 162, subpart J, it is essential that we be able to update our code mappings and lists consistent with the latest coding guidance. Therefore, to ensure that the ICD-10 mappings and lists used under PDPM reflect the most up to date codes possible, we propose to update any ICD-10 code mappings and lists used under PDPM, as well as the SNF GROUPER software and other such products related to patient classification and billing, through a subregulatory process which would consist of posting updated code mappings and lists on the PDPM website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/PDPM.html>. More specifically, beginning with the updates for FY 2020 (see discussion below), nonsubstantive changes to the ICD-10 codes included on the code mappings and lists under the PDPM would be applied through the subregulatory process described above, and substantive revisions to the ICD–10 codes on the code mappings and lists used under the PDPM would be proposed and finalized through notice and comment rulemaking.

Nonsubstantive changes would be limited to those specific changes that are necessary to maintain consistency with the most current ICD–10 medical code data set, which Medicare providers are generally required to use. Our intent in applying these nonsubstantive changes through the proposed subregulatory process would be to keep the same conditions in the PDPM clinical categories and comorbidities lists, but ensure that the codes used to identify those conditions are synchronized with the most current ICD–10 medical code data set. For example, to the extent that the ICD–10–CM Coordination and Maintenance Committee changes an ICD–10 code for a comorbid condition on our comorbidities lists into one or more codes that provide additional detail, we would update the SNF GROUPER software and ICD-10 mappings and lists

on the CMS website to reflect the new codes through the subregulatory process proposed above. By contrast, we would use notice and comment rulemaking to make substantive changes to the ICD-10 code mappings and lists under the PDPM. For the purposes of this policy, a substantive change would be defined simply as any change that does not fall within the definition of a nonsubstantive change—that is, changes that go beyond the intention of maintaining consistency with the most current ICD-10 medical code data set. For instance, changes to the assignment of a code to a comorbidity list or other changes that amount to changes in policy would be substantive changes. Taking the example above, there may be situations in which the addition of one or more of these new codes to the list of comorbidities may not be appropriate. For example, the ICD-10 code for a particular condition is divided into two more detailed codes, one of which represents a condition that generally is predictive of the costs of care in a SNF and one of which is not. We would propose through notice and comment rulemaking to delete the code that does not reflect increased costs of care in a SNF from the list of comorbidities in the SNF GROUPER software because removing the code would constitute a substantive change. We propose to indicate all changes to codes in the GROUPER software by posting a complete ICD-10 mapping table, including new, discontinued, and modified codes, on the PDPM website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/PDPM.html>. We also propose to report the complete list of ICD-10 codes associated with the SNF PDPM clinical categories and SLP/NTA comorbidities in the SNF GROUPER documentation, which is also posted on the PDPM website. All changes would be included in these documents, with substantive changes being included only after being finalized through notice and comment rulemaking.

We believe that the proposed subregulatory update process (by which nonsubstantive changes to the ICD-10 code mappings and lists used under PDPM as well as the SNF

GROUPER software and other such products related to patient classification and billing would be posted on the CMS websites specified above), is the best way for us to convey information about changes to the ICD-10 medical code data set that affect the code mappings and lists used under the PDPM. We believe the proposed subregulatory process would help ensure providers have the most up-to-date information as soon as possible, in the clearest and most useful format, as opposed to publishing each nonsubstantive change to the ICD-10 codes in a rule after notice and comment rulemaking.

Additionally, the proposed subregulatory process is in alignment with similar policies in the SNF PPS and the IRF PPS settings. For example, the SNF PPS already uses a subregulatory process to make nonsubstantive updates to the list of Healthcare Common Procedure Coding System (HCPCS) codes that are subject to the consolidated billing (CB) provision of the SNF PPS. We post routine annual updates to the lists of codes that are included or excluded from CB on the SNF CB website at <https://www.cms.gov/Medicare/Billing/SNFConsolidatedBilling/index.html>. The new codes identified in each update describe the same services that are subject to SNF PPS CB. No additional services are added by these routine updates; that is, these updates are necessary because of changes to the coding system, not because the services subject to SNF CB are being redefined. We believe the proposed subregulatory process to update ICD-10 codes associated with PDPM clinical categories and comorbidity lists is appropriate given that it is consistent with this subregulatory process already in use under the SNF PPS to make nonsubstantive coding updates.

Likewise, the IRF PPS also utilizes processes similar to that proposed here. In the FY 2007 IRF PPS final rule (71 FR 48360 through 48361), we implemented a similar subregulatory updating process for the IRF tier comorbidities list, and the FY 2018 IRF PPS final rule (82 FR

36267 through 36269) established a similar process for updating the ICD-10 code lists used for the IRF presumptive compliance methodology. Both the IRF tier comorbidities list and the IRF presumptive compliance methodology also use ICD-10 codes. Therefore, we believe the subregulatory process proposed in this rule is appropriate because it is also consistent with processes used in another Medicare setting.

We are proposing that this subregulatory process for updating the ICD-10 codes used under the PDPM would take effect beginning with the updates for FY 2020. The proposed ICD-10 code mappings and lists for use under the PDPM are available for download from the SNF PPS Web site (<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/PDPM.html>). These mappings and lists reflect the adoption of the ICD-10 Coordination and Maintenance Committee's draft changes to the ICD-10 medical code data sets, effective October 1, 2018. The version of these mappings and lists that is finalized in conjunction with the FY 2020 SNF PPS final rule would constitute the baseline for any future updates to the mappings and lists using the proposed process above.

C. Revisions to the Regulation Text

Along with our proposed revisions as discussed elsewhere in this proposed rule, we are also proposing to make certain revisions to the regulations text itself to reflect the revised assessment schedule under the PDPM, as finalized in the FY 2019 SNF PPS final rule (83 FR 39229). Specifically, we propose to revise the prescribed PPS assessment schedule as set forth in § 413.343(b), to reflect the elimination, upon the conversion from RUG-IV to PDPM on October 1, 2019, of all scheduled assessments after the initial 5-day, Medicare-required assessment. We note that even though this assessment is commonly referred to as the "5-day" assessment (reflecting its original 5-day assessment window), an additional 3 grace days have always been available beyond that window for its actual completion. Further, because those

additional 3 grace days will be directly incorporated into the assessment window itself effective October 1, 2019 (as finalized in the FY 2019 SNF PPS final rule (83 FR 39231, 39232, and 39234)), thus resulting in an overall 8-day assessment window, we additionally propose to include a conforming revision in § 413.343(b) to make clear that the actual deadline for completing this assessment is no later than the 8th day of posthospital SNF care. In addition, because under the PDPM, there is only one scheduled patient assessment, we also propose to replace the phrase “patient assessments” in § 413.343(b) with the phrase “an initial patient assessment.” Accordingly, we propose to revise § 413.343(b) to state that the assessment schedule must include performance of an initial patient assessment no later than the 8th day of posthospital SNF care.

We further propose to revise the existing language in § 413.343(b) that additionally requires the completion of “such other assessments that are necessary to account for changes in patient care needs,” to state “such other interim payment assessments as the SNF determines are necessary to account for changes in patient care needs.” As we finalized in the FY 2019 SNF PPS final rule (83 FR 39230 through 39234), the optional Interim Payment Assessment (IPA) will serve as the instrument for conducting assessments under the PDPM that the SNF determines are necessary after the completion of the 5-day, Medicare-required assessment to address clinical changes throughout a SNF stay. We believe that our proposed language is consistent with the expectation expressed in the FY 2019 SNF PPS final rule for SNFs “. . . to provide excellent skilled nursing and rehabilitative care and continually monitor and document patient status” (83 FR 39233), and makes clear that the SNF’s responsibility in this context would include recognizing those situations that warrant a decision to complete an IPA in order to account appropriately for a change in patient status. Finally, to ensure consistency, we also propose to make a conforming revision to the regulations text in the introductory paragraph of

§ 409.30, so that it would use the same terminology of “initial patient assessment” as would appear in revised § 413.343(b). Specifically, in the introductory paragraph of § 409.30, we would replace the phrase “the 5-day assessment” with “the initial patient assessment.” We note that the regulations text in the introductory paragraph of § 409.30 would continue to specify that the assessment reference date (ARD) for this assessment must occur no later than the 8th day of posthospital SNF care, consistent with the instructions set forth in sections 2.8 and 2.9 of the RAI Version 3.0 Manual.

VI. Other Issues

A. Skilled Nursing Facility (SNF) Quality Reporting Program (QRP)

1. Background

The Skilled Nursing Facility Quality Reporting Program (SNF QRP) is authorized by section 1888(e)(6) of the Act and it applies to freestanding SNFs, SNFs affiliated with acute care facilities, and all non-CAH swing-bed rural hospitals. Under the SNF QRP, the Secretary must reduce by 2 percentage points the annual market basket percentage update described in section 1888(e)(5)(B)(i) of the Act applicable to a SNF for a fiscal year, after application of section 1888(e)(5)(B)(ii) of the Act (the MFP adjustment) and section 1888(e)(5)(B)(iii) of the Act, in the case of a SNF that does not submit data in accordance with sections 1888(e)(6)(B)(i) of the Act for that fiscal year. For more information on the requirements we have adopted for the SNF QRP, we refer readers to the FY 2016 SNF PPS final rule (80 FR 46427 through 46429), FY 2017 SNF PPS final rule (81 FR 52009 through 52010), FY 2018 SNF PPS final rule (82 FR 36566), and FY 2019 SNF PPS final rule (83 FR 39162 through 39272).

2. General Considerations Used for the Selection of Measures for the SNF QRP

For a detailed discussion of the considerations we historically used for the selection of SNF QRP quality, resource use, and other measures, we refer readers to the FY 2016 SNF PPS

final rule (80 FR 46429 through 46431).

3. Quality Measures Currently Adopted for the FY 2021 SNF QRP

The SNF QRP currently has 11 measures for the FY 2021 SNF QRP, which are set out in Table 12.

TABLE 12: Quality Measures Currently Adopted for the FY 2021 SNF QRP

Short Name	Measure Name & Data Source
Resident Assessment Instrument Minimum Data Set	
Pressure Ulcer/Injury	Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury.
Application of Falls	Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674).
Application of Functional Assessment/Care Plan	Application of Percent of Long-Term Care Hospital (LTCH) Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631).
Change in Mobility Score	Application of IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634).
Discharge Mobility Score	Application of IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (NQF #2636).
Change in Self-Care Score	Application of the IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (NQF #2633).
Discharge Self-Care Score	Application of IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (NQF #2635).
DRR	Drug Regimen Review Conducted With Follow-Up for Identified Issues–Post Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP).
Claims-Based	
MSPB SNF	Medicare Spending Per Beneficiary (MSPB)–Post Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP).
DTC	Discharge to Community (DTC)–Post Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP).
PPR	Potentially Preventable 30-Day Post-Discharge Readmission Measure for Skilled Nursing Facility (SNF) Quality Reporting Program (QRP).

4. SNF QRP Quality Measure Proposals Beginning with the FY 2022 SNF QRP

In this proposed rule, we are proposing to adopt two process measures for the SNF QRP that, as required by section 1888(e)(6)(B)(i)(II) of the Act, would satisfy section 1899B(c)(1)(E)(ii) of the Act, which requires that the quality measures specified by the Secretary include measures with respect to the quality measure domain titled “Accurately communicating the existence of and providing for the transfer of health information and care preferences of an individual to the individual, family caregiver of the individual, and providers of services

furnishing items and services to the individual when the individual transitions from a post-acute care (PAC) provider to another applicable setting, including a different PAC provider, a hospital, a critical access hospital, or the home of the individual.” Given the length of this domain title, hereafter, we will refer to this quality measure domain as “Transfer of Health Information.”

The two measures we are proposing to adopt are: (1) Transfer of Health Information to the Provider–Post-Acute Care (PAC); and (2) Transfer of Health Information to the Patient–Post-Acute Care (PAC). Both of these proposed measures support our Meaningful Measures priority of promoting effective communication and coordination of care, specifically the Meaningful Measure area of the transfer of health information and interoperability.

In addition to the two measure proposals, we are proposing to update the specifications for the Discharge to Community – PAC SNF QRP measure to exclude baseline nursing facility (NF) residents from the measure.

We are seeking public comment on each of these proposals.

a. Proposed Transfer of Health Information to the Provider–Post-Acute Care (PAC) Measure

The proposed Transfer of Health Information to the Provider–Post-Acute Care (PAC) Measure is a process-based measure that assesses whether or not a current reconciled medication list is given to the subsequent provider when a patient is discharged or transferred from his or her current PAC setting.

(1) Background

In 2013, 22.3 percent of all acute hospital discharges were discharged to PAC settings, including 11 percent who were discharged to home under the care of a home health agency, and

nine percent who were discharged to SNFs.¹ The proportion of patients being discharged from an acute care hospital to a PAC setting was greater among beneficiaries enrolled in Medicare fee-for-service (FFS). Among Medicare FFS patients discharged from an acute hospital, 42 percent went directly to PAC settings. Of that 42 percent, 20 percent were discharged to a SNF, 18 percent were discharged to a home health agency (HHA), 3 percent were discharged to an IRF, and 1 percent were discharged to an LTCH.² Of the Medicare FFS beneficiaries with a SNF stay in FY 2017, an estimated 21 percent were discharged or transferred to an acute care hospital, 11 percent discharged home with home health services, and two percent discharged or transferred to another PAC setting (for example, an IRF, a hospice, or another SNF).³

The transfer and/or exchange of health information from one provider to another can be done verbally (for example, clinician-to-clinician communication in-person or by telephone), paper-based (for example, faxed or printed copies of records), and via electronic communication (for example, through a health information exchange network using an electronic health/medical record, and/or secure messaging). Health information, such as medication information, that is incomplete or missing increases the likelihood of a patient or resident safety risk, and is often life-threatening.^{4,5,6,7,8,9} Poor communication and coordination across health care settings

1 Tian, W. "An all-payer view of hospital discharge to post-acute care," May 2016. Available at <https://www.hcup-us.ahrq.gov/reports/statbriefs/sb205-Hospital-Discharge-Postacute-Care.jsp>.

2 Ibid.

3 RTI International analysis of Medicare claims data for index stays in SNF 2017. (RTI program reference: IB55).

4 Kwan, J. L., Lo, L., Sampson, M., & Shojania, K. G., "Medication reconciliation during transitions of care as a patient safety strategy: a systematic review," *Annals of Internal Medicine*, 2013, Vol. 158(5), pp. 397-403.

5 Boockvar, K. S., Blum, S., Kugler, A., Livote, E., Mergenhagen, K. A., Nebeker, J. R., & Yeh, J., "Effect of admission medication reconciliation on adverse drug events from admission medication changes," *Archives of Internal Medicine*, 2011, Vol. 171(9), pp. 860-861.

6 Bell, C. M., Brener, S. S., Gunraj, N., Huo, C., Bierman, A. S., Scales, D. C., & Urbach, D. R., "Association of ICU or hospital admission with unintentional discontinuation of medications for chronic diseases," *JAMA*, 2011, Vol. 306(8), pp. 840-847.

7 Basey, A. J., Krska, J., Kennedy, T. D., & Mackridge, A. J., "Prescribing errors on admission to hospital and their potential impact: a mixed-methods study," *BMJ Quality & Safety*, 2014, Vol. 23(1), pp. 17-25.

contributes to patient complications, hospital readmissions, emergency department visits, and medication errors.^{10,11,12,13,14,15,16,17,18,19} Communication has been cited as the third most frequent root cause in sentinel events, which The Joint Commission²⁰ defines as a patient safety event that results in death, permanent harm, or severe temporary harm. Failed or ineffective patient handoffs are estimated to play a role in 20 percent of serious preventable adverse events.²¹ When care transitions are enhanced through care coordination activities, such as expedited patient information flow, these activities can reduce duplication of care services and costs of care, resolve conflicting care plans, and prevent medical errors.^{22,23,24,25,26}

8 Desai, R., Williams, C. E., Greene, S. B., Pierson, S., & Hansen, R. A., "Medication errors during patient transitions into nursing homes: characteristics and association with patient harm," *The American Journal of Geriatric Pharmacotherapy*, 2011, Vol. 9(6), pp. 413-422.

9 Boling, P. A., "Care transitions and home health care," *Clinical Geriatric Medicine*, 2009, Vol.25(1), pp. 135-48.

10 Barnsteiner, J. H., "Medication Reconciliation: Transfer of medication information across settings—keeping it free from error," *The American Journal of Nursing*, 2005, Vol. 105(3), pp. 31-36.

11 Arbaje, A. I., Kansagara, D. L., Salanitro, A. H., Englander, H. L., Kripalani, S., Jencks, S. F., & Lindquist, L. A., "Regardless of age: incorporating principles from geriatric medicine to improve care transitions for patients with complex needs," *Journal of General Internal Medicine*, 2014, Vol. 29(6), pp. 932-939.

12 Jencks, S. F., Williams, M. V., & Coleman, E. A., "Rehospitalizations among patients in the Medicare fee-for-service program," *New England Journal of Medicine*, 2009, Vol. 360(14), pp. 1418-1428.

13 Institute of Medicine. "Preventing medication errors: quality chasm series," Washington, DC: The National Academies Press 2007. Available at <https://www.nap.edu/read/11623/chapter/1>.

14 Kitson, N. A., Price, M., Lau, F. Y., & Showler, G., "Developing a medication communication framework across continuums of care using the Circle of Care Modeling approach," *BMC Health Services Research*, 2013, Vol. 13(1), pp. 1-10.

15 Mor, V., Intrator, O., Feng, Z., & Grabowski, D. C., "The revolving door of rehospitalization from skilled nursing facilities," *Health Affairs*, 2010, Vol. 29(1), pp. 57-64.

16 Institute of Medicine. "Preventing medication errors: quality chasm series," Washington, DC: The National Academies Press 2007. Available at <https://www.nap.edu/read/11623/chapter/1>.

17 Kitson, N. A., Price, M., Lau, F. Y., & Showler, G., "Developing a medication communication framework across continuums of care using the Circle of Care Modeling approach," *BMC Health Services Research*, 2013, Vol. 13(1), pp. 1-10.

18 Forster, A. J., Murff, H. J., Peterson, J. F., Gandhi, T. K., & Bates, D. W., "The incidence and severity of adverse events affecting patients after discharge from the hospital," *Annals of Internal Medicine*, 2003, 138(3), pp. 161-167.

19 King, B. J., Gilmore- Bykovskyi, A. L., Roiland, R. A., Polnaszek, B. E., Bowers, B. J., & Kind, A. J. "The consequences of poor communication during transitions from hospital to skilled nursing facility: a qualitative study," *Journal of the American Geriatrics Society*, 2013, Vol. 61(7), 1095-1102.

20 The Joint Commission, "Sentinel Event Policy" available at https://www.jointcommission.org/sentinel_event_policy_and_procedures/.

21 The Joint Commission. "Sentinel Event Data Root Causes by Event Type 2004 –2015." 2016. Available at https://www.jointcommission.org/assets/1/23/jconline_Mar_2_2016.pdf.

22 Mor, V., Intrator, O., Feng, Z., & Grabowski, D. C., "The revolving door of rehospitalization from skilled nursing facilities," *Health Affairs*, 2010, Vol. 29(1), pp. 57-64.

23 Institute of Medicine, "Preventing medication errors: quality chasm series," Washington, DC: The National Academies Press, 2007. Available at <https://www.nap.edu/read/11623/chapter/1>.

24 Starmer, A. J., Sectish, T. C., Simon, D. W., Keohane, C., McSweeney, M. E., Chung, E. Y., Yoon, C.S., Lipsitz, S.R., Wassner, A.J., Harper, M. B., & Landrigan, C. P., "Rates of medical errors and preventable adverse events among hospitalized

Care transitions across health care settings have been characterized as complex, costly, and potentially hazardous, and may increase the risk for multiple adverse outcomes.^{27,28} The rising incidence of preventable adverse events, complications, and hospital readmissions have drawn attention to the importance of the timely transfer of health information and care preferences at the time of transition. Failures of care coordination, including poor communication of information, were estimated to cost the U.S. health care system between \$25 billion and \$45 billion in wasteful spending in 2011.²⁹ The communication of health information and patient care preferences is critical to ensuring safe and effective transitions from one health care setting to another.^{30,31}

Patients in PAC settings often have complicated medication regimens and require efficient and effective communication and coordination of care between settings, including detailed transfer of medication information.^{32,33,34} Individuals in PAC settings may be

children following implementation of a resident handoff bundle,” *JAMA*, 2013, Vol. 310(21), pp. 2262-2270.

25 Pronovost, P., M. M. E. Johns, S. Palmer, R. C. Bono, D. B. Fridsma, A. Gettinger, J. Goldman, W. Johnson, M. Karney, C. Samitt, R. D. Sriram, A. Zenooz, and Y. C. Wang, Editors. *Procuring Interoperability: Achieving High-Quality, Connected, and Person-Centered Care*. Washington, DC, 2018. National Academy of Medicine. Available at https://nam.edu/wp-content/uploads/2018/10/Procuring-Interoperability_web.pdf.

26 Balaban RB, Weissman JS, Samuel PA, & Woolhandler, S., “Redefining and redesigning hospital discharge to enhance patient care: a randomized controlled study,” *J Gen Intern Med*, 2008, Vol. 23(8), pp. 1228-33.

27 Arbaje, A. I., Kansagara, D. L., Salanitro, A. H., Englander, H. L., Kripalani, S., Jencks, S. F., & Lindquist, L. A., “Regardless of age: incorporating principles from geriatric medicine to improve care transitions for patients with complex needs,” *Journal of General Internal Medicine*, 2014, Vol 29(6), pp. 932-939.

28 Simmons, S., Schnelle, J., Slagle, J., Sathe, N. A., Stevenson, D., Carlo, M., & McPheeters, M. L., “Resident safety practices in nursing home settings.” Technical Brief No. 24 (Prepared by the Vanderbilt Evidence-based Practice Center under Contract No. 290-2015-00003-I.) AHRQ Publication No. 16-EHC022-EF. Rockville, MD: Agency for Healthcare Research and Quality. May 2016. Available at <https://www.ncbi.nlm.nih.gov/books/NBK384624/>.

29 Berwick, D. M. & Hackbarth, A. D. “Eliminating Waste in US Health Care,” *JAMA*, 2012, Vol. 307(14), pp.1513-1516.

30 McDonald, K. M., Sundaram, V., Bravata, D. M., Lewis, R., Lin, N., Kraft, S. A. & Owens, D. K. Care Coordination. Vol. 7 of: Shojania K.G., McDonald K.M., Wachter R.M., Owens D.K., editors. “Closing the quality gap: A critical analysis of quality improvement strategies.” Technical Review 9 (Prepared by the Stanford University-UCSF Evidence-based Practice Center under contract 290-02-0017). AHRQ Publication No. 04(07)-0051-7. Rockville, MD: Agency for Healthcare Research and Quality. June 2006. Available at <https://www.ncbi.nlm.nih.gov/books/NBK44015/>.

31 Lattimer, C., “When it comes to transitions in patient care, effective communication can make all the difference,” *Generations*, 2011, Vol. 35(1), pp. 69-72.

32 Starmer A. J, Spector N. D., Srivastava R., West, D. C., Rosenbluth, G., Allen, A. D., Noble, E. L., & Landrigan, C. P., “Changes in medical errors after implementation of a handoff program,” *N Engl J Med*, 2014, Vol. 37(1), pp. 1803-1812.

33 Kruse, C.S. Marquez, G., Nelson, D., & Polomares, O., “The use of health information exchange to augment patient handoff in long-term care: a systematic review,” *Applied Clinical Informatics*, 2018, Vol. 9(4), pp. 752-771.

vulnerable to adverse health outcomes due to insufficient medication information on the part of their health care providers, and the higher likelihood for multiple comorbid chronic conditions, polypharmacy, and complicated transitions between care settings.^{35,36} Preventable adverse drug events (ADEs) may occur after hospital discharge in a variety of settings including PAC.³⁷ A 2014 Office of Inspector General report found that almost one-tenth of Medicare beneficiaries experienced an ADE, such as delirium, bleeding, fall or injury, or constipation, during their stay in a SNF in 2011. Of these, two-thirds were classified as preventable.³⁸ Medication errors and one-fifth of ADEs occur during transitions between settings, including admission to or discharge from a hospital to home or a PAC setting, or transfer between hospitals.^{39,40}

Patients in PAC settings are often taking multiple medications. Consequently, PAC providers regularly are in the position of starting complex new medication regimens with little knowledge of the patients or their medication history upon admission. Furthermore, inter-facility communication barriers delay resolving medication discrepancies during transitions of care.⁴¹

34 Brody, A. A., Gibson, B., Tresner-Kirsch, D., Kramer, H., Thraen, I., Coarr, M. E., & Rupper, R., "High prevalence of medication discrepancies between home health referrals and Centers for Medicare and Medicaid Services home health certification and plan of care and their potential to affect safety of vulnerable elderly adults,"

Journal of the American Geriatrics Society, 2016, Vol. 64(11), pp. e166-e170.

35 Chhabra, P. T., Rattinger, G. B., Dutcher, S. K., Hare, M. E., Parsons, K., L., & Zuckerman, I. H., "Medication reconciliation during the transition to and from long-term care settings: a systematic review," *Res Social Adm Pharm*, 2012, Vol. 8(1), pp. 60-75.

36 Levinson, D. R., & General, I., "Adverse events in skilled nursing facilities: national incidence among Medicare beneficiaries." Washington, DC: U.S. Department of Health and Human Services, Office of Inspector General, February 2014. Available at <https://oig.hhs.gov/oei/reports/oei-06-11-00370.pdf>.

37 Battles J., Azam I., Grady M., & Reback K., "Advances in patient safety and medical liability," AHRQ Publication No. 17-0017-EF. Rockville, MD: Agency for Healthcare Research and Quality, August 2017. Available at https://www.ahrq.gov/sites/default/files/publications/files/advances-complete_3.pdf.

38 Health and Human Services Office of Inspector General. Adverse events in skilled nursing facilities: National incidence among Medicare beneficiaries. OEI-06-11-00370). 2014. Available at <https://oig.hhs.gov/oei/reports/oei-06-11-00370.pdf>.

39 Barnsteiner, J. H., "Medication Reconciliation: Transfer of medication information across settings—keeping it free from error," *The American Journal of Nursing*, 2005, Vol. 105(3), pp. 31-36.

40 Gleason, K. M., Groszek, J. M., Sullivan, C., Rooney, D., Barnard, C., Noskin, G. A., "Reconciliation of discrepancies in medication histories and admission orders of newly hospitalized patients," *American Journal of Health System Pharmacy*, 2004, Vol. 61(16), pp. 1689-1694.

41 Patterson M., Foust J. B., Bollinger, S., Coleman, C., Nguyen, D., "Inter-facility communication barriers delay resolving medication discrepancies during transitions of care," *Research in Social & Administrative Pharmacy* (2018), doi: 10.1016/j.sapharm.2018.05.124.

Medication discrepancies are common,⁴² and found to occur in 86 percent of all transitions, increasing the likelihood of ADEs.^{43,44,45} Up to 90 percent of patients experience at least one medication discrepancy in the transition from hospital to home care, and discrepancies occur within all therapeutic classes of medications.^{46,47}

Transfer of a medication list between providers is necessary for medication reconciliation interventions, which have been shown to be a cost-effective way to avoid ADEs by reducing errors,^{48,49,50} especially when medications are reviewed by a pharmacist using electronic medical records.⁵¹

(2) Stakeholder and Technical Expert Panel (TEP) Input

The proposed measure was developed after consideration of feedback we received from stakeholders and four TEPs convened by our contractors. Further, the proposed measure was developed after evaluation of data collected during two pilot tests we conducted in accordance with the CMS Measures Management System Blueprint.

⁴² Manias, E., Annaikis, N., Considine, J., Weerasuriya, R., & Kusljic, S. "Patient-, medication- and environment-related factors affecting medication discrepancies in older patients," *Collegian*, 2017, Vol. 24, pp. 571-577.

⁴³ Tjia, J., Bonner, A., Briesacher, B. A., McGee, S., Terrill, E., Miller, K., "Medication discrepancies upon hospital to skilled nursing facility transitions," *J Gen Intern Med*, 2009, Vol. 24(5), pp. 630-635.

⁴⁴ Sinvani, L. D., Beizer, J., Akerman, M., Pekmezaris, R., Nouryan, C., Lutsky, L., Cal, C., Dlugacz, Y., Masick, K., Wolf-Klein, G., "Medication reconciliation in continuum of care transitions: a moving target," *J Am Med Dir Assoc*, 2013, Vol. 14(9), 668-672.

⁴⁵ Coleman E. A., Parry C., Chalmers S., & Min, S. J., "The Care Transitions Intervention: results of a randomized controlled trial," *Arch Intern Med*, 2006, Vol. 166, pp. 1822-1828.

⁴⁶ Corbett C. L., Setter S. M., Neumiller J. J., & Wood, I. D., "Nurse identified hospital to home medication discrepancies: implications for improving transitional care," *Geriatr Nurs*, 2011, Vol. 31(3), pp. 188-196.

⁴⁷ Setter S. M., Corbett C. F., Neumiller J. J., Gates, B. J., Sclar, D. A., & Sonnett, T. E., "Effectiveness of a pharmacist-nurse intervention on resolving medication discrepancies in older patients transitioning from hospital to home care: impact of a pharmacy/nursing intervention," *Am J Health Syst Pharm*, 2009, Vol. 66, pp. 2027-2031.

⁴⁸ Boockvar, K. S., Blum, S., Kugler, A., Livote, E., Mergenhausen, K. A., Nebeker, J. R., & Yeh, J., "Effect of admission medication reconciliation on adverse drug events from admission medication changes," *Archives of Internal Medicine*, 2011, Vol. 171(9), pp. 860-861.

⁴⁹ Kwan, J. L., Lo, L., Sampson, M., & Shojania, K. G., "Medication reconciliation during transitions of care as a patient safety strategy: a systematic review," *Annals of Internal Medicine*, 2013, Vol. 158(5), pp. 397-403.

⁵⁰ Chhabra, P. T., Rattinger, G. B., Dutcher, S. K., Hare, M. E., Parsons, K., L., & Zuckerman, I. H., "Medication reconciliation during the transition to and from long-term care settings: a systematic review," *Res Social Adm Pharm*, 2012, Vol. 8(1), pp. 60-75.

⁵¹ Agrawal A, Wu WY. "Reducing medication errors and improving systems reliability using an electronic medication reconciliation system," *The Joint Commission Journal on Quality and Patient Safety*, 2009, Vol. 35(2), pp. 106-114.

Our measure development contractors constituted a TEP which met on September 27, 2016⁵², January 27, 2017, and August 3, 2017⁵³ to provide input on a prior version of this measure. Based on this input, we updated the measure concept in late 2017 to include the transfer of a specific component of health information—medication information. Our measure development contractors reconvened this TEP on April 20, 2018 for the purpose of obtaining expert input on the proposed measure, including the measure’s reliability, components of face validity, and feasibility of being implemented across PAC settings. Overall, the TEP was supportive of the proposed measure, affirming that the measure provides an opportunity to improve the transfer of medication information. A summary of the April 20, 2018 TEP proceedings titled “Transfer of Health Information TEP Meeting 4-June 2018” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>

Our measure development contractors solicited stakeholder feedback on the proposed measure by requesting comment on the CMS Measures Management System Blueprint website, and accepted comments that were submitted from March 19, 2018 to May 3, 2018. The comments received expressed overall support for the measure. Several commenters suggested ways to improve the measure, primarily related to what types of information should be included

⁵² Technical Expert Panel Summary Report: Development of two quality measures to satisfy the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) Domain of Transfer of health Information and Care Preferences When an Individual Transitions to Skilled Nursing Facilities (SNFs), Inpatient Rehabilitation Facilities (IRFs), Long Term Care Hospitals (LTCHs) and Home Health Agencies (HHAs). Available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Transfer-of-Health-Information-TEP_Summary_Report_Final-June-2017.pdf.

⁵³ Technical Expert Panel Summary Report: Development of two quality measures to satisfy the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) Domain of Transfer of health Information and Care Preferences When an Individual Transitions to Skilled Nursing Facilities (SNFs), Inpatient Rehabilitation Facilities (IRFs), Long Term Care Hospitals (LTCHs) and Home Health Agencies (HHAs). Available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Transfer-of-Health-Information-TEP-Meetings-2-3-Summary-Report_Final_Feb2018.pdf.

at transfer. We incorporated this input into development of the proposed measure. The summary report for the March 19 to May 3, 2018 public comment period titled “IMPACT Medication–Profile- Transferred–Public-Comment-Summary-Report” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

(3) Pilot Testing

The proposed measure was tested between June and August 2018 in a pilot test that involved 24 PAC facilities/agencies, including five IRFs, six SNFs, six LTCHs, and seven HHAs. The 24 pilot sites submitted a total of 801 records. Analysis of agreement between coders within each participating facility (266 qualifying pairs) indicated a 93-percent agreement for this measure. Overall, pilot testing enabled us to verify its reliability, components of face validity, and feasibility of being implemented across PAC settings. Further, more than half of the sites that participated in the pilot test stated during the debriefing interviews that the measure could distinguish facilities or agencies with higher quality medication information transfer from those with lower quality medication information transfer at discharge. The pilot test summary report titled “Transfer of Health Information 2018 Pilot Test Summary Report” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

(4) Measure Applications Partnership (MAP) Review and Related Measures

We included the proposed measure in the SNF QRP section of the 2018 Measures Under Consideration (MUC) list. The MAP conditionally supported this measure pending NQF endorsement, noting that the measure can promote the transfer of important medication information. The MAP also suggested that CMS consider a measure that can be adapted to capture bi-directional information exchange, and recommended that the medication information

transferred include important information about supplements and opioids. More information about the MAP's recommendations for this measure is available at http://www.qualityforum.org/Publications/2019/02/MAP_2019_Considerations_for_Implementing_Measures_Final_Report_-_PAC-LTC.aspx.

As part of the measure development and selection process, we also identified one NQF-endorsed quality measure similar to the proposed measure, titled Documentation of Current Medications in the Medical Record (NQF #0419, CMS eCQM ID: CMS68v8). This measure was adopted as one of the recommended adult core clinical quality measures for eligible professionals for the EHR Incentive Program beginning in 2014, and was also adopted under the Merit-based Incentive Payment System (MIPS) quality performance category beginning in 2017. The measure is calculated based on the percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all resources immediately available on the date of the encounter.

The proposed Transfer of Health Information to the Provider–Post-Acute Care (PAC) measure addresses the transfer of information whereas the NQF-endorsed measure #0419 assesses the documentation of medications, but not the transfer of such information. This is important as the proposed measure assesses for the transfer of medication information for the proposed measure calculation. Further, the proposed measure utilizes standardized patient assessment data elements (SPADEs), which is a requirement for measures specified under the Transfer of Health Information measure domain under section 1899B(c)(1)(E) of the Act, whereas NQF #0419 does not.

After review of the NQF-endorsed measure, we determined that the proposed Transfer of Health Information to the Provider–Post-Acute Care (PAC) measure better addresses the Transfer of Health Information measure domain, which requires that at least some of the data

used to calculate the measure be collected as standardized patient assessment data through the post-acute care assessment instruments. Section 1899B(e)(2)(A) of the Act requires that any measure specified by the Secretary be endorsed by the entity with a contract under section 1890(a) of the Act, which is currently the National Quality Form (NQF). However, when a feasible and practical measure has not been NQF endorsed for a specified area or medical topic determined appropriate by the Secretary, section 1899B(e)(2)(B) of the Act allows the Secretary to specify a measure that is not NQF endorsed as long as due consideration is given to the measures that have been endorsed or adopted by a consensus organization identified by the Secretary. For the reasons discussed above, we believe that there is currently no feasible NQF-endorsed measure that we could adopt under section 1899B(c)(1)(E) of the Act. However, we note that we intend to submit the proposed measure to the NQF for consideration of endorsement when feasible.

(5) Quality Measure Calculation

The proposed Transfer of Health Information to the Provider–Post-Acute Care (PAC) quality measure is calculated as the proportion of resident stays with a discharge assessment indicating that a current reconciled medication list was provided to the subsequent provider at the time of discharge. The proposed measure denominator is the total number of SNF resident stays, ending in discharge to a “subsequent provider,” which is defined as a short-term general acute-care hospital, a skilled nursing facility (SNF), intermediate care (intellectual and developmental disabilities providers), home under care of an organized home health service organization or hospice, hospice in an institutional facility, an inpatient rehabilitation facility (IRF), an LTCH, a Medicaid nursing facility, an inpatient psychiatric facility, or a critical access hospital (CAH). These health care providers were selected for inclusion in the denominator because they are identified as subsequent providers on the discharge destination item that is currently included on

the resident assessment instrument minimum data set (MDS), the current version being MDS 3.0. The proposed measure numerator is the number of SNF resident stays with an MDS discharge assessment indicating a current reconciled medication list was provided to the subsequent provider at the time of discharge. For additional technical information about this proposed measure, we refer readers to the document titled, “Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,” available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>. The data source for the proposed quality measure is the MDS assessment instrument for SNF residents.

For more information about the data submission requirements we are proposing for this measure, we refer readers to section VI.A.8.c. of this proposed rule.

b. Proposed Transfer of Health Information to the Patient–Post-Acute Care (PAC) Measure

Beginning with the FY 2022 SNF QRP, we are proposing to adopt the Transfer of Health Information to the Patient–Post-Acute Care (PAC) measure, a measure that satisfies the IMPACT Act domain of Transfer of Health Information, with data collection for discharges beginning October 1, 2020. This process-based measure assesses whether or not a current reconciled medication list was provided to the patient, family, or caregiver when the patient was discharged from a PAC setting to a private home/apartment, a board and care home, assisted living, a group home, transitional living or home under care of an organized home health service organization, or a hospice.

(1) Background

In 2013, 22.3 percent of all acute hospital discharges were discharged to PAC settings, including 11 percent who were discharged to home under the care of a home health agency.⁵⁴ Of the Medicare FFS beneficiaries with a SNF stay in fiscal year 2017, an estimated 11 percent were discharged home with home health services, 41 percent were discharged home with self-care, and 0.2 percent were discharged with home hospice services.⁵⁵

The communication of health information, such as a reconciled medication list, is critical to ensuring safe and effective patient transitions from health care settings to home and/or other community settings. Incomplete or missing health information, such as medication information, increases the likelihood of a patient safety risk, often life-threatening.^{56,57,58,59,60} Individuals who use PAC care services are particularly vulnerable to adverse health outcomes due to their higher likelihood of having multiple comorbid chronic conditions, polypharmacy, and complicated transitions between care settings.^{61,62} Upon discharge to home, individuals in PAC settings may be faced with numerous medication changes, new medication regimes, and follow-up

54 Tian, W. "An all-payer view of hospital discharge to postacute care," May 2016. Available at <https://www.hcup-us.ahrq.gov/reports/statbriefs/sb205-Hospital-Discharge-Postacute-Care.jsp>.

55 RTI International analysis of Medicare claims data for index stays in SNF 2017. (RTI program reference: IB55).

56 Kwan, J. L., Lo, L., Sampson, M., & Shojania, K. G., "Medication reconciliation during transitions of care as a patient safety strategy: a systematic review," *Annals of Internal Medicine*, 2013, Vol. 158(5), pp. 397-403.

57 Boockvar, K. S., Blum, S., Kugler, A., Livote, E., Mergenhagen, K. A., Nebeker, J. R., & Yeh, J., "Effect of admission medication reconciliation on adverse drug events from admission medication changes," *Archives of Internal Medicine*, 2011, Vol. 171(9), pp. 860-861.

58 Bell, C. M., Brener, S. S., Gunraj, N., Huo, C., Bierman, A. S., Scales, D. C., & Urbach, D. R., "Association of ICU or hospital admission with unintentional discontinuation of medications for chronic diseases," *JAMA*, 2011, Vol. 306(8), pp. 840-847.

59 Basey, A. J., Krska, J., Kennedy, T. D., & Mackridge, A. J., "Prescribing errors on admission to hospital and their potential impact: a mixed-methods study," *BMJ Quality & Safety*, 2014, Vol. 23(1), pp. 17-25.

60 Desai, R., Williams, C. E., Greene, S. B., Pierson, S., & Hansen, R. A., "Medication errors during patient transitions into nursing homes: characteristics and association with patient harm," *The American Journal of Geriatric Pharmacotherapy*, 2011, Vol. 9(6), pp. 413-422.

61 Brody, A. A., Gibson, B., Tresner-Kirsch, D., Kramer, H., Thraen, I., Coarr, M. E., & Rupper, R. "High prevalence of medication discrepancies between home health referrals and Centers for Medicare and Medicaid Services home health certification and plan of care and their potential to affect safety of vulnerable elderly adults," *Journal of the American Geriatrics Society*, 2016, Vol. 64(11), pp. e166-e170.

62 Chhabra, P. T., Rattinger, G. B., Dutcher, S. K., Hare, M. E., Parsons, K., L., & Zuckerman, I. H., "Medication reconciliation during the transition to and from long-term care settings: a systematic review," *Res Social Adm Pharm*, 2012, Vol. 8(1), pp. 60-75.

details.^{63,64,65} The efficient and effective communication and coordination of medication information may be critical to prevent potentially deadly adverse effects. When care coordination activities enhance care transitions, these activities can reduce duplication of care services and costs of care, resolve conflicting care plans, and prevent medical errors.^{66,67}

Finally, the transfer of a patient's discharge medication information to the patient, family, or caregiver is common practice and supported by discharge planning requirements for participation in Medicare and Medicaid programs.^{68, 69} Most PAC EHR systems generate a discharge medication list to promote patient participation in medication management, which has been shown to be potentially useful for improving patient outcomes and transitional care.⁷⁰

(2) Stakeholder and Technical Expert Panel (TEP) Input

The proposed measure was developed after consideration of feedback we received from stakeholders and four TEPs convened by our contractors. Further, the proposed measure was developed after evaluation of data collected during two pilot tests we conducted in accordance

63 Brody, A. A., Gibson, B., Tresner-Kirsch, D., Kramer, H., Thraen, I., Coarr, M. E., & Rupper, R. "High prevalence of medication discrepancies between home health referrals and Centers for Medicare and Medicaid Services home health certification and plan of care and their potential to affect safety of vulnerable elderly adults,"

Journal of the American Geriatrics Society, 2016, Vol. 64(11), pp. e166-e170.

64 Bell, C. M., Brener, S. S., Gunraj, N., Huo, C., Bierman, A. S., Scales, D. C., & Urbach, D. R., "Association of ICU or hospital admission with unintentional discontinuation of medications for chronic diseases," *JAMA*, 2011, Vol. 306(8), pp. 840-847.

65 Sheehan, O. C., Kharrazi, H., Carl, K. J., Leff, B., Wolff, J. L., Roth, D. L., Gabbard, J., & Boyd, C. M., "Helping older adults improve their medication experience (HOME) by addressing medication regimen complexity in home healthcare," *Home Healthcare Now*, 2018, Vol. 36(1) pp. 10-19.

66 Mor, V., Intrator, O., Feng, Z., & Grabowski, D. C., "The revolving door of rehospitalization from skilled nursing facilities," *Health Affairs*, 2010, Vol. 29(1), pp. 57-64.

67 Starmer, A. J., Sectish, T. C., Simon, D. W., Keohane, C., McSweeney, M. E., Chung, E. Y., Yoon, C.S., Lipsitz, S.R., Wassner, A.J., Harper, M. B., & Landrigan, C. P., "Rates of medical errors and preventable adverse events among hospitalized children following implementation of a resident handoff bundle," *JAMA*, 2013, Vol. 310(21), pp. 2262-2270.

68 CMS, "Revision to state operations manual (SOM), Hospital Appendix A - Interpretive Guidelines for 42 CFR 482.43, Discharge Planning" May 17, 2013. Available at <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-32.pdf>.

69 The State Operations Manual Guidance to Surveyors for Long Term Care Facilities (Guidance §483.21(c)(1) Rev. 11-22-17) for discharge planning process. Available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf.

70 Toles, M., Colon-Emeric, C., Naylor, M. D., Asafu-Adjei, J., Hanson, L. C., "Connect-home: transitional care of skilled nursing facility patients and their caregivers," *Am Geriatr Soc.*, 2017, Vol. 65(10), pp. 2322-2328.

with the CMS MMS Blueprint.

Our measure development contractors constituted a TEP which met on September 27, 2016⁷¹, January 27, 2017, and August 3, 2017⁷² to provide input on a prior version of this measure. Based on this input, we updated the measure concept in late 2017 to include the transfer of a specific component of health information—medication information. Our measure development contractors reconvened this TEP on April 20, 2018 to seek expert input on the measure. Overall, the TEP members supported the proposed measure, affirming that the measure provides an opportunity to improve the transfer of medication information. Most of the TEP members believed that the measure could improve the transfer of medication information to patients, families, and caregivers. Several TEP members emphasized the importance of transferring information to patients and their caregivers in a clear manner using plain language. A summary of the April 20, 2018 TEP proceedings titled “Transfer of Health Information TEP Meeting 4 – June 2018” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

Our measure development contractors solicited stakeholder feedback on the proposed measure by requesting comment on the CMS Measures Management System Blueprint website,

⁷¹ Technical Expert Panel Summary Report: Development of two quality measures to satisfy the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) Domain of Transfer of health Information and Care Preferences When an Individual Transitions to Skilled Nursing Facilities (SNFs), Inpatient Rehabilitation Facilities (IRFs), Long Term Care Hospitals (LTCHs) and Home Health Agencies (HHAs). Available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Transfer-of-Health-Information-TEP_Summary_Report_Final-June-2017.pdf.

⁷² Technical Expert Panel Summary Report: Development of two quality measures to satisfy the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) Domain of Transfer of health Information and Care Preferences When an Individual Transitions to Skilled Nursing Facilities (SNFs), Inpatient Rehabilitation Facilities (IRFs), Long Term Care Hospitals (LTCHs) and Home Health Agencies (HHAs). Available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Transfer-of-Health-Information-TEP-Meetings-2-3-Summary-Report_Final_Feb2018.pdf.

and accepted comments that were submitted from March 19, 2018 to May 3, 2018. Several commenters noted the importance of ensuring that the instruction provided to patients and caregivers is clear and understandable to promote transparent access to medical record information and meet the goals of the IMPACT Act. The summary report for the March 19 to May 3, 2018 public comment period titled “IMPACT- Medication Profile Transferred Public Comment Summary Report” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

(3) Pilot Testing

Between June and August 2018, we held a pilot test involving 24 PAC facilities/agencies, including five IRFs, six SNFs, six LTCHs, and seven HHAs. The 24 pilot sites submitted a total of 801 assessments. Analysis of agreement between coders within each participating facility (241 qualifying pairs) indicated an 87 percent agreement for this measure. Overall, pilot testing enabled us to verify its reliability, components of face validity, and feasibility of being implemented across PAC settings. Further, more than half of the sites that participated in the pilot test stated, during debriefing interviews, that the measure could distinguish facilities or agencies with higher quality medication information transfer from those with lower quality medication information transfer at discharge. The pilot test summary report titled “Transfer of Health Information 2018 Pilot Test Summary Report” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

(4) Measure Applications Partnership (MAP) Review and Related Measures

We included the proposed measure in the SNF QRP section of the 2018 MUC list. The MAP conditionally supported this measure pending NQF endorsement, noting that the measure

can promote the transfer of important medication information to the patient. The MAP recommended that providers transmit medication information to patients that is easy to understand because health literacy can impact a person's ability to take medication as directed. More information about the MAP's recommendations for this measure is available at http://www.qualityforum.org/Publications/2019/02/MAP_2019_Considerations_for_Implementing_Measures_Final_Report_-_PAC-LTC.aspx.

Section 1899B(e)(2)(A) of the Act, requires that any measure specified by the Secretary be endorsed by the entity with a contract under section 1890(a) of the Act, which is currently the NQF. However, when a feasible and practical measure has not been NQF-endorsed for a specified area or medical topic determined appropriate by the Secretary, section 1899B(e)(2)(B) of the Act allows the Secretary to specify a measure that is not NQF-endorsed as long as due consideration is given to the measures that have been endorsed or adopted by a consensus organization identified by the Secretary. Therefore, in the absence of any NQF-endorsed measures that address the proposed Transfer of Health Information to the Patient–Post-Acute Care (PAC), which requires that at least some of the data used to calculate the measure be collected as standardized patient assessment data through the post-acute care assessment instruments, we believe that there is currently no feasible NQF-endorsed measure that we could adopt under section 1899B(c)(1)(E) of the Act. However, we note that we intend to submit the proposed measure to the NQF for consideration of endorsement when feasible.

(5) Quality Measure Calculation

The calculation of the proposed Transfer of Health Information to the Patient–Post-Acute Care (PAC) measure would be based on the proportion of resident stays with a discharge assessment indicating that a current reconciled medication list was provided to the resident, family, or caregiver at the time of discharge.

The proposed measure denominator is the total number of SNF resident stays ending in discharge to a private home/apartment, a board and care home, assisted living, a group home, transitional living or home under care of an organized home health service organization, or a hospice. These locations were selected for inclusion in the denominator because they are identified as home locations on the discharge destination item that is currently included on the MDS. The proposed measure numerator is the number of SNF resident stays with an MDS discharge assessment indicating a current reconciled medication list was provided to the resident, family, or caregiver at the time of discharge. For technical information about this proposed measure we refer readers to the document titled “Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,” available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>. Data for the proposed quality measure would be calculated using data from the MDS assessment instrument for SNF residents.

For more information about the data submission requirements we are proposing for this measure, we refer readers to section VI.A.8.c. of this proposed rule.

c. Proposed Update to the Discharge to Community – Post Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP) Measure

We are proposing to update the specifications for the Discharge to Community–PAC SNF QRP measure to exclude baseline nursing facility (NF) residents from the measure. This measure reports a SNF’s risk-standardized rate of Medicare FFS residents who are discharged to the community following a SNF stay, do not have an unplanned readmission to an acute care hospital or LTCH in the 31 days following discharge to community, and who remain alive during the 31 days following discharge to community. We adopted this measure in the FY 2017 SNF

PPS final rule (81 FR 52021 through 52029).

In the FY 2017 SNF PPS final rule (81 FR 52025), we addressed public comments recommending exclusion of SNF residents who were baseline NF residents, as these residents lived in a NF prior to their SNF stay and may not be expected to return to the community following their SNF stay. In the FY 2018 SNF PPS final rule (82 FR 36596), we addressed public comments expressing support for a potential future modification of the measure that would exclude baseline NF residents; commenters stated that the exclusion would result in the measure more accurately portraying quality of care provided by SNFs, while controlling for factors outside of SNF control.

We assessed the impact of excluding baseline NF residents from the measure using CY 2015 and CY 2016 data, and found that this exclusion impacted both patient- and facility-level discharge to community rates. We defined baseline NF residents as SNF residents who had a long-term NF stay in the 180 days preceding their hospitalization and SNF stay, with no intervening community discharge between the NF stay and qualifying hospitalization for measure inclusion. Baseline NF residents represented 10.4 percent of the measure population after all measure exclusions were applied. Observed resident-level discharge to community rates were significantly lower for baseline NF residents (2.37 percent) compared with non-NF residents (53.32 percent). The national observed resident-level discharge to community rate was 48.01 percent when baseline NF residents were included in the measure, increasing to 53.32 percent when they were excluded from the measure. After excluding baseline NF residents, 38.5 percent of SNFs had an increase in their risk-standardized discharge to community rate that exceeded the increase in the national observed resident-level discharge to community rate.

Based on public comments received and our impact analysis, we are proposing to exclude baseline NF residents from the Discharge to Community–PAC SNF QRP measure beginning

with the FY 2020 SNF QRP, with baseline NF residents defined as SNF residents who had a long-term NF stay in the 180 days preceding their hospitalization and SNF stay, with no intervening community discharge between the NF stay and hospitalization.

For additional technical information regarding the Discharge to Community–PAC SNF QRP measure, including technical information about the proposed exclusion, we refer readers to the document titled “Proposed Specifications for SNF QRP Quality Measures and Standardized Resident Assessment Data Elements,” available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

We are inviting public comment on this proposal.

5. SNF QRP Quality Measures, Measure Concepts, and Standardized Patient Assessment Data Elements under Consideration for Future Years: Request for Information

We are seeking input on the importance, relevance, appropriateness, and applicability of each of the measures, standardized patient assessment data elements (SPADEs), and concepts under consideration listed in the Table 13 for future years in the SNF QRP.

TABLE 13: Future Measures, Measure Concepts, and Standardized Patient Assessment Data Elements (SPADEs) Under Consideration for the SNF QRP

Assessment-Based Quality Measures and Measure Concepts
Functional maintenance outcomes
Opioid use and frequency
Exchange of electronic health information and interoperability
Claims-Based
Healthcare-Associated Infections in Skilled Nursing Facility (SNF) – claims-based
Standardized Patient Assessment Data Elements (SPADEs)
Cognitive complexity, such as executive function and memory
Dementia
Bladder and bowel continence including appliance use and episodes of incontinence
Care preferences, advance care directives, and goals of care
Caregiver Status
Veteran Status
Health disparities and risk factors, including education, sex and gender identity, and sexual orientation.

While we will not be responding to specific comments submitted in response to this Request for Information in the FY 2020 SNF PPS final rule, we intend to use this input to inform our future measure and SPADE development efforts

6. Proposed Standardized Patient Assessment Data Reporting beginning with the FY 2022 SNF QRP

Section 1888(e)(6)(B)(i)(III) of the Act requires that, for fiscal years 2019 and each subsequent year, SNFs must report standardized patient⁷³ assessment data (SPADE) required under section 1899B(b)(1) of the Act. Section 1899B(a)(1)(C) of the Act requires, in part, the Secretary to modify the PAC assessment instruments in order for PAC providers, including SNFs, to submit SPADEs under the Medicare program. Section 1899B(b)(1)(A) of the Act requires PAC providers to submit SPADEs under applicable reporting provisions (which, for SNFs, is the SNF QRP) with respect to the admission and discharge of an individual (and more frequently as the Secretary deems appropriate), and section 1899B(b)(1)(B) of the Act defines standardized patient assessment data as data required for at least the quality measures described in section 1899B(c)(1) of the Act and that is with respect to the following categories: (1) functional status, such as mobility and self-care at admission to a PAC provider and before discharge from a PAC provider; (2) cognitive function, such as ability to express ideas and to understand, and mental status, such as depression and dementia; (3) special services, treatments, and interventions, such as need for ventilator use, dialysis, chemotherapy, central line placement, and total parenteral nutrition; (4) medical conditions and comorbidities, such as diabetes, congestive heart failure, and pressure ulcers; (5) impairments, such as incontinence and an

⁷³ In the FY 2018 SNF PPS final rule, we used the term “standardized resident assessment data” to refer to standardized assessment data elements collected from SNF residents. However, in this proposed rule and going forward, we will use the term “standardized patient assessment data” to refer to the collect of SPADEs from SNF residents.

impaired ability to hear, see, or swallow, and (6) other categories deemed necessary and appropriate by the Secretary.

In the FY 2018 SNF PPS proposed rule (82 FR 21059 through 21076), we proposed to adopt SPADEs that would satisfy the first five categories. In the FY 2018 SNF PPS final rule, commenters expressed support for our adoption of SPADEs in general, including support for our broader standardization goal and support for the clinical usefulness of specific proposed SPADEs. However, we did not finalize the majority of our SPADE proposals in recognition of the concern raised by many commenters that we were moving too fast to adopt the SPADEs and modify our assessment instruments in light of all of the other requirements we were also adopting under the IMPACT Act at that time (82 FR 36598 through 36600). In addition, we noted our intention to conduct extensive testing to ensure that the standardized patient assessment data elements we select are reliable, valid, and appropriate for their intended use (82 FR 36599).

We did, however, finalize the adoption of SPADEs for two of the categories described in section 1899B(b)(1)(B) of the Act: (1) Functional status: Data elements currently reported by SNFs to calculate the measure Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631); and (2) Medical conditions and comorbidities: the data elements used to calculate the pressure ulcer measures, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) and the replacement measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury. We stated that these data elements were important for care planning, known to be valid and reliable, and already being reported by SNFs for the calculation of quality measures.

Since we issued the FY 2018 SNF PPS final rule, SNFs have had an opportunity to

familiarize themselves with other new reporting requirements that we have adopted under the IMPACT Act. We have also conducted further testing of the SPADEs, as described more fully below, and believe that this testing supports the use of the SPADEs in our PAC assessment instruments. Therefore, we are now proposing to adopt many of the same SPADEs that we previously proposed to adopt, along with other SPADEs.

We are proposing that SNFs would be required to report these SPADEs beginning with the FY 2022 SNF QRP. If finalized as proposed, SNFs would be required to report these data with respect to SNF admissions and discharges that occur between October 1, 2020 and December 31, 2020 for the FY 2022 SNF QRP. Beginning with the FY 2023 SNF QRP, we propose that SNFs must report data with respect to admissions and discharges that occur during the subsequent calendar year (for example, CY 2021 for the FY 2023 SNF QRP, CY 2022 for the FY 2024 SNF QRP).

We are also proposing that SNFs that submit the Hearing, Vision, Race, and Ethnicity SPADEs with respect to admission only will be deemed to have submitted those SPADEs with respect to both admission and discharge, because it is unlikely that the assessment of those SPADEs at admission will differ from the assessment of the same SPADEs at discharge.

In selecting the proposed SPADEs below, we considered the burden of assessment-based data collection and aimed to minimize additional burden by evaluating whether any data that is currently collected through one or more PAC assessment instruments could be collected as SPADE. In selecting the proposed SPADEs below, we also took into consideration the following factors with respect to each data element:

- (1) Overall clinical relevance;
- (2) Interoperable exchange to facilitate care coordination during transitions in care;
- (3) Ability to capture medical complexity and risk factors that can inform both payment

and quality; and

(4) Scientific reliability and validity, general consensus agreement for its usability.

In identifying the SPADEs proposed below, we additionally drew on input from several sources, including TEPs held by our data element contractor, public input, and the results of a recent National Beta Test of candidate data elements conducted by our data element contractor (hereafter “National Beta Test”).

The National Beta Test collected data from 3,121 patients and residents across 143 LTCHs, SNFs, IRFs, and HHAs from November 2017 to August 2018 to evaluate the feasibility, reliability, and validity of candidate data elements across PAC settings. The National Beta Test also gathered feedback on the candidate data elements from staff who administered the test protocol in order to understand usability and workflow of the candidate data elements. More information on the methods, analysis plan, and results for the National Beta Test are available in the document titled, “Development and Evaluation of Candidate Standardized Patient Assessment Data Elements: Findings from the National Beta Test (Volume 2),” available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

Further, to inform the proposed SPADEs, we took into account feedback from stakeholders, as well as from technical and clinical experts, including feedback on whether the candidate data elements would support the factors described above. Where relevant, we also took into account the results of the Post-Acute Care Payment Reform Demonstration (PAC PRD) that took place from 2006 to 2012.

7. Proposed Standardized Patient Assessment Data by Category

a. Cognitive Function and Mental Status Data

A number of underlying conditions, including dementia, stroke, traumatic brain injury,

side effects of medication, metabolic and/or endocrine imbalances, delirium, and depression, can affect cognitive function and mental status in PAC patient and resident populations.⁷⁴ The assessment of cognitive function and mental status by PAC providers is important because of the high percentage of patients and residents with these conditions,⁷⁵ and because these assessments provide opportunity for improving quality of care.

Symptoms of dementia may improve with pharmacotherapy, occupational therapy, or physical activity,^{76, 77,78} and promising treatments for severe traumatic brain injury are currently being tested.⁷⁹ For older patients and residents diagnosed with depression, treatment options to reduce symptoms and improve quality of life include antidepressant medication and psychotherapy,^{80, 81,82,83} and targeted services, such as therapeutic recreation, exercise, and restorative nursing, to increase opportunities for psychosocial interaction.⁸⁴

In alignment with our Meaningful Measures Initiative, accurate assessment of cognitive function and mental status of patients and residents in PAC is expected to make care safer by

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

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

76 Casey D.A., Antimisiaris D., O'Brien J. (2010). Drugs for Alzheimer's Disease: Are They Effective? *Pharmacology & Therapeutics*, 35, 208–211.

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

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

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

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

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

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

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

reducing harm caused in the delivery of care; promote effective prevention and treatment of chronic disease; strengthen person and family engagement as partners in their care; and promote effective communication and coordination of care. For example, standardized assessment of cognitive function and mental status of patients and residents in PAC will support establishing a baseline for identifying changes in cognitive function and mental status (for example, delirium), anticipating the patient's or resident's ability to understand and participate in treatments during a PAC stay, ensuring patient and resident safety (for example, risk of falls), and identifying appropriate support needs at the time of discharge or transfer. Standardized patient assessment data elements will enable or support clinical decision-making and early clinical intervention; person-centered, high quality care through facilitating better care continuity and coordination; better data exchange and interoperability between settings; and longitudinal outcome analysis. Therefore, reliable standardized patient assessment data elements assessing cognitive function and mental status are needed in order to initiate a management program that can optimize a patient's or resident's prognosis and reduce the possibility of adverse events.

The data elements related to cognitive function and mental status were first proposed as standardized patient assessment data elements in the FY 2018 SNF PPS proposed rule (82 FR 21060 through 21063). In response to our proposals, a few commenters noted that the proposed data elements did not capture some dimensions of cognitive function and mental status, such as functional cognition, communication, attention, concentration, and agitation. One commenter also suggested that other cognitive assessments should be considered for standardization. Another commenter stated support for the standardized assessment of cognitive function and mental status, because it could support appropriate use of skilled therapy for beneficiaries with degenerative conditions, such as dementia, and appropriate use of medications for behavioral and psychological symptoms of dementia.

We are inviting comment on our proposals to collect as standardized patient assessment data the following data with respect to cognitive function and mental status.

- Brief Interview for Mental Status (BIMS)

We are proposing that the data elements that comprise the BIMS meet the definition of standardized patient assessment data with respect to cognitive function and mental status under section 1899B(b)(1)(B)(ii) of the Act.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21060 through 21061), dementia and cognitive impairment are associated with long-term functional dependence and, consequently, poor quality of life and increased health care costs and mortality.⁸⁵ This makes assessment of mental status and early detection of cognitive decline or impairment critical in the PAC setting. The intensity of routine nursing care is higher for patients and residents with cognitive impairment than those without, and dementia is a significant variable in predicting readmission after discharge to the community from PAC providers.⁸⁶

The BIMS is a performance-based cognitive assessment screening tool that assesses repetition, recall with and without prompting, and temporal orientation. The data elements that make up the BIMS are seven questions on the repetition of three words, temporal orientation, and recall that result in a cognitive function score. The BIMS was developed to be a brief, objective screening tool, with a focus on learning and memory. As a brief screener, the BIMS was not designed to diagnose dementia or cognitive impairment, but rather to be a relatively quick and easy to score assessment that could identify cognitively impaired patients as well as

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

86 RTI International. Proposed Measure Specifications for Measures Proposed in the FY 2017 IRF QRP NPRM. Research Triangle Park, NC. 2016.

those who may be at risk for cognitive decline and require further assessment. It is currently in use in two of the PAC assessments: the MDS used by SNFs and the IRF-PAI used by IRFs. For more information on the BIMS, we refer readers to the document titled “Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,” available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

The data elements that comprise the BIMS were first proposed as standardized patient assessment data elements in the FY 2018 SNF PPS proposed rule (82 FR 21060 through 21061). In that proposed rule, we stated that the proposal was informed by input we received through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 expressed support for use of the BIMS, noting that it is reliable, feasible to use across settings, and will provide useful information about patients and residents. We also stated that the data collected through the BIMS will provide a clearer picture of patient or resident complexity, help with the care planning process, and be useful during care transitions and when coordinating across providers. A summary report for the August 12 to September 12, 2016 public comment period titled “SPADE August 2016 Public Comment Summary Report” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

In response to our proposal in the FY 2018 SNF PPS proposed rule, a few commenters supported the use of the BIMS as standardized patient assessment data elements. Other commenters were critical of the BIMS, noting its limitations for assessing mild cognitive impairment and functional cognition. Another stated that the BIMS should be administered with

respect to discharge, as well as admission to capture changes during the stay. One expressed concern that the BIMS cannot be completed by patients and residents who are unable to communicate.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the BIMS was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the BIMS to be feasible and reliable for use with PAC patients and residents. More information about the performance of the BIMS in the National Beta Test can be found in the document titled “Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,” available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

In addition, our data element contractor convened a TEP on September 17, 2018, for the purpose of soliciting input on the proposed standardized patient assessment data elements and the TEP supported the assessment of patient or resident cognitive status at both admission and discharge. A summary of the September 17, 2018 TEP meeting titled “SPADE Technical Expert Panel Summary (Third Convening)” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-going SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and

concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. Some commenters also expressed concern that the BIMS, if used alone, may not be sensitive enough to capture the range of cognitive impairments, including mild cognitive impairment (MCI). A summary of the public input received from the November 27, 2018 stakeholder meeting titled “Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

We understand the concerns raised by stakeholders that BIMS, if used alone, may not be sensitive enough to capture the range of cognitive impairments, including functional cognition and MCI, but note that the purpose of the BIMS data elements as SPADEs is to screen for cognitive impairment in a broad population. We also acknowledge that further cognitive tests may be required based on a patient’s condition and will take this feedback into consideration in the development of future standardized assessment data elements. However, taking together the importance of assessing for cognitive status, stakeholder input, and strong test results, we are proposing that the BIMS data elements meet the definition of standardized patient assessment data with respect to cognitive function and mental status under section 1899B(b)(1)(B)(ii) of the Act and to adopt the BIMS as standardized patient assessment data for use in the SNF QRP.

- Confusion Assessment Method (CAM)

We are proposing that the data elements that comprise the Confusion Assessment Method (CAM) meet the definition of standardized patient assessment data with respect to cognitive function and mental status under section 1899B(b)(1)(B)(ii) of the Act.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21061), the CAM was developed to identify the signs and symptoms of delirium. It results in a score that suggests

whether a patient or resident should be assigned a diagnosis of delirium. Because patients and residents with multiple comorbidities receive services from PAC providers, it is important to assess delirium, which is associated with a high mortality rate and prolonged duration of stay in hospitalized older adults.⁸⁷ Assessing these signs and symptoms of delirium is clinically relevant for care planning by PAC providers.

The CAM is a patient assessment that screens for overall cognitive impairment, as well as distinguishes delirium or reversible confusion from other types of cognitive impairment. The CAM is currently in use in two of the PAC assessments: a four-item version of the CAM is used in the MDS in SNFs and a six-item version of the CAM is used in the LTCH CARE Data Set (LCDS) in LTCHs. We are proposing the four-item version of the CAM that assesses acute change in mental status, inattention, disorganized thinking, and altered level of consciousness. For more information on the CAM, we refer readers to the document titled “Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,” available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

The data elements that comprise the CAM were first proposed as standardized patient assessment data elements in the FY 2018 SNF PPS proposed rule (82 FR 21061). In that proposed rule, we stated that the proposal was informed by input we received on the CAM through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 expressed support for use of the CAM,

⁸⁷ Fick, D. M., Steis, M. R., Waller, J. L., & Inouye, S. K. (2013). “Delirium superimposed on dementia is associated with prolonged length of stay and poor outcomes in hospitalized older adults.” *J of Hospital Med* 8(9): 500-505.

noting that it would provide important information for care planning and care coordination and, therefore, contribute to quality improvement. We also stated that those commenters had noted the CAM is particularly helpful in distinguishing delirium and reversible confusion from other types of cognitive impairment. A summary report for the August 12 to September 12, 2016 public comment period titled “SPADE August 2016 Public Comment Summary Report” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

In response to our proposal in the FY 2018 SNF PPS proposed rule, a few commenters supported the use of the CAM as standardized patient assessment data elements, with one noting that it distinguishes delirium or reversible confusion from other types of cognitive impairments to share across settings for care coordination.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the CAM was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the CAM to be feasible and reliable for use with PAC patients and residents. More information about the performance of the CAM in the National Beta Test can be found in the document titled “Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,” available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

In addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although they did not specifically discuss the CAM data elements, the TEP supported the

assessment of patient or resident cognitive status with respect to both admission and discharge.

A summary of the September 17, 2018 TEP meeting titled “SPADE Technical Expert Panel Summary (Third Convening)” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-going SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled “Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

Taking together the importance of assessing for delirium, stakeholder input, and strong test results, we are proposing that the CAM data elements meet the definition of standardized patient assessment data with respect to cognitive function and mental status under section 1899B(b)(1)(B)(ii) of the Act and to adopt the CAM as standardized patient assessment data elements for use in the SNF QRP.

b. Patient Health Questionnaire-2 to 9 (PHQ-2 to 9)

We are proposing that the Patient Health Questionnaire-2 to 9 (PHQ-2 to 9) data elements meet the definition of standardized patient assessment data with respect to cognitive function and

mental status under section 1899B(b)(1)(B)(ii) of the Act. The proposed data elements are based on the PHQ-2 mood interview, which focuses on only the two cardinal symptoms of depression, and the longer PHQ-9 mood interview, which assesses presence and frequency of nine signs and symptoms of depression. The name of the data element, the PHQ-2 to 9, refers to an embedded skip pattern that transitions residents with a threshold level of symptoms in the PHQ-2 to the longer assessment of the PHQ-9. The skip pattern is described further below.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21062 through 21063), depression is a common and under-recognized mental health condition. Assessments of depression help PAC providers better understand the needs of their patients and residents by: prompting further evaluation after establishing a diagnosis of depression; elucidating the patient's or resident's ability to participate in therapies for conditions other than depression during their stay; and identifying appropriate ongoing treatment and support needs at the time of discharge.

The proposed PHQ-2 to 9 is based on the PHQ-9 mood interview. The PHQ-2 consists of questions about only the first two symptoms addressed in the PHQ-9: depressed mood and anhedonia (inability to feel pleasure), which are the cardinal symptoms of depression. The PHQ-2 has performed well as both a screening tool for identifying depression, to assess depression severity, and to monitor patient mood over time.^{88,89} If a patient demonstrates signs of depressed mood and anhedonia under the PHQ-2, then the patient is administered the lengthier PHQ-9. This skip pattern (also referred to as a gateway) is designed to reduce the length of the interview

88 Li, C., Friedman, B., Conwell, Y., & Fiscella, K. (2007). "Validity of the Patient Health Questionnaire 2 (PHQ- 2) in identifying major depression in older people." *J of the A Geriatrics Society*, 55(4): 596-602.

89 Löwe, B., Kroenke, K., & Gräfe, K. (2005). "Detecting and monitoring depression with a two-item questionnaire (PHQ-2)." *J of Psychosomatic Research*, 58(2): 163-171.

assessment for residents who fail to report the cardinal symptoms of depression. The design of the PHQ-2 to 9 reduces the burden that would be associated with the full PHQ-9, while ensuring that patients with indications of depressive symptoms based on the PHQ-2 receive the longer assessment.

Components of the proposed data elements are currently used in the OASIS for HHAs (PHQ-2) and the MDS for SNFs (PHQ-9). We are proposing altering the administration instructions for the existing data elements to adopt the PHQ-2 to 9 gateway logic, meaning that administration of the full PHQ-9 is contingent on resident responses to questions about the cardinal symptoms of depression. For more information on the PHQ-2 to 9, we refer readers to the document titled “Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,” available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

The PHQ-2 data elements were first proposed as SPADEs in the FY 2018 SNF PPS proposed rule (82 FR 21062 through 21063). In that proposed rule we stated that the proposal was informed by input we received from the TEP convened by our data element contractor on April 6 and 7, 2016. The TEP members particularly noted that the brevity of the PHQ-2 made it feasible to administer with low burden for both assessors and PAC patients or residents. A summary of the April 6 and 7, 2016 TEP meeting titled “SPADE Technical Expert Panel Summary (First Convening)” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>. That proposed rule was also informed by public input through a call for input published on the CMS Measures Management System Blueprint website. Input was submitted from August 12 to September 12, 2016 on three versions

of the PHQ depression screener: the PHQ-2; the PHQ-9; and the PHQ-2 to 9 with the skip pattern design. Many commenters provided feedback on using the PHQ-2 for the assessment of mood. Overall, commenters believed that collecting these data elements across PAC provider types was appropriate, given the role that depression plays in well-being. Several commenters expressed support for an approach that would use PHQ-2 as a gateway to the longer PHQ-9 while still potentially reducing burden on most patients and residents, as well as test administrators, and ensuring the administration of the PHQ-9, which exhibits higher specificity,⁹⁰ for patients and residents who showed signs and symptoms of depression on the PHQ-2. A summary report for the August 12 to September 12, 2016 public comment period titled “SPADE August 2016 Public Comment Summary Report” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

In response to our proposal to use the PHQ-2 in the FY 2018 SNF PPS proposed rule, a few commenters supported screening residents for depression with the PHQ-2. One commenter opposed the replacement of the PHQ-9 on the MDS with PHQ-2 because of the clinical significance of depression on quality of care and resident outcomes in the SNF population. Another expressed concern about the use of multi-step “gateway” questions, because use of the PHQ-2 and PHQ-9 may result in data not being standardized across settings and providers gathering data unrelated to the appropriateness of care.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the PHQ-2 to 9 was included in the National Beta Test of candidate data elements conducted by our data element

⁹⁰ Arroll B, Goodyear-Smith F, Crengle S, Gunn J, Kerse N, Fishman T, et al. Validation of PHQ-2 and PHQ-9 to screen for major depression in the primary care population. *Annals of family medicine*. 2010;8(4):348–353. doi: 10.1370/afm.1139 pmid:20644190; PubMed Central PMCID: PMC2906530.

contractor from November 2017 to August 2018. Results of this test found the PHQ-2 to 9 to be feasible and reliable for use with PAC patients and residents. More information about the performance of the PHQ-2 to 9 in the National Beta Test can be found in the document titled “Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,” available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

In addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the PHQ-2 to 9. The TEP was supportive of the PHQ-2 to 9 data element set as a screener for signs and symptoms of depression. The TEP’s discussion noted that symptoms evaluated by the full PHQ-9 (for example, concentration, sleep, appetite) had relevance to care planning and the overall well-being of the patient or resident, but that the gateway approach of the PHQ-2 to 9 would be appropriate as a depression screening assessment, as it depends on the well-validated PHQ-2 and focuses on the cardinal symptoms of depression. A summary of the September 17, 2018 TEP meeting titled “SPADE Technical Expert Panel Summary (Third Convening)” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-going SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email

through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled “Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

Taking together the importance of assessing for depression, stakeholder input, and strong test results, we are proposing that the PHQ-2 to 9 data elements meet the definition of standardized patient assessment data with respect to cognitive function and mental status under section 1899B(b)(1)(B)(ii) of the Act and to adopt the PHQ-2 to 9 data elements as standardized patient assessment data elements for use in the SNF QRP.

c. Special Services, Treatments, and Interventions Data

Special services, treatments, and interventions performed in PAC can have a major effect on an individual’s health status, self-image, and quality of life. The assessment of these special services, treatments, and interventions in PAC is important to ensure the continuing appropriateness of care for the patients and residents receiving them, and to support care transitions from one PAC provider to another, an acute care hospital, or discharge. In alignment with our Meaningful Measures Initiative, accurate assessment of special services, treatments, and interventions of patients and residents served by PAC providers is expected to make care safer by reducing harm caused in the delivery of care; promote effective prevention and treatment of chronic disease; strengthen person and family engagement as partners in their care; and promote effective communication and coordination of care.

For example, standardized assessment of special services, treatments, and interventions used in PAC can promote patient and resident safety through appropriate care planning (for example, mitigating risks such as infection or pulmonary embolism associated with central

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

A TEP convened by our data element contractor provided input on all of the proposed data elements for special services, treatments, and interventions. In a meeting held on January 5 and 6, 2017, this TEP found that these data elements are appropriate for standardization because they would provide useful clinical information to inform care planning and care coordination. The TEP affirmed that assessment of these services and interventions is standard clinical practice, and that the collection of these data by means of a list and checkbox format would conform with common workflow for PAC providers. A summary of the January 5 and 6, 2017 TEP meeting titled "SPADE Technical Expert Panel Summary (Second Convening)" is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

Comments on the category of special services, treatments, and interventions were also submitted by stakeholders during the FY 2018 SNF PPS proposed rule (82 FR 21063 through 21073) public comment period. A comment across all special services, treatments, and interventions data elements requested that the additional reporting burden of the special services,

treatments, and interventions data elements be addressed in payment calculations. Another comment submitted for several special services, treatments, and interventions data elements requested additional time be allowed before the providers are required to submit these data. One commenter expressed concern about increased reporting burden of the data elements proposed in FY 2018 because they would require an additional look-back time frame. Several commenters supported the inclusion of nutritional data elements as standardized data elements noting their importance in capturing information on care coordination and safe care transitions. One commenter noted the limitations of the nutritional data elements, namely that they do not capture information on swallowing or the clinical rationale for feeding/nutrition needs.

Information on data element performance in the National Beta Test, which collected data between November 2017 and August 2018, is reported within each data element proposal below. Clinical staff who participated in the National Beta Test supported these data elements because of their importance in conveying patient or resident significant health care needs, complexity, and progress. However, clinical staff also noted that, despite the simple “check box” format of these data element, they sometimes needed to consult multiple information sources to determine a patient’s or resident’s treatments.

We are inviting comment on our proposals to collect as standardized patient assessment data the following data with respect to special services, treatments, and interventions.

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

We are proposing that the Chemotherapy (IV, Oral, Other) data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21063 through 21064), chemotherapy is a type of cancer treatment that uses drugs to destroy cancer cells. It is

sometimes used when a patient has a malignancy (cancer), which is a serious, often life-threatening or life-limiting condition. Both intravenous (IV) and oral chemotherapy have serious side effects, including nausea/vomiting, extreme fatigue, risk of infection due to a suppressed immune system, anemia, and an increased risk of bleeding due to low platelet counts. Oral chemotherapy can be as potent as chemotherapy given by IV, and can be significantly more convenient and less resource-intensive to administer. Because of the toxicity of these agents, special care must be exercised in handling and transporting chemotherapy drugs. IV chemotherapy is administered either peripherally, or more commonly, given via an indwelling central line, which raises the risk of bloodstream infections. Given the significant burden of malignancy, the resource intensity of administering chemotherapy, and the side effects and potential complications of these highly-toxic medications, assessing the receipt of chemotherapy is important in the PAC setting for care planning and determining resource use. The need for chemotherapy predicts resource intensity, both because of the complexity of administering these potent, toxic drug combinations under specific protocols, and because of what the need for chemotherapy signals about the patient's underlying medical condition. Furthermore, the resource intensity of IV chemotherapy is higher than for oral chemotherapy, as the protocols for administration and the care of the central line (if present) for IV chemotherapy require significant resources.

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

(for example, intraventricular or intrathecal). If the assessor indicates that the resident is receiving chemotherapy on the principal Chemotherapy data element, the assessor would then indicate by which route or routes (for example, IV, Oral, Other) the chemotherapy is administered.

A single Chemotherapy data element that does not include the proposed three sub-elements is currently in use in the MDS in SNFs. We are proposing to expand the existing Chemotherapy data element in the MDS to include sub-elements for IV, Oral, and Other. For more information on the Chemotherapy (IV, Oral, Other) data element, we refer readers to the document titled “Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,” available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

The Chemotherapy data element was first proposed as a standardized patient assessment data element in the FY 2018 SNF PPS proposed rule (82 FR 21063 through 21064). In that proposed rule, we stated that the proposal was informed by input we received through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 expressed support for the IV Chemotherapy data element and suggested it be included as standardized patient assessment data. We also stated that those commenters had noted that assessing the use of chemotherapy services is relevant to share across the care continuum to facilitate care coordination and care transitions and noted the validity of the data element. Commenters also noted the importance of capturing all types of chemotherapy, regardless of route, and stated that collecting data only on patients and residents who received chemotherapy by IV would limit the usefulness of this standardized data element. A summary report for the August 12 to September 12, 2016 public comment period titled “SPADE August

2016 Public Comment Summary Report” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

In response to our proposal in the FY 2018 SNF PPS proposed rule, two commenters supported the adoption of Chemotherapy (IV, Oral, Other) as standardized patient assessment data elements.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the Chemotherapy data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Chemotherapy data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Chemotherapy data element in the National Beta Test can be found in the document titled “Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,” available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

In addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although the TEP members did not specifically discuss the Chemotherapy data element, the TEP members supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled “SPADE Technical Expert Panel Summary (Third Convening)” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled “Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

Taking together the importance of assessing for chemotherapy, stakeholder input, and strong test results, we are proposing, we are proposing that the Chemotherapy (IV, Oral, Other) data element with a principal data element and three sub-elements meet the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Chemotherapy (IV, Oral, Other) data element as standardized patient assessment data for use in the SNF QRP.

(2) Cancer Treatment: Radiation

We are proposing that the Radiation data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21064 through 21065), radiation is a type of cancer treatment that uses high-energy radioactivity to stop cancer by damaging cancer cell DNA, but it can also damage normal cells. Radiation is an important

therapy for particular types of cancer, and the resource utilization is high, with frequent radiation sessions required, often daily for a period of several weeks. Assessing whether a patient or resident is receiving radiation therapy is important to determine resource utilization because PAC patients and residents will need to be transported to and from radiation treatments, and monitored and treated for side effects after receiving this intervention. Therefore, assessing the receipt of radiation therapy, which would compete with other care processes given the time burden, would be important for care planning and care coordination by PAC providers.

The proposed data element consists of the single Radiation data element. The Radiation data element is currently in use in the MDS in SNFs. For more information on the Radiation data element, we refer readers to the document titled “Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,” available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

The Radiation data element was first proposed as a SPADE in the FY 2018 SNF PPS proposed rule (82 FR 21064 through 21065). In that proposed rule, we stated that the proposal was informed by input we received through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016, expressed support for the Radiation data element, noting its importance and clinical usefulness for patients and residents in PAC settings, due to the side effects and consequences of radiation treatment on patients and residents that need to be considered in care planning and care transitions, the feasibility of the item, and the potential for it to improve quality. A summary report for the August 12 to September 12, 2016 public comment period titled “SPADE August 2016 Public Comment Summary Report” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act->

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

In response to our proposal in the FY 2018 SNF PPS proposed rule, two commenters supported the adoption of Radiation as a standardized patient assessment data element.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the Radiation data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Radiation data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Radiation data element in the National Beta Test can be found in the document titled “Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,” available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

In addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although the TEP members did not specifically discuss the Radiation data element, the TEP members supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled “SPADE Technical Expert Panel Summary (Third Convening)” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor

hosted a public meeting of stakeholders to present results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled “Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

Taking together the importance of assessing for radiation, stakeholder input, and strong test results, we are proposing that the Radiation data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Radiation data element as standardized patient assessment data for use in the SNF QRP.

(3) Respiratory Treatment: Oxygen Therapy (Intermittent, Continuous, High-Concentration Oxygen Delivery System)

We are proposing that the Oxygen Therapy (Intermittent, Continuous, High-Concentration Oxygen Delivery System) data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21065), oxygen therapy provides a patient or resident with extra oxygen when medical conditions such as chronic obstructive pulmonary disease, pneumonia, or severe asthma prevent the patient or resident from getting enough oxygen from breathing. Oxygen administration is a resource-intensive intervention, as it requires specialized equipment such as a source of oxygen, delivery systems

(for example, oxygen concentrator, liquid oxygen containers, and high-pressure systems), the patient interface (for example, nasal cannula or mask), and other accessories (for example, regulators, filters, tubing). The data element proposed here captures patient or resident use of three types of oxygen therapy (intermittent, continuous, and high-concentration oxygen delivery system), which reflects the intensity of care needed, including the level of monitoring and bedside care required. Assessing the receipt of this service is important for care planning and resource use for PAC providers.

The proposed data element, Oxygen Therapy, consists of the principal Oxygen Therapy data element and three response option sub-elements: Continuous (whether the oxygen was delivered continuously, typically defined as ≥ 14 hours per day); Intermittent; or High-concentration oxygen delivery system. Based on public comments and input from expert advisors about the importance and clinical usefulness of documenting the extent of oxygen use, we added a third sub-element, high-concentration oxygen delivery system, to the sub-elements, which previously included only intermittent and continuous. If the assessor indicates that the resident is receiving oxygen therapy on the principal oxygen therapy data element, the assessor then would indicate the type of oxygen the patient receives (for example, Continuous, Intermittent, High-concentration oxygen delivery system).

These three proposed sub-elements were developed based on similar data elements that assess oxygen therapy, currently in use in the MDS in SNFs (“Oxygen Therapy”), previously used in the OASIS (“Oxygen (intermittent or continuous)”), and a data element tested in the PAC PRD that focused on intensive oxygen therapy (“High O₂ Concentration Delivery System with FiO₂ > 40 percent”). For more information on the proposed Oxygen Therapy (Continuous, Intermittent, High-concentration oxygen delivery system) data element, we refer readers to the document titled “Proposed Specifications for SNF QRP Quality Measures and Standardized

Patient Assessment Data Elements,” available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

The Oxygen Therapy (Continuous, Intermittent) data element was first proposed as standardized patient assessment data in the FY 2018 SNF PPS proposed rule (82 FR 21065). In that proposed rule, we stated that the proposal was informed by input we received on the single data element, Oxygen (inclusive of intermittent and continuous oxygen use), through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 expressed the importance of the Oxygen data element, noting feasibility of this item in PAC, and the relevance of it to facilitating care coordination and supporting care transitions, but suggesting that the extent of oxygen use be documented. A summary report for the August 12 to September 12, 2016 public comment period titled “SPADE August 2016 Public Comment Summary Report” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

In response to our proposal in the FY 2018 SNF PPS proposed rule, a few commenters supported the adoption of Oxygen Therapy (Continuous, Intermittent) as a standardized patient assessment data element. Another commenter recommended that an option for high-concentration oxygen be added. In response to public comments, we added a third sub-element for “High-Concentration Oxygen Delivery System” to the Oxygen Therapy data element.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the Oxygen Therapy data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Oxygen Therapy data element to be feasible and reliable for use with PAC patients and residents.

More information about the performance of the Oxygen Therapy data element in the National Beta Test can be found in the document titled “Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,” available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

In addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although the TEP did not specifically discuss the Oxygen Therapy data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled “SPADE Technical Expert Panel Summary (Third Convening)” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled “Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute->

Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.

Taking together the importance of assessing oxygen therapy, stakeholder input, and strong test results, we are proposing that the Oxygen Therapy (Continuous, Intermittent, High-concentration Oxygen Delivery System) data element with a principal data element and three sub-elements meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Oxygen Therapy (Continuous, Intermittent, High-concentration Oxygen Delivery System) data element as standardized patient assessment data for use in the SNF QRP.

(4) Respiratory Treatment: Suctioning (Scheduled, As needed)

We are proposing that the Suctioning (Scheduled, As needed) data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21065 through 21066), suctioning is a process used to clear secretions from the airway when a person cannot clear those secretions on his or her own. It is done by aspirating secretions through a catheter connected to a suction source. Types of suctioning include oropharyngeal and nasopharyngeal suctioning, nasotracheal suctioning, and suctioning through an artificial airway such as a tracheostomy tube. Oropharyngeal and nasopharyngeal suctioning are a key part of many patients' care plans, both to prevent the accumulation of secretions than can lead to aspiration pneumonias (a common condition in patients and residents with inadequate gag reflexes), and to relieve obstructions from mucus plugging during an acute or chronic respiratory infection, which often lead to desaturations and increased respiratory effort. Suctioning can be done on a scheduled basis if the patient is judged to clinically benefit from regular interventions, or can be done as needed when secretions become so prominent that gurgling or choking is noted, or a sudden desaturation

occurs from a mucus plug. As suctioning is generally performed by a care provider rather than independently, this intervention can be quite resource intensive if it occurs every hour, for example, rather than once a shift. It also signifies an underlying medical condition that prevents the patient from clearing his/her secretions effectively (such as after a stroke, or during an acute respiratory infection). Generally, suctioning is necessary to ensure that the airway is clear of secretions which can inhibit successful oxygenation of the individual. The intent of suctioning is to maintain a patent airway, the loss of which can lead to death or complications associated with hypoxia.

The Suctioning (Scheduled, As needed) data element consists of a principal data element, and two sub-elements: Scheduled; and As needed. These sub-elements capture two types of suctioning. Scheduled indicates suctioning based on a specific frequency, such as every hour; As needed means suctioning only when indicated. If the assessor indicates that the resident is receiving suctioning on the principal Suctioning data element, the assessor would then indicate the frequency (for example, Scheduled, As needed). The proposed data element is based on an item currently in use in the MDS in SNFs which does not include our proposed two sub-elements, as well as data elements tested in the PAC PRD that focused on the frequency of suctioning required for patients with tracheostomies (“Trach Tube with Suctioning: Specify most intensive frequency of suctioning during stay [Every __ hours]”). We are proposing to expand the existing Suctioning data element on the MDS to include sub-elements for Scheduled and As Needed. For more information on the Suctioning data element, we refer readers to the document titled “Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,” available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

The Suctioning data element was first proposed as standardized patient assessment data in the FY 2018 SNF PPS proposed rule (82 FR 21065 through 21066). In that proposed rule, we stated that the proposal was informed by input we received on the Suctioning data element currently included in the MDS in SNFs through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 expressed support for this data element. The input noted the feasibility of this item in PAC, and the relevance of this data element to facilitating care coordination and supporting care transitions. We also stated that those commenters had suggested that we examine the frequency of suctioning to better understand the use of staff time, the impact on a patient or resident's capacity to speak and swallow, and intensity of care required. Based on these comments, we decided to add two sub-elements (Scheduled and As needed) to the suctioning element. The proposed Suctioning data element includes both the principal Suctioning data element that is included on the MDS in SNFs and two sub-elements, Scheduled and As needed. A summary report for the August 12 to September 12, 2016 public comment period titled "SPADE August 2016 Public Comment Summary Report" is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

In response to our proposal in the FY 2018 SNF PPS proposed rule, two commenters supported the adoption of Suctioning (Scheduled, As needed) as a standardized patient assessment data element. One commenter objected to "scheduled" suctioning as a response option due to a clinical practice guideline recommendation that suctioning should only be performed when clinically indicated and not on a scheduled basis.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the Suctioning data element was included in the National Beta Test of candidate data elements conducted by our data

element contractor from November 2017 to August 2018. Results of this test found the Suctioning data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Suctioning data element in the National Beta Test can be found in the document titled “Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,” available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

In addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although the TEP did not specifically discuss the Suctioning data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled “SPADE Technical Expert Panel Summary (Third Convening)” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-going SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicited additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled “Input on Standardized Patient Assessment Data Elements (SPADEs)

Received After November 27, 2018 Stakeholder Meeting” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

Taking together the importance of assessing for suctioning, stakeholder input, and strong test results, we are proposing that the Suctioning (Scheduled, As needed) data element with a principal data element and two sub-elements meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Suctioning (Scheduled, As needed) data element as standardized patient assessment data for use in the SNF QRP.

(5) Respiratory Treatment: Tracheostomy Care

We are proposing that the Tracheostomy Care data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21066 through 21067), a tracheostomy provides an air passage to help a patient or resident breathe when the usual route for breathing is obstructed or impaired. Generally, in all of these cases, suctioning is necessary to ensure that the tracheostomy is clear of secretions, which can inhibit successful oxygenation of the individual. Often, individuals with tracheostomies are also receiving supplemental oxygenation. The presence of a tracheostomy, albeit permanent or temporary, warrants careful monitoring and immediate intervention if the tracheostomy becomes occluded or if the device used becomes dislodged. While in rare cases the presence of a tracheostomy is not associated with increased care demands (and in some of those instances, the care of the ostomy is performed by the patient) in general the presence of such as device is associated with increased patient risk, and clinical care services will necessarily include close monitoring to ensure that no

life-threatening events occur as a result of the tracheostomy. In addition, tracheostomy care, which primarily consists of cleansing, dressing changes, and replacement of the tracheostomy cannula (tube), is a critical part of the care plan. Regular cleansing is important to prevent infection such as pneumonia, and to prevent any occlusions with which there are risks for inadequate oxygenation.

The proposed data element consists of the single Tracheostomy Care data element. The proposed data element is currently in use in the MDS in SNFs (“Tracheostomy care”). For more information on the Tracheostomy Care data element, we refer readers to the document titled “Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,” available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

The Tracheostomy Care data element was first proposed as standardized patient assessment data in the FY 2018 SNF PPS proposed rule (82 FR 21066 through 21067). In that proposed rule, we stated that the proposal was informed by input we received on the Tracheostomy Care data element through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016, supported this data element, noting the feasibility of this item in PAC, and the relevance of this data element to facilitating care coordination and supporting care transitions. A summary report for the August 12 to September 12, 2016 public comment period titled “SPADE August 2016 Public Comment Summary Report” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

In response to our proposal in the FY 2018 SNF PPS proposed rule, we received a few

comments in support of the adoption of Tracheostomy Care as a standardized patient assessment data element.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the Tracheostomy Care data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Tracheostomy Care data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Tracheostomy Care data element in the National Beta Test can be found in the document titled “Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,” available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

In addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although the TEP did not specifically discuss the Tracheostomy Care data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled “SPADE Technical Expert Panel Summary (Third Convening)” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and

solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled “Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

Taking together the importance of assessing for tracheostomy care, stakeholder input, and strong test results, we are proposing that the Tracheostomy Care data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Tracheostomy Care data element as standardized patient assessment data for use in the SNF QRP.

(6) Respiratory Treatment: Non-invasive Mechanical Ventilator (BiPAP, CPAP)

We are proposing that the Non-invasive Mechanical Ventilator (Bilevel Positive Airway Pressure [BiPAP], Continuous Positive Airway Pressure [CPAP]) data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21067), BiPAP and CPAP are respiratory support devices that prevent the airways from closing by delivering slightly pressurized air via electronic cycling throughout the breathing cycle (BiPAP) or through a mask continuously (CPAP). Assessment of non-invasive mechanical ventilation is important in care planning, as both CPAP and BiPAP are resource-intensive (although less so than invasive mechanical ventilation) and signify underlying medical conditions about the patient or resident who requires the use of this intervention. Particularly when used in settings of acute illness or

progressive respiratory decline, additional staff (for example, respiratory therapists) are required to monitor and adjust the CPAP and BiPAP settings and the patient or resident may require more nursing resources.

The proposed data element, Non-invasive Mechanical Ventilator (BiPAP, CPAP), consists of the principal Non-invasive Mechanical Ventilator data element and two response option sub-elements: BiPAP and CPAP. If the assessor indicates that the resident is receiving non-invasive mechanical ventilation on the principal Non-invasive Mechanical Ventilator data element, the assessor would then indicate which type (for example, BiPAP, CPAP). Data elements that assess non-invasive mechanical ventilation are currently included on LCDS for the LTCH setting (“Non-invasive Ventilator (BiPAP, CPAP)”), and the MDS for the SNF setting (“Non-invasive Mechanical Ventilator (BiPAP/CPAP)”). We are proposing to expand the existing BiPAP/CPAP data element on the MDS, retaining and relabeling the BiPAP/CPAP data element to be Non-invasive Mechanical Ventilator (BiPAP, CPAP), and adding two sub-elements for BiPAP and CPAP. For more information on the Non-invasive Mechanical Ventilator (BiPAP, CPAP) data element, we refer readers to the document titled “Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,” available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

The Non-invasive Mechanical Ventilator data element was first proposed as standardized patient assessment data elements in the FY 2018 SNF PPS proposed rule (82 FR 21067). In that proposed rule, we stated that the proposal was informed by input we received through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 on a single data element, BiPAP/CPAP, that captures

equivalent clinical information but uses a different label than the data element currently used in the MDS in SNFs and LCDS in LTCHs, expressed support for this data element, noting the feasibility of these items in PAC, and the relevance of this data element for facilitating care coordination and supporting care transitions. In addition, we also stated that some commenters supported separating out BiPAP and CPAP as distinct sub-elements, as they are therapies used for different types of patients and residents. A summary report for the August 12 to September 12, 2016 public comment period titled “SPADE August 2016 Public Comment Summary Report” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

In response to our proposal in the FY 2018 SNF PPS proposed rule, two commenters supported the adoption of Non-Invasive Mechanical Ventilator (BiPAP, CPAP) as a standardized patient assessment data element.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the Non-invasive Mechanical Ventilator data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Non-invasive Mechanical Ventilator data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Non-invasive Mechanical Ventilator data element in the National Beta Test can be found in the document titled “Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,” available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

In addition, our data element contractor convened a TEP on September 17, 2018, for the

purpose of soliciting input on the proposed standardized patient assessment data elements.

Although the TEP did not specifically discuss the Non-invasive Mechanical Ventilator data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled “SPADE Technical Expert Panel Summary (Third Convening)” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled “Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

Taking together the importance of assessing for non-invasive mechanical ventilation, stakeholder input, and strong test results, we are proposing that the Non-invasive Mechanical Ventilator (BiPAP, CPAP) data element with a principal data element and two sub-elements meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Non-

invasive Mechanical Ventilator (BiPAP, CPAP) data element as standardized patient assessment data for use in the SNF QRP.

(7) Respiratory Treatment: Invasive Mechanical Ventilator

We are proposing that the Invasive Mechanical Ventilator data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21067 through 21068), invasive mechanical ventilation includes ventilators and respirators that ventilate the patient through a tube that extends via the oral airway into the pulmonary region or through a surgical opening directly into the trachea. Thus, assessment of invasive mechanical ventilation is important in care planning and risk mitigation. Ventilation in this manner is a resource-intensive therapy associated with life-threatening conditions without which the patient or resident would not survive. However, ventilator use has inherent risks requiring close monitoring. Failure to adequately care for the patient or resident who is ventilator dependent can lead to iatrogenic events such as death, pneumonia, and sepsis. Mechanical ventilation further signifies the complexity of the patient's underlying medical or surgical condition. Of note, invasive mechanical ventilation is associated with high daily and aggregate costs.⁹¹

The proposed data element, Invasive Mechanical Ventilator, consists of a single data element. Data elements that capture invasive mechanical ventilation are currently in use in the MDS in SNFs and LCDS in LTCHs. The MDS currently assesses invasive mechanical ventilation with the Ventilator or Respirator data element. We are proposing to rename this data

91 Wunsch, H., Linde-Zwirble, W. T., Angus, D. C., Hartman, M. E., Milbrandt, E. B., & Kahn, J. M. (2010). "The epidemiology of mechanical ventilation use in the United States." *Critical Care Med* 38(10): 1947-1953.

element in the MDS to be Invasive Mechanical Ventilator. For more information on the Invasive Mechanical Ventilator data element, we refer readers to the document titled “Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,” available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

The Invasive Mechanical Ventilator data element was first proposed as standardized patient assessment data in the FY 2018 SNF PPS proposed rule (82 FR 21067 through 21068). In that proposed rule, we stated that the proposal was informed by input we received through a call for input published on the CMS Measures Management System Blueprint website on data elements that assess invasive ventilator use and weaning status that were tested in the PAC PRD (“Ventilator – Weaning” and “Ventilator – Non-Weaning”). Input submitted from August 12 to September 12, 2016 expressed support for this data element, highlighting the importance of this information in supporting care coordination and care transitions. We also stated that some commenters had expressed concern about the appropriateness for standardization given: the prevalence of ventilator weaning across PAC providers; the timing of administration; how weaning is defined; and how weaning status in particular relates to quality of care. These public comments guided our decision to propose a single data element focused on current use of invasive mechanical ventilation only, which does not attempt to capture weaning status. A summary report for the August 12 to September 12, 2016 public comment period titled “SPADE August 2016 Public Comment Summary Report” we received is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

In response to our proposal in the FY 2018 SNF PPS proposed rule, a few commenters

supported the adoption of Invasive Mechanical Ventilator as a standardized patient assessment data element. One commenter stated that a data element to indicate “weaning” is important because it indicates higher resource utilization.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the Invasive Mechanical Ventilator data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Invasive Mechanical Ventilator data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Invasive Mechanical Ventilator data element in the National Beta Test can be found in the document titled “Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,” available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

In addition, our data element contractor convened a TEP on September 17, 2018, for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although the TEP did not specifically discuss the Invasive Mechanical Ventilator data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled “SPADE Technical Expert Panel Summary (Third Convening)” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-

going SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled “Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

Taking together the importance of assessing for invasive mechanical ventilation, stakeholder input, and strong test results, we are proposing that the Invasive Mechanical Ventilator data element that assesses the use of an invasive mechanical ventilator meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Invasive Mechanical Ventilator data element as standardized patient assessment data for use in the SNF QRP.

(8) Intravenous (IV) Medications (Antibiotics, Anticoagulants, Vasoactive Medications, Other)

We are proposing that the IV Medications (Antibiotics, Anticoagulants, Vasoactive Medications, Other) data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21068 through 21069), when we proposed a similar data element related to IV medications, IV medications are solutions

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

The clinical indications for each of the sub-elements of the IV Medications data element (Antibiotics, Anticoagulants, Vasoactive Medications, and Other) are very different. IV antibiotics are used for severe infections when the bioavailability of the oral form of the medication would be inadequate to kill the pathogen or an oral form of the medication does not exist. IV anticoagulants refer to anti-clotting medications (that is, “blood thinners”). IV anticoagulants are commonly used for hospitalized patients who have deep venous thrombosis, pulmonary embolism, or myocardial infarction, as well as those undergoing interventional cardiac procedures. Vasoactive medications refer to the IV administration of vasoactive drugs, including vasopressors, vasodilators, and continuous medication for pulmonary edema, which increase or decrease blood pressure or heart rate. The indications, risks, and benefits of each of these classes of IV medications are distinct, making it important to assess each separately in PAC. Knowing whether or not patients and residents are receiving IV medication and the type of medication provided by each PAC provider will improve quality of care.

The IV Medications (Antibiotics, Anticoagulants, Vasoactive Medications, and Other) data element we are proposing consists of a principal data element (IV Medications) and four response option sub-elements: Antibiotics, Anticoagulants, Vasoactive Medications, and Other. The Vasoactive Medications sub-element was not proposed in the FY 2018 SNF PPS proposed rule. We added the Vasoactive Medications sub-element to our proposal in order to harmonize the proposed IV Medications element with the data currently collected in the LCDS.

If the assessor indicates that the resident is receiving IV medications on the principal IV Medications data element, the assessor would then indicate which types of medications (for example, Antibiotics, Anticoagulants, Vasoactive Medications, Other). An IV Medications data element is currently in use on the MDS in SNFs and there is a related data element in OASIS that collects information on Intravenous and Infusion Therapies. We are proposing to expand the existing IV Medications data element in the MDS to include sub-elements for Antibiotics, Anticoagulants, Vasoactive Medications, and Other. For more information on the IV Medications (Antibiotics, Anticoagulants, Vasoactive Medications, Other) data element, we refer readers to the document titled “Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,” available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

An IV Medications data element was first proposed as SPADEs in the FY 2018 SNF PPS proposed rule (82 FR 21068 through 21069). In that proposed rule, we stated that the proposal was informed by input we received on Vasoactive Medications through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 supported this data element with one noting the importance of this data element in supporting care transitions. We also stated that those commenters had criticized the need for collecting specifically Vasoactive Medications, giving feedback that the data element was too narrowly focused. In addition, public comment received indicated that the clinical significance of vasoactive medications administration alone was not high enough in PAC to merit mandated assessment, noting that related and more useful information could be captured in an item that assessed all IV medication use. A summary report for the August 12 to September 12, 2016 public comment period titled “SPADE August 2016 Public Comment Summary

Report” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

In response to our proposal in the FY 2018 SNF PPS proposed rule, two commenters supported the adoption of Intravenous (IV) Medications (Antibiotics, Anticoagulation, Other) as a standardized patient assessment data element.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the IV Medications data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the IV Medications data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the IV Medications data element in the National Beta Test can be found in the document titled “Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,” available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

In addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although the TEP did not specifically discuss the IV Medications data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled “SPADE Technical Expert Panel Summary (Third Convening)” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled “Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

Taking together the importance of assessing for IV medications, stakeholder input, and strong test results, we are proposing that the IV Medications (Antibiotics, Anticoagulants, Vasoactive Medications, Other) data element with a principal data element and four sub-elements meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the IV Medications (Antibiotics, Anticoagulants, Vasoactive Medications, Other) data element as standardized patient assessment data for use in the SNF QRP.

(9) Transfusions

We are proposing that the Transfusions data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21069), transfusion refers to introducing blood or blood products into the circulatory system of a person. Blood transfusions

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

The proposed data element consists of the single Transfusions data element. A data element on transfusion is currently in use in the MDS in SNFs ("Transfusions") and a data element tested in the PAC PRD ("Blood Transfusions") was found feasible for use in each of the four PAC settings. For more information on the Transfusions data element, we refer readers to the document titled "Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements," available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

In response to our proposal in the FY 2018 SNF PPS proposed rule, two commenters supported the adoption of Transfusions as a standardized patient assessment data element.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the Transfusions data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Transfusions data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Transfusions data element in the National Beta Test can be found in the document titled "Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements," available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute->

Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.

In addition, our data element contractor convened a TEP on September 17, 2018, for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although the TEP did not specifically discuss the Transfusions data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled “SPADE Technical Expert Panel Summary (Third Convening)” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled “Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

Taking together the importance of assessing for transfusions, stakeholder input, and strong test results, we are proposing that the Transfusions data element meets the definition of standardized patient assessment data with respect to special services, treatments, and

interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Transfusions data element as standardized patient assessment data for use in the SNF QRP.

(10) Dialysis (Hemodialysis, Peritoneal dialysis)

We are proposing that the Dialysis (Hemodialysis, Peritoneal dialysis) data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21070), dialysis is a treatment primarily used to provide replacement for lost kidney function. Both forms of dialysis (hemodialysis and peritoneal dialysis) are resource intensive, not only during the actual dialysis process but before, during, and following. Patients and residents who need and undergo dialysis procedures are at high risk for physiologic and hemodynamic instability from fluid shifts and electrolyte disturbances, as well as infections that can lead to sepsis. Further, patients or residents receiving hemodialysis are often transported to a different facility, or at a minimum, to a different location in the same facility for treatment. Close monitoring for fluid shifts, blood pressure abnormalities, and other adverse effects is required prior to, during, and following each dialysis session. Nursing staff typically perform peritoneal dialysis at the bedside, and as with hemodialysis, close monitoring is required.

The proposed data element, Dialysis (Hemodialysis, Peritoneal dialysis) consists of the principal Dialysis data element and two response option sub-elements: Hemodialysis and Peritoneal dialysis. If the assessor indicates that the resident is receiving dialysis on the principal Dialysis data element, the assessor would then indicate which type (Hemodialysis or Peritoneal dialysis). Dialysis data elements are currently included on the MDS in SNFs and the LCDS in LTCHs and assess the overall use of dialysis. We are proposing to expand the existing Dialysis data element in the MDS to include sub-elements for Hemodialysis and Peritoneal dialysis.

As the result of public feedback described below, in this proposed rule, we are proposing a data element that includes the principal Dialysis data element and two sub-elements (Hemodialysis and Peritoneal dialysis). For more information on the Dialysis data elements, we refer readers to the document titled “Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,” available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

The Dialysis data element was first proposed as standardized patient assessment data in the FY 2018 SNF PPS proposed rule (82 FR 21070). In that proposed rule, we stated that the proposal was informed by input we received on a singular Hemodialysis data element through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 supported the assessment of hemodialysis and recommended that the data element be expanded to include peritoneal dialysis. We also stated that those commenters had supported the singular Hemodialysis data element, noting the relevance of this information for sharing across the care continuum to facilitate care coordination and care transitions, the potential for this data element to be used to improve quality, and the feasibility for use in PAC. In addition, we received comment that the item would be useful in improving patient and resident transitions of care. We also noted that several commenters had stated that peritoneal dialysis should be included in a standardized data element on dialysis and recommended collecting information on peritoneal dialysis in addition to hemodialysis. The rationale for including peritoneal dialysis from commenters included the fact that patients and residents receiving peritoneal dialysis will have different needs at post-acute discharge compared to those receiving hemodialysis or not having any dialysis. Based on these comments, the Hemodialysis data element was expanded to include a principal Dialysis data element and two

sub-elements, Hemodialysis and Peritoneal dialysis. We are proposing the version of the Dialysis element that includes two types of dialysis. A summary report for the August 12 to September 12, 2016 public comment period titled “SPADE August 2016 Public Comment Summary Report” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

In response to our proposal in the FY 2018 SNF PPS proposed rule, two commenters supported the adoption of Dialysis (Hemodialysis, Peritoneal dialysis) as a standardized patient assessment data element.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the Dialysis data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Dialysis data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Dialysis data element in the National Beta Test can be found in the document titled “Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,” available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

In addition, our data element contractor convened a TEP on September 17, 2018, for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although they did not specifically discuss the Dialysis data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled “SPADE Technical Expert Panel Summary (Third Convening)” is available at

<https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-going SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled “Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

Taking together the importance of assessing for dialysis, stakeholder input, and strong test results, we are proposing that the Dialysis (Hemodialysis, Peritoneal dialysis) data element with a principal data element and two sub-elements meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Dialysis (Hemodialysis, Peritoneal dialysis) data element as standardized patient assessment data for use in the SNF QRP.

(11) Intravenous (IV) Access (Peripheral IV, Midline, Central line)

We are proposing that the IV Access (Peripheral IV, Midline, Central line) data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21070 through 21071),

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

The proposed data element, IV Access (Peripheral IV, Midline, Central line), consists of the principal IV Access data element and three response option sub-elements: Peripheral IV, Midline, and Central line. The proposed IV Access data element is not currently included on any of the PAC assessment instruments. For more information on the IV Access (Peripheral IV, Midline, Central line) data element, we refer readers to the document titled “Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,” available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

The IV Access data element was first proposed as standardized patient assessment data in the FY 2018 SNF PPS proposed rule (82 FR 21070 through 21071). In that proposed rule, we stated that the proposal was informed by input we received on one of the PAC PRD data elements, Central Line Management, a type of IV access, through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 supported the assessment of central line management and recommended that

the data element be broadened to also include other types of IV access. Several commenters noted feasibility and importance of facilitating care coordination and care transitions. However, a few commenters recommended that the definition of this data element be broadened to include peripherally inserted central catheters (“PICC lines”) and midline IVs. Based on public comment feedback and in consultation with expert input, described below, we created an overarching IV Access data element with sub-elements for other types of IV access in addition to central lines (that is, peripheral IV and midline). This expanded version of IV Access is the data element being proposed. A summary report for the August 12 to September 12, 2016 public comment period titled “SPADE August 2016 Public Comment Summary Report” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

In response to our proposal in the FY 2018 SNF PPS proposed rule, two commenters supported the adoption of the IV Access (Peripheral IV, Midline, Central line, Other) as a standardized patient assessment data element, with one commenter encouraging clear guidance in the Resident Assessment Instrument User Manual to distinguish between coding instructions for this data element and those for other data elements on IV treatments.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the IV Access data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the IV Access data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the IV Access data element in the National Beta Test can be found in the document titled “Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,” available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute->

Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.

In addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although the TEP did not specifically discuss the IV Access data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled “SPADE Technical Expert Panel Summary (Third Convening)” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-going SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled “Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

Taking together the importance of assessing for IV access, stakeholder input, and strong test results, we are proposing that the IV access (Peripheral IV, Midline, Central line) data element with a principal data element and three sub-elements meets the definition of standardized patient assessment data with respect to special services, treatments, and

interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the IV Access (Peripheral IV, Midline, Central line) data element as standardized patient assessment data for use in the SNF QRP.

(12) Nutritional Approach: Parenteral/IV Feeding

We are proposing that the Parenteral/IV Feeding data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21071 through 21072), parenteral nutrition/IV feeding refers to a patient or resident being fed intravenously using an infusion pump, bypassing the usual process of eating and digestion. The need for IV/parenteral feeding indicates a clinical complexity that prevents the patient or resident from meeting his or her nutritional needs enterally, and is more resource intensive than other forms of nutrition, as it often requires monitoring of blood chemistries and the maintenance of a central line. Therefore, assessing a patient's or resident's need for parenteral feeding is important for care planning and resource use. In addition to the risks associated with central and peripheral intravenous access, total parenteral nutrition is associated with significant risks such as air embolism and sepsis.

The proposed data element consists of the single Parenteral/IV Feeding data element. The proposed Parenteral/IV Feeding data element is currently in use in the MDS in SNFs, and equivalent or related data elements are in use in the LCDS, IRF-PAI, and OASIS. For more information on the Parenteral/IV Feeding data element, we refer readers to the document titled "Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements," available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

The Parenteral/IV Feeding data element was first proposed as a SPADE in the FY 2018 SNF PPS proposed rule (82 FR 21071 through 21072). In that proposed rule, we stated that the proposal was informed by input we received on Total Parenteral Nutrition (an item with nearly the same meaning as the proposed data element, but with the label used in the PAC PRD) through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 supported this data element, noting its relevance to facilitating care coordination and supporting care transitions. After the public comment period, the Total Parenteral Nutrition data element was renamed Parenteral/IV Feeding, to be consistent with how this data element is referred to in the MDS in SNFs. A summary report for the August 12 to September 12, 2016 public comment period titled “SPADE August 2016 Public Comment Summary Report” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

In response to our proposal in the FY 2018 SNF PPS proposed rule, two commenters supported the adoption of the Parenteral/IV Feeding as a standardized patient assessment data element, with one requesting “universal” guidance for coding, which would be clearly defined and more broadly applicable to patients and residents in all PAC settings.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the Parenteral/IV Feeding data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Parenteral/IV Feeding data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Parenteral/IV Feeding data element in the National Beta Test can be found in the document titled “Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data

Elements,” available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

In addition, our data element contractor convened a TEP on September 17, 2018, for the purpose of soliciting input on the proposed standardized patient assessment data elements.

Although the TEP did not specifically discuss the Parenteral/IV Feeding data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled “SPADE Technical Expert Panel Summary (Third Convening)” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled “Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

Taking together the importance of assessing for parenteral/IV feeding, stakeholder input,

and strong test results, we are proposing that the Parenteral/IV Feeding data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Parenteral/IV Feeding data element as standardized patient assessment data for use in the SNF QRP.

(13) Nutritional Approach: Feeding Tube

We are proposing that the Feeding Tube data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21072), the majority of patients admitted to acute care hospitals experience deterioration of their nutritional status during their hospital stay, making assessment of nutritional status and method of feeding if unable to eat orally very important in PAC. A feeding tube can be inserted through the nose or the skin on the abdomen to deliver liquid nutrition into the stomach or small intestine. Feeding tubes are resource intensive and, therefore, are important to assess for care planning and resource use. Patients with severe malnutrition are at higher risk for a variety of complications.⁹² In PAC settings, there are a variety of reasons that patients and residents may not be able to eat orally (including clinical or cognitive status).

The proposed data element consists of the single Feeding Tube data element. The Feeding Tube data element is currently included in the MDS for SNFs, and in the OASIS for HHAs, where it is labeled Enteral Nutrition. A related data element, collected in the IRF-PAI for IRFs (“Tube/Parenteral Feeding”), assesses use of both feeding tubes and parenteral nutrition.

⁹² Dempsey, D. T., Mullen, J. L., & Buzby, G. P. (1988). “The link between nutritional status and clinical outcome: can nutritional intervention modify it?” *Am J of Clinical Nutrition*, 47(2): 352-356.

For more information on the Feeding Tube data element, we refer readers to the document titled “Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,” available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

The Feeding Tube data element was first proposed as a SPADE in the FY 2018 SNF PPS proposed rule (82 FR 21072). In that proposed rule, we stated that the proposal was informed by input we received through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 on an Enteral Nutrition data element (the Enteral Nutrition data item is the same as the data element we are proposing in this proposed rule, but is used in the OASIS under a different name) supported the data element, noting the importance of assessing enteral nutrition status for facilitating care coordination and care transitions. After the public comment period, the Enteral Nutrition data element used in public comment was renamed Feeding Tube, indicating the presence of an assistive device. A summary report for the August 12 to September 12, 2016 public comment period titled “SPADE August 2016 Public Comment Summary Report” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

In response to our proposal in the FY 2018 SNF PPS proposed rule, two commenters supported the adoption of the Feeding Tube as a standardized patient assessment data element. Another commenter recommended that the term “enteral feeding” be used instead of “feeding tube.”

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the Feeding Tube data element was included in the National Beta Test of candidate data elements conducted by our data

element contractor from November 2017 to August 2018. Results of this test found the Feeding Tube data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Feeding Tube data element in the National Beta Test can be found in the document titled “Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,” available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

In addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although the TEP did not specifically discuss the Feeding Tube data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled “SPADE Technical Expert Panel Summary (Third Convening)” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled “Input on Standardized Patient Assessment Data Elements (SPADEs)

Received After November 27, 2018 Stakeholder Meeting” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

Taking together the importance of assessing for feeding tubes, stakeholder input, and strong test results, we are proposing that the Feeding Tube data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Feeding Tube data element as standardized patient assessment data for use in the SNF QRP.

(14) Nutritional Approach: Mechanically Altered Diet

We are proposing that the Mechanically Altered Diet data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21072 through 21073), the Mechanically Altered Diet data element refers to food that has been altered to make it easier for the patient or resident to chew and swallow, and this type of diet is used for patients and residents who have difficulty performing these functions. Patients with severe malnutrition are at higher risk for a variety of complications.⁹³

In PAC settings, there are a variety of reasons that patients and residents may have impairments related to oral feedings, including clinical or cognitive status. The provision of a mechanically altered diet may be resource intensive, and can signal difficulties associated with swallowing/eating safety, including dysphagia. In other cases, it signifies the type of altered

93 Dempsey, D. T., Mullen, J. L., & Buzby, G. P. (1988). “The link between nutritional status and clinical outcome: can nutritional intervention modify it?” *Am J of Clinical Nutrition*, 47(2): 352-356.

food source, such as ground or puree that will enable the safe and thorough ingestion of nutritional substances and ensure safe and adequate delivery of nourishment to the patient. Often, patients and residents on mechanically altered diets also require additional nursing supports, such as individual feeding or direct observation, to ensure the safe consumption of the food product. Assessing whether a patient or resident requires a mechanically altered diet is therefore important for care planning and resource identification.

The proposed data element consists of the single Mechanically Altered Diet data element. The proposed data element is currently included on the MDS for SNFs. A related data element (“Modified food consistency/supervision”) is currently included on the IRF-PAI for IRFs. Another related data element is included in the OASIS for HHAs that collects information about independent eating that requires “a liquid, pureed or ground meat diet.” For more information on the Mechanically Altered Diet data element, we refer readers to the document titled “Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,” available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

The Mechanically Altered Diet data element was first proposed as standardized patient assessment data in the FY 2018 SNF PPS proposed rule (82 FR 21072 through 21073).

In response to our proposal in the FY 2018 SNF PPS proposed rule, two commenters supported the adoption of the Mechanically Altered Diet as a standardized patient assessment data element, with one requesting “universal” guidance for coding, which would be clearly defined and more broadly applicable to patients and residents in all PAC settings.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the Mechanically Altered Diet data element was included in the National Beta Test of candidate data elements

conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Mechanically Altered Diet data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Mechanically Altered Diet data element in the National Beta Test can be found in the document titled “Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,” available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

In addition, our data element contractor convened a TEP on September 17, 2018, for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although the TEP did not specifically discuss the Mechanically Altered Diet data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled “SPADE Technical Expert Panel Summary (Third Convening)” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018

stakeholder meeting titled “Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

Taking together the importance of assessing for mechanically altered diet, stakeholder input, and strong test results, we are proposing that the Mechanically Altered Diet data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Mechanically Altered Diet data element as standardized patient assessment data for use in the SNF QRP.

(15) Nutritional Approach: Therapeutic Diet

We are proposing that the Therapeutic Diet data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21073), a therapeutic diet refers to meals planned to increase, decrease, or eliminate specific foods or nutrients in a patient’s or resident’s diet, such as a low-salt diet, for the purpose of treating a medical condition. The use of therapeutic diets among patients and residents in PAC provides insight on the clinical complexity of these patients and residents and their multiple comorbidities. Therapeutic diets are less resource intensive from the bedside nursing perspective, but do signify one or more underlying clinical conditions that preclude the patient from eating a regular diet. The communication among PAC providers about whether a patient is receiving a particular therapeutic diet is critical to ensure safe transitions of care.

The proposed data element consists of the single Therapeutic Diet data element. This data element is currently in use in the MDS in SNFs. For more information on the Therapeutic Diet data element, we refer readers to the document titled “Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,” available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

The Therapeutic Diet data element was first proposed as standardized patient assessment data in the FY 2018 SNF PPS proposed rule (82 FR 21073). In response to our proposal in the FY 2018 SNF PPS proposed rule, commenters supported the adoption of the Therapeutic Diet as a standardized patient assessment data element. Two commenters stated that the coding instructions should be clear and more broadly applicable to patients and residents in all PAC settings. Another two commenters suggested that the definition of Therapeutic Diet should be aligned with the Academy of Nutrition and Dietetics’ definition, with one stating that “medically altered diet” should be added to the nutritional data elements.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the Therapeutic Diet data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Therapeutic Diet data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Therapeutic Diet data element in the National Beta Test can be found in the document titled “Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,” available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

In addition, our data element contractor convened a TEP on September 17, 2018, for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although the TEP did not specifically discuss the Therapeutic Diet data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled “SPADE Technical Expert Panel Summary (Third Convening)” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-going SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled “Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

Taking together the importance of assessing for therapeutic diet, stakeholder input, and strong test results, we are proposing that the Therapeutic Diet data element meets the definition of standardized patient assessment data with respect to special services, treatments, and

interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Therapeutic data element as standardized patient assessment data for use in the SNF QRP.

(16) High Risk Drug Classes: Use and Indication

We are proposing that the High-Risk Drug Classes: Use and Indication data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

Most patients and residents receiving PAC services depend on short- and long-term medications to manage their medical conditions. However, as a treatment, medications are not without risk; medications are in fact a leading cause of adverse events. A study by the U.S. Department of Health and Human Services found that 31 percent of adverse events that occurred in 2008 among hospitalized Medicare beneficiaries were related to medication.⁹⁴ Moreover, changes in a patient's condition, medications, and transitions between care settings put patients and residents at risk of medication errors and adverse drug events (ADEs). ADEs may be caused by medication errors such as drug omissions, errors in dosage, and errors in dosing frequency.⁹⁵

ADEs are known to occur across different types of healthcare settings. For example, the incidence of ADEs in the outpatient setting has been estimated at 1.15 ADEs per 100 person-months,⁹⁶ while the rate of ADEs in the long-term care setting is approximately 9.80 ADEs per 100 resident-months.⁹⁷ In the hospital setting, the incidence has been estimated at 15 ADEs per

94 U.S. Department of Health and Human Services. Office of Inspector General. Daniel R. Levinson. Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries. OEI-06-09-00090. November 2010.

95 Boockvar KS, Liu S, Goldstein N, Nebeker J, Siu A, Fried T. Prescribing discrepancies likely to cause adverse drug events after patient transfer. *Qual Saf Health Care*. 2009;18(1):32–6.

96 Gandhi TK, Seger AC, Overhage JM, et al. Outpatient adverse drug events identified by screening electronic health records. *J Patient Saf* 2010;6:91–6. doi:10.1097/PTS.0b013e3181dcae06.

97 Gurwitz JH, Field TS, Judge J, Rochon P, Harrold LR, Cadoret C, et al. The incidence of adverse drug events in two large academic long-term care facilities. *Am J Med*. 2005; 118(3):251±8. Epub 2005/03/05.

<https://doi.org/10.1016/j.amjmed.2004.09.018> PMID: 15745723.

100 admissions.⁹⁸ In addition, approximately half of all hospital-related medication errors and 20 percent of ADEs occur during transitions within, admission to, transfer to, or discharge from a hospital.^{99,100,101} ADEs are more common among older adults, who make up most patients receiving PAC services. The rate of emergency department visits for ADEs is three times higher among adults 65 years of age and older compared to that among those younger than age 65.¹⁰²

Understanding the types of medication a patient is taking and the reason for its use are key facets of a patient's treatment with respect to medication. Some classes of drugs are associated with more risk than others.¹⁰³ We are proposing one High-Risk Drug Class data element with six sub-elements. The six medication classes response options are: anticoagulants; antiplatelets; hypoglycemics (including insulin); opioids; antipsychotics; and antibiotics. These drug classes are high-risk due to the adverse effects that may result from use. In particular: bleeding risk is associated with anticoagulants and antiplatelets;^{104,105} fluid retention, heart failure, and lactic acidosis are associated with hypoglycemics;¹⁰⁶ misuse is associated with

98 Hug BL, Witkowski DJ, Sox CM, Keohane CA, Seger DL, Yoon C, Matheny ME, Bates DW. Occurrence of adverse, often preventable, events in community hospitals involving nephrotoxic drugs or those excreted by the kidney. *Kidney Int.* 2009; 76:1192–1198. [PubMed: 19759525].

99 Barnsteiner JH. Medication reconciliation: transfer of medication information across settings-keeping it free from error. *J Infus Nurs.* 2005;28(2 Suppl):31-36.

100 Rozich J, Roger, R. Medication safety: one organization's approach to the challenge. *Journal of Clinical Outcomes Management.* 2001(8):27-34.

101 Gleason KM, Groszek JM, Sullivan C, Rooney D, Barnard C, Noskin GA. Reconciliation of discrepancies in medication histories and admission orders of newly hospitalized patients. *Am J Health Syst Pharm.* 2004;61(16):1689-1695

102 Shehab N, Lovegrove MC, Geller AI, Rose KO, Weidle NJ, Budnitz DS. US emergency department visits for outpatient adverse drug events, 2013–2014. *JAMA.* doi: 10.1001/jama.2016.16201.

103 Ibid.

104 Shoeb M, Fang MC. Assessing bleeding risk in patients taking anticoagulants. *J Thromb Thrombolysis.* 2013;35(3):312–319. doi: 10.1007/s11239-013-0899-7.

105 Melkonian M, Jarzebowski W, Pautas E. Bleeding risk of antiplatelet drugs compared with oral anticoagulants in older patients with atrial fibrillation: a systematic review and meta-analysis. *J Thromb Haemost.* 2017;15:1500–1510. DOI: 10.1111/jth.13697.

106 Hamnvik OP, McMahon GT. Balancing Risk and Benefit with Oral Hypoglycemic Drugs. *The Mount Sinai journal of medicine, New York.* 2009; 76:234–243.

opioids;¹⁰⁷ fractures and strokes are associated with antipsychotics;^{108,109} and various adverse events, such as central nervous systems effects and gastrointestinal intolerance, are associated with antimicrobials,¹¹⁰ the larger category of medications that include antibiotics. Moreover, some medications in five of the six drug classes included in this data element are included in the 2019 Updated Beers Criteria[®] list as potentially inappropriate medications for use in older adults.¹¹¹ Finally, although a complete medication list should record several important attributes of each medication (for example, dosage, route, stop date), recording an indication for the drug is of crucial importance.¹¹²

The High-Risk Drug Classes: Use and Indication data element requires an assessor to record whether or not a resident is taking any medications within the six drug classes. The six response options for this data element are high-risk drug classes with particular relevance to PAC patients and residents, as identified by our data element contractor. The six response options are Anticoagulants, Antiplatelets, Hypoglycemics, Opioids, Antipsychotics, and Antibiotics. For each drug class, the assessor is asked to indicate if the resident is taking any medications within the class, and, for drug classes in which medications were being taken, whether indications for all drugs in the class are noted in the medical record. For example, for the response option Anticoagulants, if the assessor indicates that the resident is taking anticoagulant medication, the

107 Naples JG, Gellad WF, Hanlon JT. The Role of Opioid Analgesics in Geriatric Pain Management. *Clin Geriatr Med.* 2016;32 (4):725-735.

108 Rigler SK, Shireman TI, Cook-Wiens GJ, Ellerbeck EF, Whittle JC, Mehr DR, Mahnken JD. Fracture risk in nursing home residents initiating antipsychotic medications. *J Am Geriatr Soc.* 2013; 61(5):715–722. [PubMed: 23590366].

109 Wang S, Linkletter C, Dore D et al. Age, antipsychotics, and the risk of ischemic stroke in the Veterans Health Administration. *Stroke* 2012;43:28–31. doi:10.1161/STROKEAHA.111.617191.

110 Faulkner CM, Cox HL, Williamson JC. Unique aspects of antimicrobial use in older adults. *Clin Infect Dis.* 2005;40(7):997–1004.

111 American Geriatrics Society 2019 Beers Criteria Update Expert Panel. American Geriatrics Society 2019 Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. *J Am Geriatr Soc* 2019; 00:1–21. DOI: 10.1111/jgs.15767.

112 Li Y, Salmasian H, Harpaz R, Chase H, Friedman C. Determining the reasons for medication prescriptions in the EHR using knowledge and natural language processing. AMIA Annu Symp Proc. 2011;2011: 768-76.

assessor would then indicate if an indication is recorded in the medication record for the anticoagulant(s).

The High-Risk Drug Classes: Use and Indication data element that is being proposed as a SPADE was developed as part of a larger set of data elements to assess medication reconciliation, the process of obtaining a patient's multiple medication lists and reconciling any discrepancies. Similar data elements on some high-risk medications are already included in the MDS. We are proposing to modify and expand existing data elements in the MDS to include additional high-risk drug classes and indications for all drug classes. For more information on the High-Risk Drug Classes: Use and Indication data element, we refer readers to the document titled "Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements," available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

We sought public input on the relevance of conducting assessments on medication reconciliation and specifically on the proposed High-Risk Drug Classes: Use and Indication data element. Our data element contractor presented data elements related to medication reconciliation to the TEP convened on April 6 and 7, 2016. The TEP supported a focus on high-risk drugs, because of higher potential for harm to patients and residents, and were in favor of a data element to capture whether or not indications for medications were recorded in the medical record. A summary of the April 6 and 7, 2016 TEP meeting titled "SPADE Technical Expert Panel Summary (First Convening)" is available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>. Medication reconciliation data elements were also discussed at a second TEP meeting on January 5 and 6, 2017, convened by our data

element contractor. At this meeting, the TEP agreed about the importance of evaluating the medication reconciliation process, but disagreed about how this could be accomplished through standardized assessment. The TEP also disagreed about the usability and appropriateness of using the Beers Criteria to identify high-risk medications.¹¹³ A summary of the January 5 and 6, 2017 TEP meeting titled “SPADE Technical Expert Panel Summary (Second Convening)” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

We also solicited public input on data elements related to medication reconciliation during a public input period from April 26 to June 26, 2017. Several commenters expressed support for the medication reconciliation data elements that were put on display, noting the importance of medication reconciliation in preventing medication errors and stated that the items seemed feasible and clinically useful. A few commenters were critical of the choice of 10 drug classes posted during that comment period, arguing that ADEs are not limited to high-risk drugs, and raised issues related to training assessors to correctly complete a valid assessment of medication reconciliation. A summary report for the April 26 to June 26, 2017 public comment period titled “SPADE May-June 2017 Public Comment Summary Report” is available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

The High-Risk Drug Classes: Use and Indication data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from

113 American Geriatrics Society 2015 Beers Criteria Update Expert Panel. American Geriatrics Society. Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. *J Am Geriatr Soc* 2015; 63:2227–2246.

November 2017 to August 2018. Results of this test found the High-Risk Drug Classes: Use and Indication data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the High-Risk Drug Classes: Use and Indication data element in the National Beta Test can be found in the document titled “Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,” available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

In addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the proposed standardized patient assessment data elements. The TEP acknowledged the challenges of assessing medication safety, but were supportive of some of the data elements focused on medication reconciliation that were tested in the National Beta Test. The TEP was especially supportive of the focus on the six high-risk drug classes and using these classes to assess whether the indication for a drug is recorded. A summary of the September 17, 2018 TEP meeting titled “SPADE Technical Expert Panel Summary (Third Convening)” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. These activities provided updates on the field-testing work and solicited feedback on data elements considered for standardization, including the High-Risk Drug Classes: Use and Indication data element. One stakeholder group was critical of the six drug classes included as response options in the High-Risk Drug Classes: Use and Indication

data element, noting that potentially risky medications (for example, muscle relaxants) are not included in this list; that there may be important differences between drugs within classes (for example, more recent versus older style antidepressants); and that drug allergy information is not captured. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. Additionally, one commenter questioned whether the time to complete this SPADE would differ across settings. A summary of the public input received from the November 27, 2018 stakeholder meeting titled “Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

Taking together the importance of assessing high-risk drugs and for whether or not indications are noted for high-risk drugs, stakeholder input, and strong test results, we are proposing that the High-Risk Drug Classes: Use and Indication data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the High-Risk Drug Classes: Use and Indication data element as standardized patient assessment data for use in the SNF QRP.

d. Medical Condition and Comorbidity Data

Assessing medical conditions and comorbidities is critically important for care planning and safety for patients and residents receiving PAC services, and the standardized assessment of

selected medical conditions and comorbidities across PAC providers is important for managing care transitions and understanding medical complexity.

Below we discuss our proposals for data elements related to the medical condition of pain as standardized patient assessment data. Appropriate pain management begins with a standardized assessment, and thereafter establishing and implementing an overall plan of care that is person-centered, multi-modal, and includes the treatment team and the patient. Assessing and documenting the effect of pain on sleep, participation in therapy, and other activities may provide information on undiagnosed conditions and comorbidities and the level of care required, and do so more objectively than subjective numerical scores. With that, we assess that taken separately and together, these proposed data elements are essential for care planning, consistency across transitions of care, and identifying medical complexities including undiagnosed conditions. We also conclude that it is the standard of care to always consider the risks and benefits associated with a personalized care plan, including the risks of any pharmacological therapy, especially opioids.¹¹⁴ We also conclude that in addition to assessing and appropriately treating pain through the optimum mix of pharmacologic, non-pharmacologic, and alternative therapies, while being cognizant of current prescribing guidelines, clinicians in partnership with patients are best able to mitigate factors that contribute to the current opioid crisis.^{115 116 117}

114 Department of Health and Human Services: Pain Management Best Practices Inter-Agency Task Force. *Draft Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations*. Accessed April 1, 2019.

<https://www.hhs.gov/sites/default/files/final-pmtf-draft-report-on-pain-management%20-best-practices-2018-12-12-html-ready-clean.pdf>.

115. Department of Health and Human Services: Pain Management Best Practices Inter-Agency Task Force. *Draft Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations*. Accessed April 1, 2019.

<https://www.hhs.gov/sites/default/files/final-pmtf-draft-report-on-pain-management%20-best-practices-2018-12-12-html-ready-clean.pdf>.

116 Fishman SM, Carr DB, Hogans B, et al. Scope and Nature of Pain- and Analgesia-Related Content of the United States Medical Licensing Examination (USMLE). *Pain Med Malden Mass*. 2018;19(3):449-459. doi:10.1093/pm/pnx336.

117 Fishman SM, Young HM, Lucas Arwood E, et al. Core competencies for pain management: results of an interprofessional consensus summit. *Pain Med Malden Mass*. 2013;14(7):971-981. doi:10.1111/pme.12107.

In alignment with our Meaningful Measures Initiative, accurate assessment of medical conditions and comorbidities of patients and residents in PAC is expected to make care safer by reducing harm caused in the delivery of care; promote effective prevention and treatment of chronic disease; strengthen person and family engagement as partners in their care; and promote effective communication and coordination of care. The SPADEs will enable or support: clinical decision-making and early clinical intervention; person-centered, high quality care through: facilitating better care continuity and coordination; better data exchange and interoperability between settings; and longitudinal outcome analysis. Therefore, reliable data elements assessing medical conditions and comorbidities are needed in order to initiate a management program that can optimize a patient's or resident's prognosis and reduce the possibility of adverse events.

We are inviting comment that apply specifically to the standardized patient assessment data for the category of medical conditions and co-morbidities, specifically on:

(1) Pain Interference (Pain Effect on Sleep, Pain Interference with Therapy Activities, and Pain Interference with Day-to-Day Activities). In acknowledgement of the opioid crisis, we specifically are seeking comment on whether or not we should add these pain items in light of those concerns. Commenters should address to what extent collection of the data below through patient queries might encourage providers to prescribe opioids.

We are proposing that a set of three data elements on the topic of Pain Interference (Pain Effect on Sleep, Pain Interference with Therapy Activities, and Pain Interference with Day-to-Day Activities) meet the definition of standardized patient assessment data with respect to medical condition and comorbidity data under section 1899B(b)(1)(B)(iv) of the Act.

The practice of pain management began to undergo significant changes in the 1990s because the inadequate, non-standardized, non-evidence-based assessment and treatment of pain became a public health issue.¹¹⁸ In pain management, a critical part of providing comprehensive care is performance of a thorough initial evaluation, including assessment of both the medical and any biopsychosocial factors causing or contributing to the pain, with a treatment plan to address the causes of pain and to manage pain that persists over time.¹¹⁹ Quality pain management, based on current guidelines and evidence-based practices, can minimize unnecessary opioid prescribing both by offering alternatives or supplemental treatment to opioids and by clearly stating when they may be appropriate, and how to utilize risk-benefit analysis for opioid and non-opioid treatment modalities.¹²⁰ Pain is not a surprising symptom in PAC patients and residents, where healing, recovery, and rehabilitation often require regaining mobility and other functions after an acute event. Standardized assessment of pain that interferes with function is an important first step towards appropriate pain management in PAC settings. The National Pain Strategy called for refined assessment items on the topic of pain, and describes the need for these improved measures to be implemented in PAC assessments.¹²¹ Further, the focus on pain *interference*, as opposed to pain intensity or pain frequency, was supported by the TEP convened by our data element contractor as an appropriate and actionable metric for assessing pain. A summary of the September 17, 2018 TEP meeting titled “SPADE Technical Expert Panel

118 Institute of Medicine. *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research*. Washington (DC): National Academies Press (US); 2011. <http://www.ncbi.nlm.nih.gov/books/NBK91497/>.

119 Department of Health and Human Services: Pain Management Best Practices Inter-Agency Task Force. *Draft Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations*. Accessed April 1, 2019. <https://www.hhs.gov/sites/default/files/final-pmtf-draft-report-on-pain-management%20-best-practices-2018-12-12-html-ready-clean.pdf>.

120 National Academies. *Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use*. Washington DC: National Academies of Sciences, Engineering, and Medicine.; 2017.

121 National Pain Strategy: A Comprehensive Population-Health Level Strategy for Pain. https://iprc.nih.gov/sites/default/files/HHSNational_Pain_Strategy_508C.pdf.

Summary (Third Convening)” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

We appreciate the important concerns related to the misuse and overuse of opioids in the treatment of pain and to that end we note that in this proposed rule we have also proposed a SPADE that assess for the use of, as well as importantly the indication for that use of, high risk drugs, including opioids. Further, in the FY 2017 SNF PPS final rule (81 FR 52039) we adopted the Drug Regimen Review Conducted With Follow-Up for Identified Issues—Post Acute Care (PAC) SNF QRP measure which assesses whether PAC providers were responsive to potential or actual clinically significant medication issue(s), which includes issues associated with use and misuse of opioids for pain management, when such issues were identified.

We also note that the proposed SPADE related to pain assessment are not associated with any particular approach to management. Since the use of opioids is associated with serious complications, particularly in the elderly,^{122 123 124} an array of successful non-pharmacologic and non-opioid approaches to pain management may be considered PAC providers have historically used a range of pain management strategies, including non-steroidal anti-inflammatory drugs, ice, transcutaneous electrical nerve stimulation (TENS) therapy, supportive devices, acupuncture, and the like. In addition, non-pharmacological interventions for pain management include, but are not limited to, biofeedback, application of heat/cold, massage, physical therapy,

122 Chau, D. L., Walker, V., Pai, L., & Cho, L. M. (2008). Opiates and elderly: use and side effects. *Clinical interventions in aging*, 3(2), 273-8.

123 Fine, P. G. (2009). Chronic Pain Management in Older Adults: Special Considerations. *Journal of Pain and Symptom Management*, 38(2): S4-S14.

124 Solomon, D. H., Rassen, J. A., Glynn, R. J., Garneau, K., Levin, R., Lee, J., & Schneeweiss, S.. (2010). *Archives Internal Medicine*, 170(22):1979-1986.

nerve block, stretching and strengthening exercises, chiropractic, electrical stimulation, radiotherapy, and ultrasound.^{125 126 127}

We believe that standardized assessment of pain interference will support PAC clinicians in applying best-practices in pain management for chronic and acute pain, consistent with current clinical guidelines. For example, the standardized assessment of both opioids and pain interference would support providers in successfully tapering patients/residents who arrive in the PAC setting with long-term opioid use off of opioids onto non-pharmacologic treatments and non-opioid medications, as recommended by the Society for Post-Acute and Long-Term Care Medicine,¹²⁸ and consistent with HHS's 5-Point Strategy To Combat the Opioid Crisis¹²⁹ which includes "Better Pain Management."

The Pain Interference data elements consist of three data elements: Pain Effect on Sleep, Pain Interference with Therapy Activities, and Pain Interference with Day-to-Day Activities. Pain Effect on Sleep assesses the frequency with which pain affects a resident's sleep. Pain Interference with Therapy Activities assesses the frequency with which pain interferes with a resident's ability to participate in therapies. The Pain Interference with Day-to-Day Activities assesses the extent to which pain interferes with a resident's ability to participate in day-to-day activities excluding therapy.

A similar data element on the effect of pain on activities is currently included in the

125 Byrd L. Managing chronic pain in older adults: a long-term care perspective. *Annals of Long-Term Care: Clinical Care and Aging*. 2013;21(12):34-40.

126 Kligler, B., Bair, M.J., Banerjee, R. et al. (2018). Clinical Policy Recommendations from the VHA State-of-the-Art Conference on Non-Pharmacological Approaches to Chronic Musculoskeletal Pain. *Journal of General Internal Medicine*, 33(Suppl 1): 16. <https://doi.org/10.1007/s11606-018-4323-z>.

127 Chou, R., Deyo, R., Friedly, J., et al. (2017). Nonpharmacologic Therapies for Low Back Pain: A Systematic Review for an American College of Physicians Clinical Practice Guideline. *Annals of Internal Medicine*, 166(7):493-505.

128 Society for Post-Acute and Long-Term Care Medicine (AMDA). (2018). Opioids in Nursing Homes: Position Statement. <https://paltc.org/opioids%20in%20nursing%20homes>.

129 <https://www.hhs.gov/opioids/about-the-epidemic/hhs-response/index.html>.

OASIS. A similar data element on the effect on sleep is currently included in the MDS instrument. We are proposing to expand and modify the existing Pain data elements in the MDS to include the Pain Effect on Sleep; Pain Interference with Therapy Activities; and Pain Interference with Day to Day Activities data elements. For more information on the Pain Interference data elements, we refer readers to the document titled “Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,” available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

We sought public input on the relevance of conducting assessments on pain and specifically on the larger set of Pain Interview data elements included in the National Beta Test. The proposed data elements were supported by comments from the TEP meeting held by our data element contractor on April 7 to 8, 2016. The TEP affirmed the feasibility and clinical utility of pain as a concept in a standardized assessment. The TEP agreed that data elements on pain interference with ability to participate in therapies versus other activities should be addressed. Further, during a more recent convening of the same TEP on September 17, 2018, the TEP supported the interview-based pain data elements included in the National Beta Test. The TEP members were particularly supportive of the items that focused on how pain interferes with activities (that is, Pain Interference data elements), because understanding the extent to which pain interferes with function would enable clinicians to determine the need for appropriate pain treatment. A summary of the September 17, 2018 TEP meeting titled “SPADE Technical Expert Panel Summary (Third Convening)” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

We held a public input period in 2016 to solicit feedback on the standardization of pain

and several other items that were under development in prior efforts. From the prior public comment period, we included several pain data elements (Pain Effect on Sleep; Pain Interference – Therapy Activities; Pain Interference – Other Activities) in a second call for public input, open from April 26 to June 26, 2017. The items we sought comment on were modified from all stakeholder and test efforts. Commenters provided general comments about pain assessment in general in addition to feedback on the specific pain items. A few commenters shared their support for assessing pain, the potential for pain assessment to improve the quality of care, and for the validity and reliability of the data elements. Commenters affirmed that the item of pain and the effect on sleep would be suitable for PAC settings. Commenters’ main concerns included redundancy with existing data elements, feasibility and utility for cross-setting use, and the applicability of interview-based items to patients and residents with cognitive or communication impairments, and deficits. A summary report for the April 26 to June 26, 2017 public comment period titled “SPADE May-June 2017 Public Comment Summary Report” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

The Pain Interference data elements were included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Pain Interference data elements to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Pain Interference data elements in the National Beta Test can be found in the document titled “Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,” available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient->

[Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html](#).

In addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the standardized patient assessment data elements. The TEP supported the interview-based pain data elements included in the National Beta Test. The TEP members were particularly supportive of the items that focused on how pain interferes with activities (that is, Pain Interference data elements), because understanding the extent to which pain interferes with function would enable clinicians to determine the need for pain treatment. A summary of the September 17, 2018 TEP meeting titled “SPADE Technical Expert Panel Summary (Third Convening)” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-going SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. Additionally, one commenter expressed strong support for the Pain data elements and was encouraged by the fact that this portion of the assessment goes beyond merely measuring the presence of pain. A summary of the public input received from the November 27, 2018 stakeholder meeting titled “Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting” is available at

<https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

Taking together the importance of assessing for the effect of pain on function, stakeholder input, and strong test results, we are proposing that the three Pain Interference data elements (Pain Effect on Sleep, Pain Interference with Therapy Activities, and Pain Interference with Day-to-Day Activities) meet the definition of standardized patient assessment data with respect to medical conditions and comorbidities under section 1899B(b)(1)(B)(iv) of the Act and to adopt the Pain Interference data elements (Pain Effect on Sleep, Pain Interference with Therapy Activities, and Pain Interference with Day-to-Day Activities) data elements as standardized patient assessment data for use in the SNF QRP.

e. Impairment Data

Hearing and vision impairments are conditions that, if unaddressed, affect activities of daily living, communication, physical functioning, rehabilitation outcomes, and overall quality of life. Sensory limitations can lead to confusion in new settings, increase isolation, contribute to mood disorders, and impede accurate assessment of other medical conditions. Failure to appropriately assess, accommodate, and treat these conditions increases the likelihood that patients and residents will require more intensive and prolonged treatment. Onset of these conditions can be gradual, so individualized assessment with accurate screening tools and follow-up evaluations are essential to determining which patients and residents need hearing- or vision-specific medical attention or assistive devices and accommodations, including auxiliary aids and/or services, and to ensure that person-directed care plans are developed to accommodate a patient's or resident's needs. Accurate diagnosis and management of hearing or vision impairment would likely improve rehabilitation outcomes and care transitions, including transition from institutional-based care to the community. Accurate assessment of hearing and

vision impairment would be expected to lead to appropriate treatment, accommodations, including the provision of auxiliary aids and services during the stay, and ensure that patients and residents continue to have their vision and hearing needs met when they leave the facility.

In alignment with our Meaningful Measures Initiative, we expect accurate and individualized assessment, treatment, and accommodation of hearing and vision impairments of patients and residents in PAC to make care safer by reducing harm caused in the delivery of care; promote effective prevention and treatment of chronic disease; strengthen person and family engagement as partners in their care; and promote effective communication and coordination of care. For example, standardized assessment of hearing and vision impairments used in PAC will support ensuring patient safety (for example, risk of falls), identifying accommodations needed during the stay, and appropriate support needs at the time of discharge or transfer. Standardized assessment of these data elements will: enable or support clinical decision-making and early clinical intervention; person-centered, high quality care (for example, facilitating better care continuity and coordination); better data exchange and interoperability between settings; and longitudinal outcome analysis. Therefore, reliable data elements assessing hearing and vision impairments are needed to initiate a management program that can optimize a patient's or resident's prognosis and reduce the possibility of adverse events.

Comments on the category of impairments were also submitted by stakeholders during the FY 2018 SNF PPS proposed rule (82 FR 21074 through 21076) public comment period. A commenter stated hearing, vision, and communication assessments should be administered at the beginning of assessment process, to provide evidence about any sensory deficits that may affect the patient's or resident's ability to participate in the assessment and to allow the assessor to offer an assistive device. Another commenter supported the decision to assess hearing and

vision with respect to admission only and not discharge, and to use existing MDS items for hearing and vision, thereby not creating additional burden.

We are inviting comment on our proposals to collect as standardized patient assessment data the following data with respect to impairments.

(1) Hearing

We are proposing that the Hearing data element meets the definition of standardized patient assessment data with respect to impairments under section 1899B(b)(1)(B)(v) of the Act.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21074 through 21075), accurate assessment of hearing impairment is important in the PAC setting for care planning and resource use. Hearing impairment has been associated with lower quality of life, including poorer physical, mental, social functioning, and emotional health.^{130,131} Treatment and accommodation of hearing impairment led to improved health outcomes, including but not limited to quality of life.¹³² For example, hearing loss in elderly individuals has been associated with depression and cognitive impairment,^{133, 134,135} higher rates of incident cognitive impairment and cognitive decline,¹³⁶ and less time in occupational therapy.¹³⁷ Accurate

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

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

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

133 Sprinzi GM, Riechelmann H. Current trends in treating hearing loss in elderly people: a review of the technology and treatment options - a mini-review. *Gerontology*. 2010;56(3):351-358.

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

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

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

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

assessment of hearing impairment is important in the PAC setting for care planning and defining resource use.

The proposed data element consists of the single Hearing data element. This data consists of one question that assesses level of hearing impairment. This data element is currently in use in the MDS in SNFs. For more information on the Hearing data element, we refer readers to the document titled “Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,” available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

The Hearing data element was first proposed as a SPADE in the FY 2018 SNF PPS proposed rule (82 FR 21074 through 21075). In that proposed rule, we stated that the proposal was informed by input we received on the PAC PRD form of the data element (“Ability to Hear”) through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 recommended that hearing, vision, and communication assessments be administered at the beginning of patient assessment process. A summary report for the August 12 to September 12, 2016 public comment period titled “SPADE August 2016 Public Comment Summary Report” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

In response to our proposal in the FY 2018 SNF PPS proposed rule, two commenters supported Hearing as a standardized patient assessment data element to facilitate care coordination. One stated that coding instructions about use of a hearing device by the resident should be more clearly defined. Commenters were supportive of adopting the Hearing data element for standardized cross-setting use, noting that it would help address the needs of patient

and residents with disabilities and that failing to identify impairments during the initial assessment can result in inaccurate diagnoses of impaired language or cognition and can validate other information obtained from patient assessment.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the Hearing data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Hearing data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Hearing data element in the National Beta Test can be found in the document titled “Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,” available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

In addition, our data element contractor convened a TEP on January 5 and 6, 2017 for the purpose of soliciting input on all the SPADEs, including the Hearing data element. The TEP affirmed the importance of standardized assessment of hearing impairment in PAC patients and residents. A summary of the January 5 and 6, 2017 TEP meeting titled “SPADE Technical Expert Panel Summary (Second Convening)” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and

concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. Additionally, a commenter expressed support for the Hearing data element and suggested administration at the beginning of the patient assessment to maximize utility. A summary of the public input received from the November 27, 2018 stakeholder meeting titled “Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

Taking together the importance of assessing for hearing, stakeholder input, and strong test results, we are proposing that the Hearing data element meets the definition of standardized patient assessment data with respect to impairments under section 1899B(b)(1)(B)(v) of the Act and to adopt the Hearing data element as standardized patient assessment data for use in the SNF QRP.

(2) Vision

We are proposing that the Vision data element meets the definition of SPADE with respect to impairments under section 1899B(b)(1)(B)(v) of the Act.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21075 through 21076), evaluation of an individual’s ability to see is important for assessing for risks such as falls and provides opportunities for improvement through treatment and the provision of accommodations, including auxiliary aids and services, which can safeguard patients and residents and improve their overall quality of life. Further, vision impairment is often a treatable risk factor associated with adverse events and poor quality of life. For example, individuals with visual impairment

are more likely to experience falls and hip fracture, have less mobility, and report depressive symptoms.^{138, 139, 140, 141, 142, 143, 144} Individualized initial screening can lead to life-improving interventions such as accommodations, including the provision of auxiliary aids and services, during the stay and/or treatments that can improve vision and prevent or slow further vision loss. In addition, vision impairment is often a treatable risk factor associated with adverse events which can be prevented and accommodated during the stay. Accurate assessment of vision impairment is important in the SNF setting for care planning and defining resource use.

The proposed data element consists of the single Vision data element (Ability To See in Adequate Light) that consists of one question with five response categories. The Vision data element that we are proposing for standardization was tested as part of the development of the MDS in SNFs and is currently in use in that assessment. Similar data elements, but with different wording and fewer response option categories, are in use in the OASIS. For more information on the Vision data element, we refer readers to the document titled “Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,” available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

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

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

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

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

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

143 Rovner BW, Ganguli M. Depression and disability associated with impaired vision: the MoVies Project. *J Am Geriatr Soc*. 1998;46(5):617-619.

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

The Vision data element was first proposed as a SPADE in the FY 2018 SNF PPS proposed rule (82 FR 21075 through 21076). In that proposed rule, we stated that the proposal was informed by input we received on the Ability to See in Adequate Light data element (version tested in the PAC PRD with three response categories) through a call for input published on the CMS Measures Management System Blueprint website. Although the data element in public comment differed from the proposed data element, input submitted from August 12 to September 12, 2016 supported assessing vision in PAC settings and the useful information a vision data element would provide. We also stated that commenters had noted that the Ability to See item would provide important information that would facilitate care coordination and care planning, and consequently improve the quality of care. Other commenters suggested it would be helpful as an indicator of resource use and noted that the item would provide useful information about the abilities of patients and residents to care for themselves. Additional commenters noted that the item could feasibly be implemented across PAC providers and that its kappa scores from the PAC PRD support its validity. Some commenters noted a preference for MDS version of the Vision data element in SNFs over the form put forward in public comment, citing the widespread use of this data element. A summary report for the August 12 to September 12, 2016 public comment period titled “SPADE August 2016 Public Comment Summary Report” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

In response to our proposal in the FY 2018 SNF PPS proposed rule, two commenters supported Vision as a standardized patient assessment data element to facilitate care coordination. One stated that coding instructions for use of a vision device by the resident should be more clearly defined. Commenters recommended that hearing, vision, and communication assessments be administered at the beginning of patient assessment process.

One commenter supported having a SPADE for vision across PAC settings, but stated it captures only basic information for risk adjustment, and more detailed information would need to be collected to use it as an outcome measure.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the Vision data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Vision data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Vision data element in the National Beta Test can be found in the document titled “Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,” available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

In addition, our data element contractor convened a TEP on January 5 and 6, 2017 for the purpose of soliciting input on all the SPADEs including the Vision data element. The TEP affirmed the importance of standardized assessment of vision impairment in PAC patients and residents. A summary of the January 5 and 6, 2017 TEP meeting titled “SPADE Technical Expert Panel Summary (Second Convening)” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and

concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. Additionally, a commenter expressed support for the Vision data element and suggested administration at the beginning of the patient assessment to maximize utility. A summary of the public input received from the November 27, 2018 stakeholder meeting titled “Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

Taking together the importance of assessing for vision, stakeholder input, and strong test results, we are proposing that the Vision data element meets the definition of standardized patient assessment data with respect to impairments under section 1899B(b)(1)(B)(v) of the Act and to adopt the Vision data element as standardized patient assessment data for use in the SNF QRP.

f. Proposed New Category: Social Determinants of Health

(1) Proposed Social Determinants of Health Data Collection to Inform Measures and Other Purposes

Subparagraph (A) of section 2(d)(2) of the IMPACT Act requires CMS to assess appropriate adjustments to quality measures, resource measures, and other measures, and to assess and implement appropriate adjustments to payment under Medicare based on those measures, after taking into account studies conducted by ASPE on social risk factors (described below) and other information, and based on an individual’s health status and other factors.

Subparagraph (C) of section 2(d)(2) of the IMPACT Act further requires the Secretary to carry out periodic analyses, at least every three years, based on the factors referred to subparagraph (A) so as to monitor changes in possible relationships. Subparagraph (B) of section 2(d)(2) of

the IMPACT Act requires CMS to collect or otherwise obtain access to data necessary to carry out the requirement of the paragraph (both assessing adjustments described above in such subparagraph (A) and for periodic analyses in such subparagraph (C)). Accordingly we are proposing to use our authority under subparagraph (B) of section 2(d)(2) of the IMPACT Act to establish a new data source for information to meet the requirements of subparagraphs (A) and (C) of section 2(d)(2) of the IMPACT Act. In this rule, we are proposing to collect and access data about social determinants of health (SDOH) to perform CMS' responsibilities under subparagraphs (A) and (C) of section 2(d)(2) of the IMPACT Act, as explained in more detail below. Social determinants of health, also known as social risk factors, or health-related social needs, are the socioeconomic, cultural and environmental circumstances in which individuals live that impact their health. We are proposing to collect information on seven proposed SDOH SPADE data elements relating to race, ethnicity, preferred language, interpreter services, health literacy, transportation, and social isolation; a detailed discussion of each of the proposed SDOH data elements is found in section VI.A.7.f.(2) of this proposed rule.

We are also proposing to use the resident assessment instrument minimum data set (MDS), the current version being MDS 3.0, described as a PAC assessment instrument under section 1899B(a)(2)(B) of the Act, to collect these data via an existing data collection mechanism. We believe this approach will provide CMS with access to data with respect to the requirements of section 2(d)(2) of the IMPACT Act, while minimizing the reporting burden on PAC health care providers by relying on a data reporting mechanism already used and an existing system to which PAC health care providers are already accustomed.

The IMPACT Act includes several requirements applicable to the Secretary, in addition to those imposing new data reporting obligations on certain PAC providers as discussed in section VI.A.7.f.(2) of this proposed rule. Subparagraphs (A) and (B) of section 2(d)(1) of the

IMPACT Act require the Secretary, acting through the Office of the Assistant Secretary for Planning and Evaluation (ASPE), to conduct two studies that examine the effect of risk factors, including individuals' socioeconomic status, on quality, resource use and other measures under the Medicare program. The first ASPE study was completed in December 2016 and is discussed below, and the second study is to be completed in the fall of 2019. We recognize that ASPE, in its studies, is considering a broader range of social risk factors than the SDOH data elements in this proposal, and address both PAC and non-PAC settings. We acknowledge that other data elements may be useful to understand, and that some of those elements may be of particular interest in non-PAC settings. For example, for beneficiaries receiving care in the community, as opposed to an in-patient facility, housing stability and food insecurity may be more relevant. We will continue to take into account the findings from both of ASPE's reports in future policy making.

One of the ASPE's first actions under the IMPACT Act was to commission the National Academies of Sciences, Engineering, and Medicine (NASEM) to define and conceptualize socioeconomic status for the purposes of ASPE's two studies under section 2(d)(1) of the IMPACT Act. The NASEM convened a panel of experts in the field and conducted an extensive literature review. Based on the information collected, the 2016 NASEM panel report titled, "Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors," concluded that the best way to assess how social processes and social relationships influence key health-related outcomes in Medicare beneficiaries is through a framework of social risk factors instead of socioeconomic status. Social risk factors discussed in the NASEM report include socioeconomic position, race, ethnicity, gender, social context, and community context. These

factors are discussed at length in chapter 2 of the NASEM report, titled “Social Risk Factors.”¹⁴⁵ Consequently NASEM framed the results of its report in terms of “social risk factors” rather than “socioeconomic status” or “sociodemographic status.” The full text of the “Social Risk Factors” NASEM report is available for reading on the website at <https://www.nap.edu/read/21858/chapter/1>.

Each of the data elements we are proposing to collect and access pursuant to our authority under section 2(d)(2)(B) of the IMPACT Act is identified in the 2016 NASEM report as a social risk factor that has been shown to impact care use, cost and outcomes for Medicare beneficiaries. CMS uses the term social determinants of health (SDOH) to denote social risk factors, which is consistent with the objectives of Healthy People 2020.¹⁴⁶

ASPE issued its first Report to Congress, titled “Social Risk Factors and Performance Under Medicare’s Value-Based Purchasing Programs,” pursuant to section 2(d)(1)(A) of the IMPACT Act on December 21, 2016.¹⁴⁷ Using NASEM’s social risk factors framework, ASPE focused on the following social risk factors, in addition to disability: (1) dual enrollment in Medicare and Medicaid as a marker for low income, (2) residence in a low-income area, (3) Black race, (4) Hispanic ethnicity, and; (5) residence in a rural area. ASPE acknowledged that the social risk factors examined in its report were limited due to data availability. The report also noted that the data necessary to meaningfully attempt to reduce disparities and identify and reward improved outcomes for beneficiaries with social risk factors have not been collected consistently on a national level in post-acute care settings. Where these data have been

145 National Academies of Sciences, Engineering, and Medicine. 2016. *Accounting for social risk factors in Medicare payment: Identifying social risk factors*. Chapter 2. Washington, DC: The National Academies Press.

146 Social Determinants of Health. Healthy People 2020. <https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-of-health>. (February 2019).

147 U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation. 2016. Report to Congress: Social Risk Factors and Performance Under Medicare’s Value-Based Payment Programs. Washington, DC.

collected, the collection frequently involves lengthy questionnaires. More information on the Report to Congress on Social Risk Factors and Performance under Medicare's Value-Based Purchasing Programs, including the full report, is available on the website at <https://aspe.hhs.gov/social-risk-factors-and-medicares-value-based-purchasing-programs-reports>.

Section 2(d)(2) of the IMPACT Act relates to CMS activities and imposes several responsibilities on the Secretary relating to quality, resource use, and other measures under Medicare. As mentioned previously, under subparagraph (A) of section 2(d)(2) of the IMPACT Act, the Secretary is required, on an ongoing basis, taking into account the ASPE studies and other information, and based on an individual's health status and other factors, to assess appropriate adjustments to quality, resource use, and other measures, and to assess and implement appropriate adjustments to Medicare payments based on those measures. Section 2(d)(2)(A)(i) of the IMPACT Act applies to measures adopted under subsections (c) and (d) of section 1899B of the Act and to other measures under Medicare. However, CMS' ability to perform these analyses, and assess and make appropriate adjustments is hindered by limits of existing data collections on SDOH data elements for Medicare beneficiaries. In its first study in 2016, in discussing the second study, ASPE noted that information relating to many of the specific factors listed in the IMPACT Act, such as health literacy, limited English proficiency, and Medicare beneficiary activation, are not available in Medicare data.

Subparagraph 2(d)(2)(A) of the IMPACT Act specifically requires the Secretary to take the studies and considerations from ASPE's reports to Congress, as well as other information as appropriate, into account in assessing and implementing adjustments to measures and related payments based on measures in Medicare. The results of the ASPE's first study demonstrated that Medicare beneficiaries with social risk factors tended to have worse outcomes on many quality measures, and providers who treated a disproportionate share of beneficiaries with social

risk factors tended to have worse performance on quality measures. As a result of these findings, ASPE suggested a three-pronged strategy to guide the development of value-based payment programs under which all Medicare beneficiaries receive the highest quality healthcare services possible. The three components of this strategy are to: (1) measure and report quality of care for beneficiaries with social risk factors; (2) set high, fair quality standards for care provided to all beneficiaries; and (3) reward and support better outcomes for beneficiaries with social risk factors. In discussing how measuring and reporting quality for beneficiaries with social risk factors can be applied to Medicare quality payment programs, the report offered nine considerations across the three-pronged strategy, including enhancing data collection and developing statistical techniques to allow measurement and reporting of performance for beneficiaries with social risk factors on key quality and resource use measures.

Congress, in section 2(d)(2)(B) of the IMPACT Act, required the Secretary to collect or otherwise obtain access to the data necessary to carry out the provisions of paragraph (2) of section 2(d) of the IMPACT Act through both new and existing data sources. Taking into consideration NASEM's conceptual framework for social risk factors discussed above, ASPE's study, considerations under section 2(d)(1)(A) of the IMPACT Act, as well as the current data constraints of ASPE's first study and its suggested considerations, we are proposing to collect and access data about SDOH under section 2(d)(2) of the IMPACT Act. Our collection and use of the SDOH data described in section VI.A.7.f.(1) of this proposed rule, under section 2(d)(2) of the IMPACT Act, would be independent of our proposal below (in section VI.A.7.f.(2) of this proposed rule and our authority to require submission of that data for use as SPADE under section 1899B(a)(1)(B) of the Act.

Accessing standardized data relating to the SDOH data elements on a national level is necessary to permit CMS to conduct periodic analyses, to assess appropriate adjustments to

quality measures, resource use measures, and other measures, and to assess and implement appropriate adjustments to Medicare payments based on those measures. We agree with ASPE's observations, in the value-based purchasing context, that the ability to measure and track quality, outcomes, and costs for beneficiaries with social risk factors over time is critical as policymakers and providers seek to reduce disparities and improve care for these groups. Collecting the data as proposed will provide the basis for our periodic analyses of the relationship between an individual's health status and other factors and quality, resource use, and other measures, as required by section 2(d)(2) of the IMPACT Act, and to assess appropriate adjustments. These data will also permit us to develop the statistical tools necessary to maximize the value of Medicare data, reduce costs and improve the quality of care for all beneficiaries. Collecting and accessing SDOH data in this way also supports the three-part strategy put forth in the first ASPE report, specifically ASPE's consideration to enhance data collection and develop statistical techniques to allow measurement and reporting of performance for beneficiaries with social risk factors on key quality and resource use measures.

For the reasons discussed above, we are proposing under section 2(d)(2) of the IMPACT Act, to collect the data on the following SDOH: (1) Race, as described in section VI.A.7.f.(2)(a) of this proposed rule; (2) Ethnicity, as described in section VI.A.7.f.(2)(a) of this proposed rule; (3) Preferred Language, as described in section VI.A.7.f.(2)(b) of this proposed rule; (4) Interpreter Services as described in section VI.A.7.f.(2)(b) of this proposed rule; (5) Health Literacy, as described in section VI.A.7.f.(2)(c) of this proposed rule; (6) Transportation, as described in section VI.A.7.f.(2)(d) of this proposed rule; and (5) Social Isolation, as described in section VI.A.7.f.(2)(e) of this proposed rule. These data elements are discussed in more detail below in section VI.A.7.f.(2) of this proposed rule. We welcome comment on this proposal.

(2) Standardized Patient Assessment Data

Section 1899B(b)(1)(B)(vi) of the Act authorizes the Secretary to collect SPADEs with respect to other categories deemed necessary and appropriate. Below we are proposing to create a Social Determinants of Health SPADE category under section 1899B(b)(1)(B)(vi) of the Act. In addition to collecting SDOH data for the purposes outlined above under section 2(d)(2)(B) of the IMPACT Act, we are also proposing to collect as SPADE these same data elements (race, ethnicity, preferred language, interpreter services, health literacy, transportation, and social isolation) under section 1899B(b)(1)(B)(vi) of the Act. We believe that this proposed new category of Social Determinants of Health will inform provider understanding of individual patient risk factors and treatment preferences, facilitate coordinated care and care planning, and improve patient outcomes. We are proposing to deem this category necessary and appropriate, for the purposes of SPADE, because using common standards and definitions for PAC data elements is important in ensuring interoperable exchange of longitudinal information between PAC providers and other providers to facilitate coordinated care, continuity in care planning, and the discharge planning process from post-acute care settings.

All of the Social Determinants of Health data elements we are proposing under section 1899B(b)(1)(B)(vi) of the Act have the capacity to take into account treatment preferences and care goals of residents and patients, and to inform our understanding of resident and patient complexity and risk factors that may affect care outcomes. While acknowledging the existence and importance of additional SDOH, we are proposing to assess some of the factors relevant for patients and residents receiving post-acute care that PAC settings are in a position to impact through the provision of services and supports, such as connecting patients and residents with identified needs with transportation programs, certified interpreters, or social support programs.

As previously mentioned and described in more detail below we are proposing to adopt the following seven data elements as SPADE under the proposed Social Determinants of Health

category: race, ethnicity, preferred language, interpreter services, health literacy, transportation, and social isolation. To select these data elements, we reviewed the research literature, a number of validated assessment tools and frameworks for addressing SDOH currently in use (for example, Health Leads, NASEM, Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences (PRAPARE), and ICD-10), and we engaged in discussions with stakeholders. We also prioritized balancing the reporting burden for PAC providers with our policy objective to collect SPADEs that will inform care planning and coordination and quality improvement across care settings. Furthermore, incorporating SDOH data elements into care planning has the potential to reduce readmissions and help beneficiaries achieve and maintain their health goals.

We also considered feedback received during a listening session that we held on December 13, 2018. The purpose of the listening session was to solicit feedback from health systems, research organizations, advocacy organizations and state agencies, and other members of the public on collecting patient-level data on SDOH across care settings, including consideration of race, ethnicity, spoken language, health literacy, social isolation, transportation, sex, gender identity, and sexual orientation. We also gave participants an option to submit written comments. A full summary of the listening session, titled "Listening Session on Social Determinants of Health Data Elements: Summary of Findings," includes a list of participating stakeholders and their affiliations, and is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

(a) Race and Ethnicity

The persistence of racial and ethnic disparities in health and health care is widely documented, including in PAC settings.^{148,149,150,151,152} Despite the trend toward overall improvements in quality of care and health outcomes, the Agency for Healthcare Research and Quality, in its National Healthcare Quality and Disparities Reports, consistently indicates that racial and ethnic disparities persist, even after controlling for factors such as income, geography, and insurance.¹⁵³ For example, racial and ethnic minorities tend to have higher rates of infant mortality, diabetes and other chronic conditions, and visits to the emergency department, and lower rates of having a usual source of care and receiving immunizations such as the flu vaccine.¹⁵⁴ Studies have also shown that African Americans are significantly more likely than white Americans to die prematurely from heart disease and stroke.¹⁵⁵ However, our ability to identify and address racial and ethnic health disparities has historically been constrained by data limitations, particularly for smaller populations groups such as Asians, American Indians and Alaska Natives, and Native Hawaiians and other Pacific Islanders.¹⁵⁶

148 2017 National Healthcare Quality and Disparities Report. Rockville, MD: Agency for Healthcare Research and Quality; September 2018. AHRQ Pub. No. 18-0033-EF.

149 Fiscella, K. and Sanders, M.R. Racial and Ethnic Disparities in the Quality of Health Care. (2016). *Annual Review of Public Health*. 37:375-394.

150 2018 National Impact Assessment of the Centers for Medicare & Medicaid Services (CMS) Quality Measures Reports. Baltimore, MD: U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services; February 28, 2018.

151 Smedley, B.D., Stith, A.Y., & Nelson, A.R. (2003). *Unequal treatment: confronting racial and ethnic disparities in health care*. Washington, D.C., National Academy Press.

152 Chase, J., Huang, L. and Russell, D. (2017). Racial/ethnic disparities in disability outcomes among post-acute home care patients. *J of Aging and Health*. 30(9):1406-1426.

153 National Healthcare Quality and Disparities Reports. (December 2018). Agency for Healthcare Research and Quality, Rockville, MD. <http://www.ahrq.gov/research/findings/nhqrd/index.html>.

154 National Center for Health Statistics. *Health, United States, 2017: With special feature on mortality*. Hyattsville, Maryland. 2018.

155 HHS. *Heart disease and African Americans*. 2016b. (October 24, 2016). <http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=19>.

156 National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Population Health and Public Health Practice; Committee on Community-Based Solutions to Promote Health Equity in the United States; Baciu A, Negussie Y, Geller A, et al., editors. *Communities in Action: Pathways to Health Equity*. Washington (DC): National Academies Press (US); 2017 Jan 11. 2, The State of Health Disparities in the United States. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK425844/>.

The ability to improve understanding of and address racial and ethnic disparities in PAC outcomes requires the availability of better data. There is currently a Race and Ethnicity data element, collected in the MDS, LCDS, IRF-PAI, and OASIS, that consists of a single question, which aligns with the 1997 Office of Management and Budget (OMB) minimum data standards for federal data collection efforts.¹⁵⁷ The 1997 OMB Standard lists five minimum categories of race: (1) American Indian or Alaska Native; (2) Asian; (3) Black or African American; (4) Native Hawaiian or Other Pacific Islander; (5) and White. The 1997 OMB Standard also lists two minimum categories of ethnicity: (1) Hispanic or Latino, and (2) Not Hispanic or Latino. The 2011 HHS Data Standards requires a two-question format when self-identification is used to collect data on race and ethnicity. Large federal surveys such as the National Health Interview Survey, Behavioral Risk Factor Surveillance System, and the National Survey on Drug Use and Health, have implemented the 2011 HHS race and ethnicity data standards. CMS has similarly updated the Medicare Current Beneficiary Survey, Medicare Health Outcomes Survey, and the Health Insurance Marketplace Application for Health Coverage with the 2011 HHS data standards. More information about the HHS Race and Ethnicity Data Standards are available on the website at <https://minorityhealth.hhs.gov/omb/browse.aspx?lvl=3&lvlid=54>.

We are proposing to revise the current Race and Ethnicity data element for purposes of this proposal to conform to the 2011 HHS Data Standards for person-level data collection, while also meeting the 1997 OMB minimum data standards for race and ethnicity. Rather than one data element that assesses both race and ethnicity, we are proposing two separate data elements: one for Race and one for Ethnicity, that would conform with the 2011 HHS Data Standards and

¹⁵⁷ “Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity (Notice of Decision)”. Federal Register 62:210 (October 30, 1997) pp. 58782-58790. Available from: <https://www.govinfo.gov/content/pkg/FR-1997-10-30/pdf/97-28653.pdf>.

the 1997 OMB Standard. In accordance with the 2011 HHS Data Standards, a two-question format would be used for the proposed race and ethnicity data elements.

The proposed Race data element asks, “What is your race?” We are proposing to include fourteen response options under the race data element: (1) White; (2) Black or African American; (3) American Indian or Alaska Native; (4) Asian Indian; (5) Chinese; (6) Filipino; (7) Japanese; (8) Korean; (9) Vietnamese; (10) Other Asian; (11) Native Hawaiian; (12) Guamanian or Chamorro; (13) Samoan; and, (14) Other Pacific Islander.

The proposed Ethnicity data element asks, “Are you Hispanic, Latino/a, or Spanish origin?” We are proposing to include five response options under the ethnicity data element: (1) Not of Hispanic, Latino/a, or Spanish origin; (2) Mexican, Mexican American, Chicano/a; (3) Puerto Rican; (4) Cuban; and, (5) Another Hispanic, Latino, or Spanish Origin.

We believe that the two proposed data elements for race and ethnicity conform to the 2011 HHS Data Standards for person-level data collection, while also meeting the 1997 OMB minimum data standards for race and ethnicity, because under those standards, more detailed information on population groups can be collected if those additional categories can be aggregated into the OMB minimum standard set of categories.

In addition, we received stakeholder feedback during the December 13, 2018 SDOH listening session on the importance of improving response options for race and ethnicity as a component of health care assessments and for monitoring disparities. Some stakeholders emphasized the importance of allowing for self-identification of race and ethnicity for more categories than are included in the 2011 HHS Standard to better reflect state and local diversity, while acknowledging the burden of coding an open-ended health care assessment question across different settings.

We believe that the proposed modified race and ethnicity data elements more accurately reflect the diversity of the U.S. population than the current race/ethnicity data element included in MDS, LCDS, IRF-PAI and, OASIS.^{158,159,160,161} We believe, and research consistently shows, that improving how race and ethnicity data are collected is an important first step in improving quality of care and health outcomes. Addressing disparities in access to care, quality of care, and health outcomes for Medicare beneficiaries begins with identifying and analyzing how SDOH, such as race and ethnicity, align with disparities in these areas.¹⁶² Standardizing self-reported data collection for race and ethnicity allows for the equal comparison of data across multiple healthcare entities.¹⁶³ By collecting and analyzing these data, CMS and other healthcare entities will be able to identify challenges and monitor progress. The growing diversity of the US population and knowledge of racial and ethnic disparities within and across population groups supports the collection of more granular data beyond the 1997 OMB minimum standard for reporting categories. The 2011 HHS race and ethnicity data standard includes additional detail that may be used by PAC providers to target quality improvement efforts for racial and ethnic groups experiencing disparate outcomes. For more information on the Race and Ethnicity data elements, we refer readers to the document titled “Proposed Specifications for SNF QRP

158 Penman-Aguilar, A., Talih, M., Huang, D., Moonesinghe, R., Bouye, K., Beckles, G. (2016). Measurement of Health Disparities, Health Inequities, and Social Determinants of Health to Support the Advancement of Health Equity. *J Public Health Manag Pract.* 22 Suppl 1: S33-42.

159 Ramos, R., Davis, J.L., Ross, T., Grant, C.G., Green, B.L. (2012). Measuring health disparities and health inequities: do you have REGAL data? *Qual Manag Health Care.* 21(3):176-87.

160 IOM (Institute of Medicine). 2009. *Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement.* Washington, DC: The National Academies Press.

161 “Revision of Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity: Proposals From Federal Interagency Working Group (Notice and Request for Comments).” *Federal Register* 82: 39 (March 1, 2017) p. 12242.

162 National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Population Health and Public Health Practice; Committee on Community-Based Solutions to Promote Health Equity in the United States; Baciu A, Negussie Y, Geller A, et al., editors. *Communities in Action: Pathways to Health Equity.* Washington (DC): National Academies Press (US); 2017 Jan 11. 2, *The State of Health Disparities in the United States.* Available from: <https://www.ncbi.nlm.nih.gov/books/NBK425844/>.

163 IOM (Institute of Medicine). 2009. *Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement.* Washington, DC: The National Academies Press.

Measures and Standardized Patient Assessment Data Elements,” available at

<https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

In an effort to standardize the submission of race and ethnicity data among IRFs, HHAs, SNFs and LTCHs, for the purposes outlined in section 1899B(a)(1)(B) of the Act, while minimizing the reporting burden, we are proposing to adopt the Race and Ethnicity data elements described above as SPADEs with respect to the proposed Social Determinants of Health category.

Specifically, we are proposing to replace the current Race/Ethnicity data element with the proposed Race and Ethnicity data elements on the MDS. We are also proposing that SNFs that submit the Race and Ethnicity data elements with respect to admission will be considered to have submitted with respect to discharge as well, because it is unlikely that the results of these assessment findings will change between the start and end of the SNF stay, making the information submitted with respect to a resident’s admission the same with respect to a resident’s discharge.

(b) Preferred Language and Interpreter Services

More than 64 million Americans speak a language other than English at home, and nearly 40 million of those individuals have limited English proficiency (LEP).¹⁶⁴ Individuals with LEP have been shown to receive worse care and have poorer health outcomes, including higher readmission rates.^{165,166,167} Communication with individuals with LEP is an important

164 U.S. Census Bureau, 2013-2017 American Community Survey 5-Year Estimates.

165 Karliner LS, Kim SE, Meltzer DO, Auerbach AD. Influence of language barriers on outcomes of hospital care for general medicine inpatients. *J Hosp Med.* 2010 May-Jun;5(5):276-82. doi: 10.1002/jhm.658.

component of high quality health care, which starts by understanding the population in need of language services. Unaddressed language barriers between a patient and provider care team negatively affects the ability to identify and address individual medical and non-medical care needs, to convey and understand clinical information, as well as discharge and follow up instructions, all of which are necessary for providing high quality care. Understanding the communication assistance needs of residents and patients with LEP, including individuals who are Deaf or hard of hearing, is critical for ensuring good outcomes.

Presently, the preferred language of residents and patients and need for interpreter services are assessed in two PAC assessment tools. The LCDS and the MDS use the same two data elements to assess preferred language and whether a patient or resident needs or wants an interpreter to communicate with health care staff. The MDS initially implemented preferred language and interpreter services data elements to assess the needs of SNF residents and patients and inform care planning. For alignment purposes, the LCDS later adopted the same data elements for LTCHs. The 2009 NASEM (formerly Institute of Medicine) report on standardizing data for health care quality improvement emphasizes that language and communication needs should be assessed as a standard part of health care delivery and quality improvement strategies.¹⁶⁸

In developing our proposal for a standardized language data element across PAC settings, we considered the current preferred language and interpreter services data elements that are in LCDS and MDS. We also considered the 2011 HHS Primary Language Data Standard and peer-

166 Kim EJ, Kim T, Paasche-Orlow MK, et al. Disparities in Hypertension Associated with Limited English Proficiency. *J Gen Intern Med.* 2017 Jun;32(6):632-639. doi: 10.1007/s11606-017-3999-9.

167 National Academies of Sciences, Engineering, and Medicine. 2016. Accounting for social risk factors in Medicare payment: Identifying social risk factors. Washington, DC: The National Academies Press.

168 IOM (Institute of Medicine). 2009. Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement. Washington, DC: The National Academies Press.

reviewed research. The current preferred language data element in LCDS and MDS asks, “What is your preferred language?” Because the preferred language data element is open-ended, the patient or resident is able to identify their preferred language, including American Sign Language (ASL). Finally, we considered the recommendations from the 2009 NASEM (formerly Institute of Medicine) report, “Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement.” In it, the committee recommended that organizations evaluating a patient’s language and communication needs for health care purposes, should collect data on the preferred spoken language and on an individual’s assessment of his/her level of English proficiency.

A second language data element in LCDS and MDS asks, “Do you want or need an interpreter to communicate with a doctor or health care staff?” and includes yes or no response options. In contrast, the 2011 HHS Primary Language Data Standard recommends either a single question to assess how well someone speaks English or, if more granular information is needed, a two-part question to assess whether a language other than English is spoken at home and if so, identify that language. However, neither option allows for a direct assessment of a patient’s or resident’s preferred spoken or written language nor whether they want or need interpreter services for communication with a doctor or care team, both of which are an important part of assessing resident and patient needs and the care planning process. More information about the HHS Data Standard for Primary Language is available on the website at

<https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=3&lvlid=54>.

Research consistently recommends collecting information about an individual’s preferred spoken language and evaluating those responses for purposes of determining language access

needs in health care.¹⁶⁹ However, using “preferred spoken language” as the metric does not adequately account for people whose preferred language is ASL, which would necessitate adopting an additional data element to identify visual language. The need to improve the assessment of language preferences and communication needs across PAC settings should be balanced with the burden associated with data collection on the provider and patient or resident. Therefore we are proposing to retain the Preferred Language and Interpreter Services data elements currently in use on the MDS.

In addition, we received feedback during the December 13, 2018 listening session on the importance of evaluating and acting on language preferences early to facilitate communication and allowing for patient self-identification of preferred language. Although the discussion about language was focused on preferred spoken language, there was general consensus among participants that stated language preferences may or may not accurately indicate the need for interpreter services, which supports collecting and evaluating data to determine language preference, as well as the need for interpreter services. An alternate suggestion was made to inquire about preferred language specifically for discussing health or health care needs. While this suggestion does allow for ASL as a response option, we do not have data indicating how useful this question might be for assessing the desired information and thus we are not including this question in our proposal.

Improving how preferred language and need for interpreter services data are collected is an important component of improving quality by helping PAC providers and other providers

169 Guerino, P. and James, C. Race, Ethnicity, and Language Preference in the Health Insurance Marketplaces 2017 Open Enrollment Period. Centers for Medicare & Medicaid Services, Office of Minority Health. Data Highlight: Volume 7 – April 2017. Available at <https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Data-Highlight-Race-Ethnicity-and-Language-Preference-Marketplace.pdf>.

understand patient needs and develop plans to address them. For more information on the Preferred Language and Interpreter Services data elements, we refer readers to the document titled “Proposed Specifications for SNF QRP Measures and Standardized Patient Assessment Data Elements,” available on the website at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

In an effort to standardize the submission of language data among IRFs, HHAs, SNFs and LTCHs, for the purposes outlined in section 1899B(a)(1)(B) of the Act, while minimizing the reporting burden, we are proposing to adopt the Preferred Language and Interpreter Services data elements currently used on the MDS, and describe above, as SPADEs with respect to the Social Determinants of Health category.

(c) Health Literacy

The Department of Health and Human Services defines health literacy as “the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.”¹⁷⁰ Similar to language barriers, low health literacy can interfere with communication between the provider and resident or patient and the ability for residents and patients or their caregivers to understand and follow treatment plans, including medication management. Poor health literacy is linked to lower levels of knowledge about health, worse health outcomes, and the receipt of fewer preventive services, but higher medical costs and rates of emergency department use.¹⁷¹

170 U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion. National action plan to improve health literacy. Washington (DC): Author; 2010.

171 National Academies of Sciences, Engineering, and Medicine. 2016. Accounting for social risk factors in Medicare payment: Identifying social risk factors. Washington, DC: The National Academies Press.

Health literacy is prioritized by Healthy People 2020 as an SDOH.¹⁷² Healthy People 2020 is a long-term, evidence-based effort led by the Department of Health and Human Services that aims to identify nationwide health improvement priorities and improve the health of all Americans. Although not designated as a social risk factor in NASEM's 2016 report on accounting for social risk factors in Medicare payment, the NASEM noted that health literacy is impacted by other social risk factors and can affect access to care as well as quality of care and health outcomes.¹⁷³ Assessing for health literacy across PAC settings would facilitate better care coordination and discharge planning. A significant challenge in assessing the health literacy of individuals is avoiding excessive burden on patients and residents and health care providers. The majority of existing, validated health literacy assessment tools use multiple screening items, generally with no fewer than four, which would make them burdensome if adopted in MDS, LCDS, IRF-PAI, and OASIS.

The Single Item Literacy Screener (SILS) question asks, "How often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor or pharmacy?" Possible response options are: (1) Never; (2) Rarely; (3) Sometimes; (4) Often; and (5) Always. The SILS question, which assesses reading ability, (a primary component of health literacy), tested reasonably well against the 36 item Short Test of Functional Health Literacy in Adults (S-TOFHLA), a thoroughly vetted and widely adopted health literacy test, in assessing the likelihood of low health literacy in an adult sample from

172 Social Determinants of Health. Healthy People 2020. <https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-of-health>. (February 2019).

173 U.S. Department of Health & Human Services, Office of the Assistant Secretary for Planning and Evaluation. Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs. Available at <https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicare-s-value-based-purchasing-programs>. Washington, DC: 2016.

primary care practices participating in the Vermont Diabetes Information System.^{174,175} The S-TOFHLA is a more complex assessment instrument developed using actual hospital related materials such as prescription bottle labels and appointment slips, and often considered the instrument of choice for a detailed evaluation of health literacy.¹⁷⁶ Furthermore, the S-TOFHLA instrument is proprietary and subject to purchase for individual entities or users.¹⁷⁷ Given that SILS is publicly available, shorter and easier to administer than the full health literacy screen, and research found that a positive result on the SILS demonstrates an increased likelihood that an individual has low health literacy, we are proposing to use the single-item reading question for health literacy in the standardized data collection across PAC settings. We believe that use of this data element will provide sufficient information about the health literacy of SNF residents to facilitate appropriate care planning, care coordination, and interoperable data exchange across PAC settings.

In addition, we received feedback during the December 13, 2018 SDOH listening session on the importance of recognizing health literacy as more than understanding written materials and filling out forms, as it is also important to evaluate whether patients and residents understand their conditions. However, the NASEM recently recommended that health care providers implement health literacy universal precautions instead of taking steps to ensure care is provided

174 Morris, N. S., MacLean, C. D., Chew, L. D., & Littenberg, B. (2006). The Single Item Literacy Screener: evaluation of a brief instrument to identify limited reading ability. *BMC family practice*, 7, 21. doi:10.1186/1471-2296-7-21.

175 Brice, J.H., Foster, M.B., Principe, S., Moss, C., Shofer, F.S., Falk, R.J., Ferris, M.E., DeWalt, D.A. (2013). Single-item or two-item literacy screener to predict the S-TOFHLA among adult hemodialysis patients. *Patient Educ Couns*. 94(1):71-5.

176 University of Miami, School of Nursing & Health Studies, Center of Excellence for Health Disparities Research. Test of Functional Health Literacy in Adults (TOFHLA). (March 2019). Available at <https://elcentro.sonhs.miami.edu/research/measures-library/tofhla/index.html>.

177 Nurss, J.R., Parker, R.M., Williams, M.V., & Baker, D.W. David W. (2001). TOFHLA. Peppercorn Books & Press. Available from: http://www.peppercornbooks.com/catalog/information.php?info_id=5.

at an appropriate literacy level based on individualized assessment of health literacy.¹⁷⁸ Given the dearth of Medicare data on health literacy and gaps in addressing health literacy in practice, we recommend the addition of a health literacy data element.

The proposed Health Literacy data element is consistent with considerations raised by NASEM and other stakeholders and research on health literacy, which demonstrates an impact on health care use, cost, and outcomes.¹⁷⁹ For more information on the proposed Health Literacy data element, we refer readers to the document titled “Proposed Specifications for SNF QRP Measures and Standardized Patient Assessment Data Elements,” available on the website at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

In an effort to standardize the submission of health literacy data among IRFs, HHAs, SNFs and LTCHs, for the purposes outlined in section 1899B(a)(1)(B) of the Act, while minimizing the reporting burden, we are proposing to adopt the SILS question, described above for the Health Literacy data element, as SPADE under the Social Determinants of Health Category. We are proposing to add the Health Literacy data element to the MDS.

(d) Transportation

Transportation barriers commonly affect access to necessary health care, causing missed appointments, delayed care, and unfilled prescriptions, all of which can have a negative impact on health outcomes.¹⁸⁰ Access to transportation for ongoing health care and medication access needs, particularly for those with chronic diseases, is essential to successful chronic disease

178 Hudson, S., Rikard, R.V., Staiculescu, I. & Edison, K. (2017). Improving health and the bottom line: The case for health literacy. In Building the case for health literacy: Proceedings of a workshop. Washington, DC: The National Academies Press.

179 National Academies of Sciences, Engineering, and Medicine. 2016. Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors. Washington, DC: The National Academies Press.

180 Syed, S.T., Gerber, B.S., and Sharp, L.K. (2013). Traveling Towards Disease: Transportation Barriers to Health Care Access. *J Community Health*. 38(5): 976–993.

management. Adopting a data element to collect and analyze information regarding transportation needs across PAC settings would facilitate the connection to programs that can address identified needs. We are therefore proposing to adopt as SPADE a single transportation data element that is from the Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences (PRAPARE) assessment tool and currently part of the Accountable Health Communities (AHC) Screening Tool.

The proposed Transportation data element from the PRAPARE tool asks, "Has lack of transportation kept you from medical appointments, meetings, work, or from getting things needed for daily living?" The three response options are: (1) Yes, it has kept me from medical appointments or from getting my medications; (2) Yes, it has kept me from non-medical meetings, appointments, work, or from getting things that I need; and (3) No. The patient or resident would be given the option to select all responses that apply. We are proposing to use the transportation data element from the PRAPARE Tool, with permission from National Association of Community Health Centers (NACHC), after considering research on the importance of addressing transportation needs as a critical SDOH.¹⁸¹

The proposed data element is responsive to research on the importance of addressing transportation needs as a critical SDOH and would adopt the Transportation item from the PRAPARE tool.¹⁸² This data element comes from the national PRAPARE social determinants of health assessment protocol, developed and owned by NACHC, in partnership with the Association of Asian Pacific Community Health Organization, the Oregon Primary Care

181 Health Research & Educational Trust. (2017, November). Social determinants of health series: Transportation and the role of hospitals. Chicago, IL. Available at www.aha.org/transportation.

182 Health Research & Educational Trust. (2017, November). Social determinants of health series: Transportation and the role of hospitals. Chicago, IL. Available at www.aha.org/transportation.

Association, and the Institute for Alternative Futures. Similarly the Transportation data element used in the AHC Screening Tool was adapted from the PRAPARE tool. The AHC screening tool was implemented by the Center for Medicare and Medicaid Innovation's AHC Model and developed by a panel of interdisciplinary experts that looked at evidence-based ways to measure SDOH, including transportation. While the transportation access data element in the AHC screening tool serves the same purposes as our proposed SPADE collection about transportation barriers, the AHC tool has binary yes or no response options that do not differentiate between challenges for medical versus non-medical appointments and activities. We believe that this is an important nuance for informing PAC discharge planning to a community setting, as transportation needs for non-medical activities may differ than for medical activities and should be taken into account.¹⁸³ We believe that use of this data element will provide sufficient information about transportation barriers to medical and non-medical care for SNF residents and patients to facilitate appropriate discharge planning and care coordination across PAC settings. As such, we are proposing to adopt the Transportation data element from PRAPARE. More information about development of the PRAPARE tool is available on the website at <https://protect2.fireeye.com/url?k=7cb6eb44-20e2f238-7cb6da7b-0cc47adc5fa2-1751cb986c8c2f8c&u=http://www.nachc.org/prapare>.

In addition, we received stakeholder feedback during the December 13, 2018 SDOH listening session on the impact of transportation barriers on unmet care needs. While recognizing that there is no consensus in the field about whether providers should have

183 Northwestern University. (2017). PROMIS Item Bank v. 1.0 – Emotional Distress – Anger - Short Form 1.

responsibility for resolving patient transportation needs, discussion focused on the importance of assessing transportation barriers to facilitate connections with available community resources.

Adding a Transportation data element to the collection of SPADE would be an important step to identifying and addressing SDOH that impact health outcomes and patient experience for Medicare beneficiaries. For more information on the Transportation data element, we refer readers to the document titled “Proposed Specifications for SNF QRP Measures and Standardized Patient Assessment Data Elements,” available on the website at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

In an effort to standardize the submission of transportation data among IRFs, HHAs, SNFs and LTCHs, for the purposes outlined in section 1899B(a)(1)(B) of the Act, while minimizing the reporting burden, we are proposing to adopt the Transportation data element described above as SPADE with respect to the Social Determinants of Health category. If finalized as proposed, we would add the Transportation data element to the MDS.

(e) Social Isolation

Distinct from loneliness, social isolation refers to an actual or perceived lack of contact with other people, such as living alone or residing in a remote area.^{184,185} Social isolation tends to increase with age, is a risk factor for physical and mental illness, and a predictor of mortality.^{186,187,188} Post-acute care providers are well-suited to design and implement programs

184 Tomaka, J., Thompson, S., and Palacios, R. (2006). The Relation of Social Isolation, Loneliness, and Social Support to Disease Outcomes Among the Elderly. *J of Aging and Health*. 18(3): 359-384.

185 Social Connectedness and Engagement Technology for Long-Term and Post-Acute Care: A Primer and Provider Selection Guide. (2019). *Leading Age*. Available at <https://www.leadingage.org/white-papers/social-connectedness-and-engagement-technology-long-term-and-post-acute-care-primer-and#1.1>

186 Landeiro, F., Barrows, P., Nuttall Musson, E., Gray, A.M., and Leal, J. (2017). Reducing Social Loneliness in Older People: A Systematic Review Protocol. *BMJ Open*. 7(5): e013778.

to increase social engagement of patients and residents, while also taking into account individual needs and preferences. Adopting a data element to collect and analyze information about social isolation in SNFs and across PAC settings would facilitate the identification of residents and patients who are socially isolated and who may benefit from engagement efforts.

We are proposing to adopt as SPADE a single social isolation data element that is currently part of the AHC Screening Tool. The AHC item was selected from the Patient-Reported Outcomes Measurement Information System (PROMIS®) Item Bank on Emotional Distress and asks, “How often do you feel lonely or isolated from those around you?” The five response options are: (1) Never; (2) Rarely; (3) Sometimes; (4) Often; and (5) Always.¹⁸⁹ The AHC Screening Tool was developed by a panel of interdisciplinary experts that looked at evidence-based ways to measure SDOH, including social isolation. More information about the AHC Screening Tool is available on the website at

<https://innovation.cms.gov/Files/worksheets/ahcm-screeningtool.pdf>.

In addition, we received stakeholder feedback during the December 13, 2018 SDOH listening session on the value of receiving information on social isolation for purposes of care planning. Some stakeholders also recommended assessing social isolation as an SDOH as opposed to social support.

The proposed Social Isolation data element is consistent with NASEM considerations about social isolation as a function of social relationships that impacts health outcomes and increases mortality risk, as well as the current work of a NASEM committee examining how

187 Ong, A.D., Uchino, B.N. and Wethington, E. (2016). Loneliness and Health in Older Adults: A Mini-Review and Synthesis. *Gerontology*. 62:443-449.

188 Leigh-Hunt, N., Bagguley, D., Bash, K., Turner, V., Turnbull, S., Valtorta, N., and Caan, W. (2017). An overview of systematic reviews on the public health consequences of social isolation and loneliness. *Public Health*. 152:157-171.

189 Northwestern University. (2017). PROMIS Item Bank v. 1.0 – Emotional Distress – Anger - Short Form 1.

social isolation and loneliness impact health outcomes in adults 50 years and older. We believe that adding a Social Isolation data element would be an important component of better understanding resident and patient complexity and the care goals of residents and patients, thereby facilitating care coordination and continuity in care planning across PAC settings. For more information on the Social Isolation data element, we refer readers to the document titled “Proposed Specifications for SNF QRP Measures and Standardized Patient Assessment Data Elements,” available on the website at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

In an effort to standardize the submission of social isolation data among IRFs, HHAs, SNFs and LTCHs, for the purposes outlined in section 1899B(a)(1)(B) of the Act, while minimizing the reporting burden, we are proposing to adopt the Social Isolation data element described above as SPADE with respect to the proposed Social Determinants of Health category. We are proposing to add the Social Isolation data element to the MDS.

We are soliciting comment on these proposals.

8. Proposed Form, Manner, and Timing of Data Submission under the SNF QRP
 - a. Background

We refer readers to the regulatory text at §413.360(b) for information regarding the current policies for reporting SNF QRP data.

- b. Update to the CMS System for Reporting Quality Measures and Standardized Patient Assessment Data and Associated Procedural Proposals

SNFs are currently required to submit MDS data to CMS using the Quality Improvement and Evaluation System (QIES) Assessment and Submission Processing (ASAP) system. We will be migrating to a new internet Quality Improvement and Evaluation System (iQIES) that will

enable real-time upgrades over the next few years, and we are proposing to designate that system as the data submission system for the SNF QRP once it becomes available, but no later than October 1, 2021.

We are proposing to revise our regulatory text at §413.360(a) by replacing “Certification and Survey Provider Enhanced Reports (CASPER)” with “CMS designated data submission”. We are proposing to revise our regulatory text at §413.360(d)(1) by replacing the reference to the “Quality Improvement Evaluation System (QIES) Assessment Submission and Processing (ASAP)” with “CMS designated data submission” and §413.360(d)(4) by replacing the reference to “QIES ASAP” with “CMS designated data submission system” effective October 1, 2019. In addition we are proposing to notify the public of any future changes to the CMS designated system using subregulatory mechanisms, such as website postings, listserv messaging, and webinars.

We invite public comments on this proposal.

c. Proposed Schedule for Reporting the Transfer of Health Information Quality Measures Beginning With the FY 2022 SNF QRP

As discussed in section VI.A.4. of this proposed rule, we are proposing to adopt the Transfer of Health Information to Provider–Post-Acute Care (PAC) and Transfer of Health Information to Patient–Post-Acute Care (PAC) quality measures beginning with the FY 2022 SNF QRP. We also are proposing that SNFs would report the data on those measures using the MDS. SNFs would be required to collect data on both measures for residents beginning with October 1, 2020 discharges.

We refer readers to the FY 2018 SNF PPS final rule (82 FR 36601 through 36603) for the data collection and submission time frames that we finalized for the SNF QRP.

We invite public comment on this proposal.

d. Proposed Schedule for Reporting Standardized Patient Assessment Data Elements

As discussed in section VI.A.6. of this proposed rule, we are proposing to adopt SPADEs beginning with the FY 2022 SNF QRP. We are proposing that SNFs would report the data using the MDS. Similar to the proposed schedule for reporting the Transfer of Health Information to the Provider–Post-Acute Care (PAC) and Transfer of Health Information to the Patient–Post-Acute Care (PAC) quality measures, SNFs would be required to collect the SPADEs for residents beginning with October 1, 2020 admissions and discharges. SNFs that submit data with respect to admission for the Hearing, Vision, Race, and Ethnicity SPADEs would be considered to have submitted data with respect to discharges. We refer readers to the FY 2018 SNF PPS final rule (82 FR 36601 through 36603) for the data collection and submission time frames that we finalized for the SNF QRP.

e. Proposed Data Reporting on Residents for the SNF Quality Reporting Program Beginning with the FY 2022 SNF QRP

We have received public input suggesting that the quality measures used in the SNF QRP should be calculated using data collected from all residents receiving SNF services, regardless of the residents' payer. This input was provided to us via comments requested about quality measure development on the CMS Measures Management System Blueprint website,¹⁹⁰ the TEPs held by our measure development contractor,¹⁹¹ as well as through comments we received

190 Public Comment Summary Report Posting for Transfer of Health Information and Care Preferences. <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Development-of-Cross-Setting-Transfer-of-Health-Information-Quality-Meas.pdf>.

191 Technical Expert Panel Summary Report: Development and Maintenance of Quality Measures for Skilled Nursing Facility Quality Reporting Program. April 2018. https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/TEP-Summary-Report_April-2018_Development-and-Maintenance-of-Quality-Measures-for-SNF-QRP.pdf.

from stakeholders via our SNF QRP mailbox, and feedback received from the NQF-convened Measure Applications Partnership (MAP) as part of their recommendations on Coordination Strategy for Post-Acute Care and Long-Term Care Performance Measurement.¹⁹² Further, in the FY 2018 SNF PPS proposed rule (82 FR 21077), we sought input on expanding the reporting of quality data to include all residents, regardless of payer, so as to ensure that the SNF QRP makes publicly available information regarding the quality of the services furnished to the SNF population as a whole, rather than just those residents who have Medicare.

In response to that request for public input, several commenters, including MedPAC, submitted comments stating that they would be supportive of an effort to collect data specified under the SNF QRP from all SNF residents regardless of their payer. Benefits highlighted by commenters included that such data would serve to better inform beneficiaries on the broader quality of the entire SNF, as well as more comprehensive quality improvement efforts across payers. MedPAC also highlighted that while the data collection activity incurs some cost, some providers currently assess all residents routinely. For a more detailed discussion we refer readers to the FY 2018 final rule (82 FR 36603 through 36604).

Further, we believe that the most accurate representation of the quality provided in SNFs to Medicare residents would be best conveyed using data collected via the MDS on all SNF residents, regardless of payer.

Accordingly, we are proposing that for purposes of meeting the requirements of the SNF QRP, SNF would be required to collect and submit MDS data on all SNF residents regardless of their payer. We believe that this proposal will ensure that Medicare residents are receiving the

¹⁹² MAP Coordination Strategy for Post-Acute Care and Long-Term Care Performance Measurement. Feb 2012. http://www.qualityforum.org/Publications/2012/02/MAP_Coordination_Strategy_for_Post-Acute_Care_and_Long-Term_Care_Performance_Measurement.aspx.

same quality of SNF care as other residents.

While we appreciate that collecting quality data on all residents regardless of payer may create additional burden, we are aware that many SNFs currently collect MDS data on all residents, regardless of their payer, and that some SNFs may consider it burdensome to separate out Medicare beneficiaries from other residents for purposes of submitting the assessments to CMS.

We also note that collecting data on all SNF residents, regardless of their payer, would align our data collection requirements under the SNF QRP with the data collection requirements we have adopted for the LTCH QRP and Hospice QRP.

This proposal, if finalized, would be effective beginning with the FY 2022 program year.

We invite public comment on this proposal.

9. Proposed Policies Regarding Public Display of Measure Data for the SNF QRP

Section 1899B(g) of the Act requires the Secretary to establish procedures for making the SNF QRP data available to the public after ensuring that SNFs have the opportunity to review their data prior to public display. Measure data are currently displayed on the Nursing Home Compare website, an interactive web tool that assists individuals by providing information on SNF quality of care. For more information on Nursing Home Compare, we refer readers to the website at <https://www.medicare.gov/nursinghomecompare/search.html>. For a more detailed discussion about our policies regarding public display of SNF QRP measure data and procedures for the opportunity to review and correct data and information, we refer readers to the FY 2017 SNF PPS final rule (81 FR 52045 through 52048).

In this proposed rule, we are proposing to begin publicly displaying data for the Drug Regimen Review Conducted With Follow-Up for Identified Issues-Post Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP) measure beginning CY 2020

or as soon as technically feasible. We finalized the Drug Regimen Review Conducted With Follow-Up for Identified Issues-Post Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP) measure in the FY 2017 SNF PPS final rule (81 FR 52034 through 52039).

Data collection for this assessment-based measure began with patients admitted and discharged on or after October 1, 2018. We are proposing to display data based on four rolling quarters, initially using discharges from January 1, 2019 through December 31, 2019 (Quarter 1 2019 through Quarter 4 2019). To ensure the statistical reliability of the data, we are proposing that we would not publicly report a SNF's performance on the measure if the SNF had fewer than 20 eligible cases in any four consecutive rolling quarters. SNFs that have fewer than 20 eligible cases would be distinguished with a footnote that states, "The number of cases/resident stays is too small to publicly report". We invite public comment on our proposal.

B. Skilled Nursing Facility Value-Based Purchasing Program (SNF VBP)

1. Background

Section 215(b) of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93) authorized the SNF VBP Program (the "Program") by adding section 1888(h) to the Act. As a prerequisite to implementing the SNF VBP Program, in the FY 2016 SNF PPS final rule (80 FR 46409 through 46426), we adopted an all-cause, all-condition hospital readmission measure, as required by section 1888(g)(1) of the Act and discussed other policies to implement the Program such as performance standards, the performance period and baseline period, and scoring. In the FY 2017 SNF PPS final rule (81 FR 51986 through 52009), we adopted an all-condition, risk-adjusted potentially preventable hospital readmission measure for SNFs, as required by section 1888(g)(2) of the Act, and adopted policies on performance standards, performance scoring, and sought comment on an exchange function methodology to translate

SNF performance scores into value-based incentive payments, among other topics. In the FY 2018 SNF PPS final rule (82 FR 36608 through 36623), we adopted additional policies for the Program, including an exchange function methodology for disbursing value-based incentive payments. Additionally, in the FY 2019 SNF PPS final rule (83 FR 39272 through 39282), we adopted more policies for the Program, including a scoring adjustment for low-volume facilities.

The SNF VBP Program applies to freestanding SNFs, SNFs affiliated with acute care facilities, and all non-CAH swing-bed rural hospitals. Section 1888(h)(1)(B) of the Act requires that the SNF VBP Program apply to payments for services furnished on or after October 1, 2018. We believe the implementation of the SNF VBP Program is an important step towards transforming how care is paid for, moving increasingly towards rewarding better value, outcomes, and innovations instead of merely rewarding volume.

For additional background information on the SNF VBP Program, including an overview of the SNF VBP Report to Congress and a summary of the Program's statutory requirements, we refer readers to the FY 2016 SNF PPS final rule (80 FR 46409 through 46410). We also refer readers to the FY 2017 SNF PPS final rule (81 FR 51986 through 52009) for discussion of the policies that we adopted related to the potentially preventable hospital readmission measure, scoring, and other topics. We refer readers to the FY 2018 SNF PPS final rule (82 FR 36608 through 36623) for discussions of the policies that we adopted related to value-based incentive payments, the exchange function, and other topics. Finally, we refer readers to the FY 2019 SNF PPS final rule (83 FR 39272 through 39282), where we adopted a corrections policy for numerical values of performance standards, a scoring adjustment for low-volume facilities, and addressed other topics.

2. Measures

a. Background

For background on the measures we have adopted for the SNF VBP Program, we refer readers to the FY 2016 SNF PPS final rule (80 FR 46419), where we finalized the Skilled Nursing Facility 30-Day All-Cause Readmission Measure (SNFRM) (NQF #2510) that we are currently using for the SNF VBP Program. We also refer readers to the FY 2017 SNF PPS final rule (81 FR 51987 through 51995), where we finalized the Skilled Nursing Facility 30-Day Potentially Preventable Readmission Measure (SNFPPR) that we will use for the SNF VBP Program instead of the SNFRM as soon as practicable, as required by statute.

b. SNFPPR Update – Change of Measure Name

In the FY 2017 SNF PPS final rule (81 FR 51987 to 51995), we adopted the SNFPPR as the SNF all-condition risk-adjusted potentially preventable hospital readmission measure for the SNF VBP Program to meet the requirements in section 1888(g)(2) of the Act. This claims-based measure assesses the facility-level risk-standardized rate of unplanned, potentially preventable hospital readmissions for SNF patients within 30 days of discharge from a prior admission to an Inpatient Prospective Payment System (IPPS) hospital, CAH, or psychiatric hospital. However, we have not yet transitioned the SNF VBP Program to using the SNFPPR.

The SNFPPR is one of two potentially preventable readmission measures specified for use in the SNF setting. The SNFPPR is specified for use for the SNF VBP Program and a second measure, the Potentially Preventable 30-Day Post-Discharge Readmission Measure for Skilled Nursing Facility Quality Reporting Program, is specified for use in the SNF QRP. While these two measures are aligned in terms of exclusion criteria and risk adjustment approach, they differ in their readmission windows. The SNFPPR utilizes a 30-day post-hospital discharge readmission window whereas the SNF QRP potentially preventable readmission measure utilizes a 30-day post-SNF discharge readmission window, consistent with the discharge readmission window specified in other measures we have developed with respect to domains described in

section 1899B of the Act, such as the Potentially Preventable 30-Day Post-Discharge Readmission Measure for Inpatient Rehabilitation Facility QRP and the Potentially Preventable 30-Day Post-Discharge Readmission Measure for Home Health QRP.

As described in the FY 2017 SNF PPS final rule (81 FR 51992), our rationale for having two different measures was that the readmission window associated with each measure assesses different aspects of SNF care. The readmission window for the SNFPPR measure was developed to align with the SNFRM which was previously adopted for the SNF VBP Program. Both the SNFRM and SNFPPR measure specifications, including the readmission window, were designed to harmonize with CMS's Hospital Wide All-Cause Unplanned Readmission (HWR) measure used in the Hospital IQR Program. The advantage of this window is that it assesses readmissions both during the SNF stay and post-SNF discharge for most SNF patients, depending on the SNF length of stay (LOS).

The readmission window used for the SNF QRP measure aligns with the readmission window used in other readmission measures for post-acute care (PAC) providers. The focus of this post-PAC only discharge readmission window is on assessing potentially preventable hospital readmissions during the 30 days after discharge from the PAC provider.

While the SNFPPR and the SNF QRP potentially preventable readmission measures assess different aspects of SNF care, we have received stakeholder feedback that having two SNF potentially preventable readmission measures has caused confusion. To minimize the confusion surrounding these two different measures, we are changing the name of the SNFPPR to Skilled Nursing Facility Potentially Preventable Readmissions after Hospital Discharge. We believe this new measure name will clearly differentiate the SNF VBP potentially preventable readmission measure from the SNF QRP potentially preventable readmission measure, thereby reducing stakeholder confusion. We intend to submit the SNFPPR measure, hereafter referred to

as the Skilled Nursing Facility Potentially Preventable Readmissions after Hospital Discharge measure, to the National Quality Forum (NQF) for endorsement review as soon as that is feasible.

3. FY 2022 Performance Period and Baseline Period and for Subsequent Years

We refer readers to the FY 2016 SNF PPS final rule (80 FR 46422) for a discussion of our considerations for determining performance periods under the SNF VBP Program. Based on those considerations, as well as public comment, we adopted CY 2017 as the performance period for the FY 2019 SNF VBP Program, with a corresponding baseline period of CY 2015.

Additionally, in the FY 2018 SNF PPS final rule (82 FR 36613 through 36614), we adopted FY 2018 as the performance period for the FY 2020 SNF VBP Program, with a corresponding baseline period of FY 2016. We refer readers to that rule for a discussion of the need to shift the Program's measurement periods from the calendar year to the fiscal year. Finally, we refer readers to the FY 2019 SNF PPS final rule (83 FR 39277 through 39278), where we adopted FY 2019 as the performance period for the FY 2021 program year, with a corresponding baseline period of FY 2017. In that final rule, we also adopted a policy where we would adopt for each program year a performance period that is the 1-year period following the performance period for the previous program year. We adopted a similar policy for the baseline period, where we stated that we would adopt for each program year a baseline period that is the 1-year period following the baseline period for the previous year.

Under this policy, the performance period for the FY 2022 program year will be FY 2020, and the baseline period will be FY 2018.

4. Performance Standards

a. Background

We refer readers to the FY 2017 SNF PPS final rule (81 FR 51995 through 51998) for a

summary of the statutory provisions governing performance standards under the SNF VBP Program and our finalized performance standards policy, as well as the numerical values for the achievement threshold and benchmark for the FY 2019 program year. We also responded to public comments on these policies in that final rule.

We published the final numerical values for the FY 2020 performance standards in the FY 2018 SNF PPS final rule (82 FR 36613) and published the final numerical values for the FY 2021 performance standards in the FY 2019 SNF PPS final rule (83 FR 39276). We also adopted a policy allowing us to correct the numerical values of the performance standards in the FY 2019 SNF PPS final rule (83 FR 39276 through 39277).

b. FY 2022 Performance Standards

As we discuss in this proposed rule, we will adopt FY 2018 as the baseline period for the FY 2022 program year under our previously-adopted policy of advancing the performance and baseline period for each program year automatically.

Based on the baseline period for the FY 2022 program year, we are estimating that the performance standards would have the numerical values noted in Table 14. We note that these values represent estimates based on the most recently-available data, and we will update the numerical values in the FY 2020 SNF PPS final rule.

TABLE 14: Estimated FY 2022 SNF VBP Program Performance Standards

Measure ID	Measure Description	Achievement Threshold	Benchmark
SNFRM	SNF 30-Day All-Cause Readmission Measure (NQF #2510)	0.79476	0.83212

5. SNF VBP Performance Scoring

We refer readers to the FY 2017 SNF PPS final rule (81 FR 52000 through 52005) for a detailed discussion of the scoring methodology that we have finalized for the Program, along with responses to public comments on our policies and examples of scoring calculations. We

also refer readers to the FY 2018 SNF PPS final rule (82 FR 36614 through 36616) for discussion of the rounding policy we adopted, our request for comments on SNFs with zero readmissions, and our request for comments on a potential extraordinary circumstances exception policy.

We also refer readers to the FY 2019 SNF PPS final rule (83 FR 39278 through 39281), where we adopted 1) a scoring policy for SNFs without sufficient baseline period data, 2) a scoring adjustment for low-volume SNFs, and 3) an extraordinary circumstances exception policy.

We are not proposing any updates to SNF VBP scoring policies in this proposed rule.

6. SNF Value-Based Incentive Payments

We refer readers to the FY 2018 SNF PPS final rule (82 FR 36616 through 36621) for discussion of the exchange function methodology that we have adopted for the Program, as well as the specific form of the exchange function (logistic, or S-shaped curve) that we finalized, and the payback percentage of 60 percent. We adopted these policies for FY 2019 and subsequent fiscal years.

We also discussed the process that we undertake for reducing SNFs' adjusted Federal per diem rates under the Medicare SNF PPS and awarding value-based incentive payments in the FY 2019 SNF PPS final rule (83 FR 39281 through 39282).

For estimates of FY 2020 SNF VBP Program incentive payment multipliers, we encourage SNFs to refer to FY 2019 SNF VBP Program performance information, available at: <https://data.medicare.gov/Nursing-Home-Compare/SNF-VBP-Facility-Level-Dataset/284v-j9fz>. Our analysis of historical SNF VBP data shows that the Program's incentive payment multipliers appear to be relatively consistent over time. As a result, we believe that the FY 2019 payment results represent our best estimate of FY 2020 performance at this time.

We are not proposing any updates to SNF VBP payment policies in this proposed rule. However, for the reader's information, we modeled the estimated impacts of the low-volume adjustment policy that we established in the FY 2019 SNF PPS final rule for FY 2020 and estimate that the application of the low-volume adjustment policy to the FY 2020 program year would redistribute an additional \$8.1 million to these low-volume SNFs for that program year. This would increase the 60 percent payback percentage for FY 2020 by approximately 1.51 percent, resulting in a payback percentage for FY 2020 that is 61.51 percent of the estimated \$534.1 million in withheld funds for that fiscal year.

7. Public Reporting on the Nursing Home Compare Website

a. Background

Section 1888(g)(6) of the Act requires the Secretary to establish procedures to make SNFs' performance information on SNF VBP Program measures available to the public on the Nursing Home Compare website or a successor, and to provide SNFs an opportunity to review and submit corrections to that information prior to its publication. We began publishing SNFs' performance information on the SNFRM in accordance with this directive and the statutory deadline of October 1, 2017.

Additionally, section 1888(h)(9)(A) of the Act requires the Secretary to make available to the public certain information on SNFs' performance under the SNF VBP Program, including SNF Performance Scores and their ranking. Section 1888(h)(9)(B) of the Act requires the Secretary to post aggregate information on the 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.

In the FY 2017 SNF PPS final rule (81 FR 52009), we discussed the statutory requirements governing public reporting of SNFs' performance information under the SNF VBP

Program. We also sought and responded to public comments on issues that we should consider when posting performance information on Nursing Home Compare or a successor website. In the FY 2018 SNF PPS final rule (82 FR 36622 through 36623), we finalized our policy to publish SNF measure performance information under the SNF VBP Program on Nursing Home Compare after SNFs have had an opportunity to review and submit corrections to that information under the two-phase Review and Corrections process that we adopted in the FY 2017 SNF PPS final rule (81 FR 52007 through 52009) and for which we adopted additional requirements in the FY 2018 SNF PPS final rule. In the FY 2018 SNF PPS final rule, we also adopted requirements to rank SNFs and adopted data elements that we will include in the ranking to provide consumers and stakeholders with the necessary information to evaluate SNFs' performance under the Program.

b. Public Reporting of SNF Performance Scores, Achievement and Improvement Scores, and Ranking

As we have considered issues associated with public reporting of SNFs' performance information on the Nursing Home Compare website, we have identified an issue that we believe warrants additional discussion. Specifically, we are concerned that the performance information available for display for a specific SNF may, as a result of the application of two policies we have finalized for the Program, be confusing to the public. Specifically, SNFs with fewer than 25 eligible stays during the baseline period for a fiscal year will only be scored on achievement and will not have improvement information available for display. In addition, a SNF with fewer than 25 eligible stays during a performance period will receive an assigned SNF performance score for that Program year that results in a value-based incentive payment amount equal to the adjusted federal per diem rate that the SNF would have received for the fiscal year in the absence of the Program.

In these cases, we do not believe it would be appropriate to suppress the SNF's information entirely given the statutory requirements in section 1888(h)(9)(A) of the Act to publicly report SNF-specific information, but we are concerned about publishing performance information that is not based on enough data to convey a complete and reliable picture of a SNF's performance for the Program year.

Based on these considerations, we propose to suppress the SNF information available to display as follows: (1) if a SNF has fewer than 25 eligible stays during the baseline period for a Program year, we would not display the baseline RSRR or improvement score, though we would still display the performance period RSRR, achievement score and total performance score if the SNF had sufficient data during the performance period; (2) if a SNF has fewer than 25 eligible stays during the performance period for a Program year and receives an assigned SNF performance score as a result, we would report the assigned SNF performance score and we would not display the performance period RSRR, the achievement score or improvement score; and (3) if a SNF has zero eligible cases during the performance period for a Program year, we would not display any information for that SNF. Based on historical data, we estimate that approximately 16 percent of SNFs will have fewer than 25 eligible stays during the performance period and similarly approximately 16 percent of SNFs will have fewer than 25 stays in the baseline period for FY 2020.

We believe that this policy will ensure that we publish as much information as possible about the SNF VBP Program's performance assessments while ensuring that the published information is reliable and based on a sufficient quantity of information. We further believe that this policy will provide stakeholders with meaningful information about SNFs' performance under the Program.

We welcome public comment on this proposal.

8. Update to Phase One Review and Correction Deadline

In the FY 2017 SNF PPS final rule (81 FR 52007 through 52009), we adopted a two-phase review and corrections process for SNFs' quality measure data that will be made public under section 1888(g)(6) of the Act and SNF performance information that will be made public under section 1888(h)(9) of the Act. We explained that we would accept corrections to the quality measure data used to calculate the measure rates that are included in any SNF's quarterly confidential feedback report, and that we would provide SNFs with an annual confidential feedback report containing the performance information that will be made public. We detailed the process for requesting Phase One corrections and finalized a policy whereby we would accept Phase One corrections to any quarterly report provided during a calendar year until the following March 31.

However, as we have continued implementation of the SNF VBP Program, we have reconsidered what deadline would be appropriate for the Phase One correction process. Our experience managing the 2019 SNF VBP Program has shown that fewer than 10 facilities submitted sufficient correction information under the Phase One correction process after October 1, 2018 and before March 31, 2019. Additionally, we are concerned about the effects of the March 31 deadline on value-based incentive payment calculations since the deadline is currently 6 months after payment incentives begin. For example, performance score reports for the FY 2019 SNF VBP Program were provided in August 2018 and incentive payments for that FY were made beginning with services provided on October 1, 2018, but SNFs still had until March 31, 2019 to make a correction. We believe that the March 31 deadline also creates uncertainty for SNFs because, as shown above in the timeline that applied to the FY 2019 Program, their payment incentives could potentially change 6 months after they take effect. If we approve a correction request, we then need to reprocess several months of claims for the SNF in question

and potentially need to adjust the exchange function for the fiscal year depending on the scope of the correction and its effects on the payback percentage pool for the fiscal year. We do not believe these outcomes are beneficial to the Program or to SNFs that would have less predictability about their incentive payment percentages for the fiscal year. We believe that the lack of predictability for SNF payment percentages might adversely impact SNF financial planning because payment amounts would not be set for all SNFs until after the March 31 deadline.

We believe that we can mitigate this uncertainty by adopting a 30-day deadline for Phase One correction requests, and note that this proposal would align the Phase One review and correction process with the Phase Two process. Under current operations, we issue a report in June that contains all of the underlying claim information used to calculate the measure rate for the program year, as well as the measure rate itself. We are proposing that SNFs would have 30 days from the date that we issue that report to review the claims and measure rate information and to submit to us a correction request if the SNF believes that any of that information is inaccurate. We note that this proposal would not preclude a SNF from submitting a correction request for any claims for which it discovers an error prior to receiving the June report. However, the 30 day review and correction period would commence on the day that we issue the June report, and a SNF would not be able to request that we correct any underlying claims or its measure rate after the conclusion of that 30 day period.

We are proposing this deadline in lieu of the current March 31 deadline for Phase One corrections. We note that we initially proposed to adopt a 30-day deadline for Phase One corrections in the FY 2017 SNF PPS proposed rule (81 FR 24255), though we finalized a deadline of March 31 following the calendar year in which we provide the report. We adopted that extended deadline to balance our desire to ensure that measure data are sufficiently accurate

with SNFs' need for sufficient information with which to evaluate those reports, as well as to provide SNFs with more time to review each quarter's data. In addition, we encouraged SNFs to review the quarterly reports provided with stay-level information and make any corrections to claims before the proposed deadline. However, for the reasons discussed above, we now believe that a 30-day timeframe is sufficient for SNFs to determine if there were errors in its measure calculation by CMS or its contractor.

We believe that this policy will ensure that the underlying claims data that we use to calculate quality measure performance for the SNF VBP Program will be finalized prior to their use in scoring and payment calculations. We believe that this policy will also ensure that any corrections submitted under Phase One do not result in changes to quality measure data months after incentive payment calculations, which will also avoid changes to the exchange function, and as a result, changes to other SNFs' value-based incentive payment percentages for a fiscal year because of data errors for any SNFs. Our experience managing the 2019 SNF VBP Program indicates that very few SNFs would be adversely impacted by the earlier deadline. We also seek to provide SNFs with earlier final annual payment percentage information for their financial planning purposes.

We welcome public comments on this proposal.

VII. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), we are required to publish a 60-day notice in the **Federal Register** and solicit public comment before a "collection of information" requirement is submitted to the Office of Management and Budget (OMB) for review and approval. For the purposes of the PRA and this section of the preamble, collection of information is defined under 5 CFR 1320.3(c) of the PRA's implementing regulations.

To fairly evaluate whether an information collection should be approved by OMB, PRA section 3506(c)(2)(A) requires that we solicit comment on the following issues:

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

We are soliciting public comment on each of the section 3506(c)(2)(A)-required issues for the following information collection requirements (ICRs).

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2017 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm). In this regard, Table 15 presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of the mean hourly wage), and the adjusted hourly wage. The adjusted wage is used to derive this section's average cost estimates.

TABLE 15: National Occupational Employment and Wage Estimates

Occupation Title	Occupation Code	Mean Hourly Wage (\$/hr)	Fringe Benefits and Overhead (\$/hr)	Adjusted Hourly Wage (\$/hr)
Health Information Technician	29-2071	20.59	20.59	41.18
Registered Nurse	29-1141	35.36	35.36	70.72

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs

vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, we believe that doubling the mean hourly wage to help estimate the total cost is a reasonably accurate estimation method.

B. Proposed Information Collection Requirements (ICRs)

1. ICRs Regarding the SNF Quality Reporting Program (QRP)

The following proposed changes will be submitted to OMB for approval under control number 0938-1140 (CMS-10387). The changes would not impose any new or revised burden. Subject to renewal, the control number is currently set to expire on February 28, 2022. It was last approved on February 12, 2019, and remains active.

The Minimum Data Set (MDS) is part of the process for the clinical assessment of all SNF residents and serves multiple purposes. It is used as a data collection tool for SNFs in the PPS to inform the Patient Driven Payment Model (PDPM) for the purpose of reimbursement, for the SNF QRP for the purpose of monitoring the quality of care in SNFs, and under the requirements of Omnibus Budget Reconciliation Act (OBRA) 1987 for the collection of data for the purposes of comprehensive resident assessment, quality and care planning for SNF residents.

Under sections 4204(b) and 4214(d) of OBRA 1987, requirements related to the submission and retention of resident assessment data are not subject to the PRA. The MDS assessments that are used to inform payment consist of the PPS 5-day assessment, the PPS discharge assessment, and the optional Interim Payment Assessment (IPA). The requirements necessary to administer the payment rate methodology described in 42 CFR 413.337 are subject to the PRA. Thus, the PPS 5-day, PPS discharge, and IPA assessments are subject to the PRA

and are active under OMB control number 0938-1140¹⁹³. For the readers' convenience, the active burden estimates are summarized below in Table 16. It is important to note that SNFs currently collect and report data for the SNF QRP through the PPS 5-day and PPS discharge assessments, which are the same assessments used in the PDPM. The IPA is an optional assessment for the PDPM and is not used for the SNF QRP.

Section 2(a) of the IMPACT Act amended the statute by adding section 1899B to the Act, which requires, among other things, SNFs to report standardized patient assessment data, data on quality measures, and data on resource use and other measures. Under section 1899B(m) of the Act, modifications to the SNF assessment instrument, the MDS, required to achieve standardization of patient assessment data are exempt from PRA requirements. However, if the data elements for quality measures and standardized patient assessment data are finalized as proposed, then we believe that we will have met the requirements for standardization of patient assessment data. Therefore, the exemption of the SNF QRP from the PRA is no longer applicable such that the SNF QRP requirements and burden will be submitted to OMB for review and approval. The active ICR serves as the basis for which we now address the previously exempt requirements and burden.

Under our active information collection, only the PPS 5-day and PPS discharge assessments used in the PDPM are also used as the assessments for collecting quality measure and standardized patient assessment data under the SNF QRP. Our active burden sets out 51 minutes (0.85 hours) per PPS 5-day assessment and 51 minutes per PPS discharge assessment. Consistent with the FY 2019 SNF PPS final rule (August 8, 2018; 83 FR 39283) we continue to

¹⁹³ Available at https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201809-0938-009.

use the OMRA assessment (with 272 items) to estimate the amount of time to complete a PPS assessment. This is also consistent with our active information collection. In sections VI.A.4 and VI.A.7 of this rule, we propose to add 60.5 items across the PPS 5-day and PPS discharge assessments. Given that the PPS OMRA item set has 272 items (as compared to the PPS discharge assessment with 143 items) that are approved under our active collection, the added items, while increasing burden for each of the assessments, have no impact on our currently approved burden estimates since the active collection uses the PPS OMRA item set as a proxy for all assessments. Below, however, we are restating such burden as a courtesy to interested parties.

When calculating the burden for each assessment, we estimate it will take 40 minutes (0.6667 hours) at \$70.72/hr for an RN to collect the information necessary for preparing the assessment, 10 minutes (0.1667 hours) at \$55.95/hr (the average hourly wage for RN (\$70.72/hr) and health information technician (\$41.18/hr)) for staff to code the responses, and 1 minute (0.0167 hours) at \$41.18/hr for a health information technician to transmit the results. In total, we estimate that it will take 51 minutes (0.85 hours) to complete a single PPS assessment. Based on the adjusted hourly wages for the noted staff, we estimate that it will cost \$57.17 [$(\$70.72/\text{hr} \times 0.6667 \text{ hr}) + (\$55.95/\text{hr} \times 0.1667 \text{ hr}) + (\$41.18/\text{hr} \times 0.0167 \text{ hr})$] to prepare, code, and transmit each PPS assessment.

Based on our most current data, there are 15,471 Medicare Part A SNFs. Based on FY 2017 data, we estimate that 2,406,401 5-day PPS assessments will be completed and submitted by Part A SNFs each year under the PDPM and SNF QRP. We used the same number of assessments (2,406,401) as a proxy for the number of PPS discharge assessments that would be completed and submitted each year, since all residents who require a 5-day PPS assessment will also require a discharge assessment under the PDPM and SNF QRP. We use the Significant

Change in Status Assessment (SCSA) as a proxy to estimate the number of IPAs as the criteria for completing an SCSA is similar to that for the IPA. Based on FY 2017 data, 92,240 IPAs would be completed per year under the PDPM.

The total number of PPS 5-day assessments, PPS discharge assessments, and IPAs that would be completed across all facilities is 4,905,042 assessments (2,406,401 + 2,406,401 + 92,240, respectively). The total estimated time for all assessments across all facilities is 4,169,286 hours per year (4,905,042 assessments x 0.85 hours/assessment). For all assessments across all facilities, we estimate a burden of \$280,421,251 (4,905,042 assessments x \$57.17/assessment).

Given that our proposal to add 60.5 items across the PPS 5-day and PPS discharge assessments is accounted for by using the OMRA assessment as a proxy for all assessments, and given that our estimate for the number of Medicare Part A SNFs and for the number PPS 5-day and PPS discharge assessments completed and submitted by Part A SNFs each year remains unchanged, we are not proposing to revise or adjust any of our active burden estimates. In this regard, we will be submitting a revised information collection request to OMB to account for the added items.

In section VI.A.8.b. of this proposed rule, there are no burden implications associated with updating the data submission system to the iQIES for the SNF QRP once it becomes available, but no later than October 1, 2021. This designation is a replacement of the existing QIES ASAP data submission system and imposes no additional requirements or burden on the part of SNFs.

2. ICRs Regarding the SNF VBP Program

We are not proposing to remove, add, or revise any of our SNF VBP measure-related requirements or burden. Because this proposed rule would not impose any new or revised SNF

VBP collection of information requirements or burden, the rule contains no SNF-VBP related collections of information that would be subject to OMB approval under the authority of the PRA.

C. Summary of Proposed Requirements and Annual Burden Estimates

TABLE 16: Summary of Proposed Requirements and Annual Burden Estimates Under OMB Control Number 0938-1140 (CMS-10387)

Program Changes	No. Respondents	Responses (per respondent)	Total Responses	Time per Response (hr)	Total Time (hr)	Labor Cost per Hour (\$/hr)	Total Cost (\$)
Active Burden	15,471	317.04	4,905,042	0.85	4,169,286	varies	280,421,251
Proposed Changes	0	0	0	0	0	0	0
TOTAL	15,471	317.04	4,905,042	0.85	4,169,286	varies	280,421,251

D. Submission of PRA-Related Comments

We have submitted a copy of this proposed rule to OMB for its review of the rule's information collection and recordkeeping requirements. The requirements are not effective until they have been approved by OMB.

We invite public comments on our proposed information collection requirements/burden. If you wish to comment, please identify the rule (CMS-1718-P) along with the information collection's CMS ID number (CMS-10387) and OMB control number (0938-1140).

To obtain copies of the supporting statement and any applicable supplementary materials, you may make your request using one of following:

1. Access CMS' Web Site address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.
2. E-mail your request, including your address, phone number, OMB control number, and CMS document identifier to Paperwork@cms.hhs.gov.
3. Call the Reports Clearance Office at 410-786-1326.

See this rule's DATES and ADDRESSES sections for the comment due date and for additional instructions.

VIII. Response to Comments

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

IX. Economic Analyses

A. Regulatory Impact Analysis

1. Statement of Need

This proposed rule would update the FY 2019 SNF prospective payment rates 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 on these issues.

2. Introduction

We have examined the impacts of this proposed 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), the Congressional Review Act (5 U.S.C. 804(2)),

and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). 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.

3. Overall Impacts

This proposed rule sets forth updates of the SNF PPS rates contained in the SNF PPS final rule for FY 2019 (83 FR 39162). We estimate that the aggregate impact will be an increase of approximately \$887 million in payments to SNFs in FY 2020, resulting from the SNF market basket update to the payment rates. We note that these impact numbers do not incorporate the SNF VBP reductions that we estimate will total \$527.4 million in FY 2020. We would note that 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 events that may occur within the assessed impact time period.

In accordance with sections 1888(e)(4)(E) and 1888(e)(5) of the Act, we update the FY 2019 payment rates by a factor equal to the market basket index percentage change adjusted by the MFP adjustment to determine the payment rates for FY 2020. The impact to Medicare is included in the total column of Table 17. In updating the SNF PPS rates for FY 2020, we made a number of standard annual revisions and clarifications mentioned elsewhere in this proposed 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 proposed rule applies to SNF PPS payments in FY 2020. Accordingly, the analysis of the impact of the annual update that follows only describes the impact of this single year. Furthermore, in accordance with the requirements of the Act, we will publish a rule or notice for each subsequent FY that will provide for an update to the payment rates and include an associated impact analysis.

4. Detailed Economic Analysis

The FY 2020 SNF PPS payment impacts appear in Table 17. Using the most recently available data, in this case FY 2018, we apply the current FY 2019 wage index and labor-related share value to the number of payment days to simulate FY 2019 payments. Then, using the same FY 2018 data, we apply the proposed FY 2020 wage index and labor-related share value to simulate FY 2020 payments. We tabulate the resulting payments according to the classifications in Table 17 (for example, facility type, geographic region, facility ownership), and compare the simulated FY 2019 payments to the simulated FY 2020 payments to determine the overall impact. The breakdown of the various categories of data Table 17 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 transition to PDPM. This represents the effect on providers, assuming no changes in behavior or case-mix, from changing the case-mix classification model used to classify patients in a Medicare Part A SNF stay. The total impact of this change is 0.0 percent; however, there are distributional effects of this change.

- The fourth 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 0.0 percent; however, there are distributional effects of the change.

- The fifth column shows the effect of all of the changes on the FY 2020 payments. The update of 2.5 percent 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 2.5 percent, assuming facilities do not change their care delivery and billing practices in response.

As illustrated in Table 17, the combined effects of all of the changes vary by specific types of providers and by location. For example, due to changes in this proposed rule, providers in the urban Pacific region would experience a 1.7 percent increase in FY 2020 total payments.

TABLE 17: Impact to the SNF PPS for FY 2020

	Number of Facilities FY 2020	PDPM Impact	Update Wage Data	Total Change
Group				
Total	15,078	0.0%	0.0%	2.5%
Urban	10,951	-0.7%	0.0%	1.8%
Rural	4,127	3.7%	0.2%	6.4%
Hospital-based urban	380	10.0%	0.1%	12.6%
Freestanding urban	10,571	-1.0%	-0.1%	1.5%
Hospital-based rural	245	20.4%	0.4%	23.3%
Freestanding rural	3,882	3.1%	0.2%	5.8%
Urban by region				
New England	775	2.0%	-0.5%	4.0%
Middle Atlantic	1,470	-3.1%	-0.2%	-0.8%
South Atlantic	1,868	-0.7%	-0.2%	1.6%
East North Central	2,118	0.1%	0.0%	2.5%
East South Central	536	0.7%	-0.1%	3.1%
West North Central	921	3.8%	0.6%	6.9%
West South Central	1,323	-1.2%	0.3%	1.5%
Mountain	527	0.0%	0.2%	2.7%
Pacific	1,407	-0.9%	0.0%	1.7%
Outlying	6	58.7%	0.1%	61.3%
Rural by region				
New England	126	5.4%	-1.5%	6.3%
Middle Atlantic	194	2.3%	0.1%	4.9%
South Atlantic	462	4.2%	0.3%	7.0%
East North Central	908	3.4%	-0.1%	5.8%
East South Central	452	2.4%	0.4%	5.3%
West North Central	1,020	10.2%	0.5%	13.2%
West South Central	666	-0.4%	0.4%	2.5%
Mountain	207	6.0%	1.2%	9.8%
Pacific	92	1.4%	0.3%	4.2%
Ownership				
For profit	10,729	-0.6%	0.0%	1.9%
Non-profit	3,469	1.5%	0.0%	4.0%
Government	880	4.5%	0.1%	7.2%

Note: The Total column includes the 2.5 percent market basket increase factor. Additionally, we found no SNFs in rural outlying areas.

5. Estimated Impacts for the Skilled Nursing Facility (SNF) Quality Reporting Program (QRP)

Estimated impacts for the SNF QRP are based on analysis discussed in section VII.B.1. of this proposed rule. The proposed SNF QRP requirements add no additional burden to the active OMB # 0938-1140 (CMS-10387).

6. Impacts for the SNF VBP Program

Estimated impacts of the FY 2020 SNF VBP Program are based on historical data and appear in Table 18. We modeled SNF performance in the Program using SNFRM data from CY 2015 as the baseline period and CY 2017 as the performance period. Additionally, we modeled a logistic exchange function with a payback percentage of 60 percent, as we finalized in the FY 2018 SNF PPS final rule (82 FR 36619 through 36621), though we note that the 60 percent payback percentage for FY 2020 will adjust to account for the low-volume scoring adjustment that we adopted in the FY 2019 SNF PPS final rule (83 FR 39278 through 39280). Based on the 60 percent payback percentage (as modified by the low-income scoring adjustment), we estimate that we will redistribute approximately \$320.4 million in value-based incentive payments to SNFs in FY 2020, which means that the SNF VBP Program is estimated to result in approximately \$213.6 million in savings to the Medicare Program in FY 2020. We refer readers to the FY 2019 SNF PPS final rule (83 FR 39278 through 39280) for additional information about payment adjustments for low-volume SNFs in the SNF VBP Program.

Our detailed analysis of the impacts of the FY 2020 SNF VBP Program follows in Table 18.

TABLE 18: Estimated SNF VBP Program Impacts for FY 2020

Characteristic	Number of facilities	Mean Risk-Standardized Readmission Rate (SNFRM) (%)	Mean performance score	Mean incentive multiplier	Percent of total incentive payment
Group					
Total	15,421	19.42	37.2169	0.99309	100.00
Urban	11,007	19.47	36.1519	0.99262	85.16
Rural	4,414	19.31	39.8729	0.99426	14.84
Hospital-based urban	355	19.08	42.6453	0.99546	2.14
Freestanding urban	10,602	19.48	35.9056	0.99251	82.98
Hospital-based rural	246	18.98	46.9882	0.99756	0.57
Freestanding rural	3,943	19.32	39.3322	0.994	14.11
Urban by region					
New England	786	19.54	33.0786	0.99119	5.75
Middle Atlantic	1,473	19.25	38.8823	0.99365	15.92
South Atlantic	1,869	19.56	35.6803	0.99256	17.39
East North Central	2,122	19.52	34.5595	0.99174	14.08
East South Central	551	19.69	32.2849	0.99095	3.68
West North Central	923	19.46	36.7211	0.99281	4.01
West South Central	1,336	19.84	31.4446	0.99065	7.32
Mountain	530	18.92	44.5446	0.99634	3.63
Pacific	1,411	19.20	40.4522	0.99475	13.36
Outlying	6	19.38	41.5899	0.99252	0.00
Rural by region					
New England	134	19.12	39.8964	0.99396	0.67
Middle Atlantic	214	19.14	40.4625	0.99406	0.86
South Atlantic	493	19.42	36.8815	0.99294	2.22
East North Central	931	19.15	40.6763	0.99452	3.43
East South Central	520	19.60	34.5229	0.99178	2.31
West North Central	1,064	19.14	44.0171	0.99615	1.93
West South Central	738	19.85	33.6008	0.99171	2.16
Mountain	222	18.78	49.4262	0.99862	0.65
Pacific	97	18.30	55.1379	1.00141	0.62
Outlying	1	18.98	37.0195	0.98788	0.00
Ownership					
Government	982	19.11	43.3338	0.99568	3.70
Profit	10,810	19.52	35.3904	0.99229	75.38
Non-Profit	3,629	19.20	41.0027	0.99478	20.92

7. Alternatives Considered

As described in this section, we estimated that the aggregate impact for FY 2020 under the SNF PPS will be an increase of approximately \$887 million in payments to SNFs, resulting from the SNF market basket update to the payment rates.

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 base 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 this process.

8. Accounting Statement

As required by OMB Circular A-4 (available online at https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/), in Tables 19 and 20, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this proposed rule for FY 2020. Tables 17 and 19 provide our best estimate of the possible changes in Medicare payments under the SNF PPS as a result of the policies in this proposed rule, based on the data for 15,078 SNFs in our database. Tables 18 and 20 provide our best estimate of the possible changes in Medicare payments under the SNF VBP as a result of the policies in this proposed rule.

TABLE 19: Accounting Statement: Classification of Estimated Expenditures, from the 2019 SNF PPS Fiscal Year to the 2020 SNF PPS Fiscal Year

Category	Transfers
Annualized Monetized Transfers	\$887 million*
From Whom To Whom?	Federal Government to SNF Medicare Providers

* The net increase of \$887 million in transfer payments is a result of the market basket increase of \$887 million.

TABLE 20: Accounting Statement: Classification of Estimated Expenditures for the FY 2020 SNF VBP Program

Category	Transfers
Annualized Monetized Transfers	\$320.4 million*
From Whom To Whom?	Federal Government to SNF Medicare Providers

*This estimate does not include the two percent reduction to SNFs' Medicare payments (estimated to be \$527.4 million) required by statute.

9. Conclusion

This proposed rule sets forth updates of the SNF PPS rates contained in the SNF PPS final rule for FY 2019 (83 FR 39162). Based on the above, we estimate that the overall payments for SNFs under the SNF PPS in FY 2020 are projected to increase by approximately \$887 million, or 2.5 percent, compared with those in FY 2019. We estimate that in FY 2020 under PDPM, SNFs in urban and rural areas will experience, on average, a 1.8 percent increase and 6.4 percent increase, respectively, in estimated payments compared with FY 2019. Providers in the urban Outlying region will experience the largest estimated increase in payments of approximately 61.3 percent. Providers in the urban Middle Atlantic region will experience the largest estimated decrease in payments of 0.8 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, for the purposes of the RFA, we estimate that almost all SNFs are small entities as that term is used in the RFA, 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 website at <http://www.sba.gov/category/navigation-structure/contracting/contracting-officials/eligibility-size-standards>). In addition, approximately 20 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 proposed rule sets forth updates of the SNF PPS rates contained in the SNF PPS final rule for FY 2019 (83 FR 39162). Based on the above, we estimate that the aggregate impact for FY 2020 will be an increase of \$887 million in payments to SNFs, resulting from the SNF market basket update to the payment rates. While it is projected in Table 18 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 2020 wage indexes, PDPM transition 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. In their March 2019 Report to Congress (available at http://medpac.gov/docs/default-source/reports/mar19_medpac_ch8_sec.pdf), MedPAC states that Medicare covers approximately 11 percent of total patient days in freestanding facilities and 19 percent of facility revenue (March 2019 MedPAC Report to Congress, 197). 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 18. As indicated in Table 18, the effect on facilities is projected to be an aggregate positive impact of 2.5 percent for FY 2020. 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 proposed rule will not have a significant impact on a substantial number of small entities for FY 2020.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an MSA and has fewer than 100 beds. This proposed 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 will be a positive impact. Moreover, as noted in previous SNF PPS final rules (most recently, the one for FY 2019 (83 FR 39288)), the category of small rural hospitals is included within the analysis of the impact of this proposed rule on small entities in general. As indicated in Table 18, the effect on facilities for FY 2020 is projected to be an aggregate positive impact of 2.5 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 for FY 2020.

C. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2019, that threshold is approximately \$154 million. This proposed rule will impose no mandates on state, local, or tribal governments or on the private sector.

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 proposed rule would have no substantial direct effect on state and local governments, preempt state law, or otherwise have federalism implications.

E. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771 (January 30, 2017) requires that the costs associated with significant new regulations “to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.” This proposed rule is not subject to the requirements of EO 13771 because it is expected to result in no more than de minimis costs.

F. Congressional Review Act

This proposed 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.

G. Regulatory Review Costs

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

welcome any comments on the approach in estimating the number of entities which will review the proposed rule.

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

Using the wage information from the BLS for medical and health service managers (Code 11-9111), we estimate that the cost of reviewing this rule is \$107.38 per hour, including overhead and fringe benefits https://www.bls.gov/oes/current/oes_nat.htm. Assuming an average reading speed, we estimate that it would take approximately 4 hours for the staff to review half of the proposed rule. For each SNF that reviews the rule, the estimated cost is \$429.52 (4 hours x \$107.38). Therefore, we estimate that the total cost of reviewing this regulation is \$124,561 (\$429.52 x 290 reviewers).

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

List of Subjects

42 CFR Part 409

Health facilities, Medicare.

42 CFR Part 413

Diseases, Health facilities, Medicare, Reporting and recordkeeping requirements.

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

PART 409--HOSPITAL INSURANCE BENEFITS

1. The authority citation for part 409 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

§409.30 [Amended]

2. Section 409.30 is amended in the introductory text by removing the phrase “the 5-day assessment” and adding in its place the phrase “the initial patient assessment”.

PART 413--PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES; PAYMENT FOR ACUTE KIDNEY INJURY DIALYSIS

3. The authority citation for part 413 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww; and sec. 124 of Public Law 106-113, 113 Stat. 1501A-332; sec. 3201 of Public Law 112-96, 126 Stat. 156; sec. 632 of Public Law 112-240, 126 Stat. 2354; sec. 217 of Public Law 113-93, 129 Stat. 1040; and sec. 204 of Public Law 113-295, 128 Stat. 4010; and sec. 808 of Public Law 114-27, 129 Stat. 362.

4. Section 413.343 is amended by revising paragraph (b) to read as follows:

§413.343 Resident assessment data.

* * * * *

(b) *Assessment schedule.* In accordance with the methodology described in §413.337(c) related to the adjustment of the Federal rates for case-mix, SNFs must submit assessments according to an assessment schedule. This schedule must include performance of an initial

patient assessment no later than the 8th day of posthospital SNF care and such other interim payment assessments as the SNF determines are necessary to account for changes in patient care needs.

* * * * *

5. Section 413.360 is amended by revising paragraphs (a) and (d)(1) and (4) to read as follows:

§ 413.360 Requirements under the Skilled Nursing Facility (SNF) Quality Reporting Program (QRP).

(a) *Participation start date.* Beginning with the FY 2018 program year, a SNF must begin reporting data in accordance with paragraph (b) of this section 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, which designates the SNF as operating in the CMS designated data submission system. For purposes of this section, a program year is the fiscal year in which the market basket percentage described in §413.337(d) is reduced by two percentage points if the SNF does not report data in accordance with paragraph (b) of this section.

* * * * *

(d) * * *

(1) SNFs that do not meet the requirements in paragraph (b) of this section for a program year will receive a notification of non-compliance sent through at least one of the following methods: the CMS designated data submission system, the United States Postal Service, or via an email from the Medicare Administrative Contractor (MAC). A SNF may request reconsideration no later than 30 calendar days after the date identified on the letter of non-compliance.

* * * * *

(4) CMS will notify SNFs, in writing, of its final decision regarding any reconsideration request through at least one of the following methods: CMS designated data submission system, the United States Postal Service, or via email from the CMS Medicare Administrative Contractor (MAC).

* * * * *

CMS-1718-P

Dated: March 26, 2019.

Seema Verma

Administrator,

Centers for Medicare & Medicaid Services.

Dated: April 2, 2019.

Alex M. Azar II,

Secretary,

Department of Health and Human Services.

[FR Doc. 2019-08108 Filed: 4/19/2019 4:15 pm; Publication Date: 4/25/2019]