



[Billing Code: 4120-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 409 and 413

[CMS-1718-F]

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: **Final rule.**

SUMMARY: This final rule updates the payment rates used under the prospective payment system (PPS) for skilled nursing facilities (SNFs) for fiscal year (FY) 2020. We also are making minor revisions to the regulation text to reflect the **revised assessment schedule** under the Patient Driven Payment Model (PDPM). Additionally, we are **revising the definition of group therapy under the SNF PPS**, and are implementing a subregulatory process for updating the **code lists** (International Classification of Diseases, Tenth Version (ICD-10) codes) used **under PDPM**. In addition, the final rule **updates requirements for the SNF Quality Reporting Program (QRP) and the SNF Value-Based Purchasing (VBP) Program.**

DATES: These regulations are effective on **October 1, 2019.**

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 the skilled nursing facility quality reporting program.

Lang Le, (410) 786-5693, for information related to the skilled nursing facility value-based purchasing program.

SUPPLEMENTARY INFORMATION:

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 final rule can be accessed on the SNF PPS Wage Index home page, at

<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPSP/WageIndex.html>.

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

I. Executive Summary

A. Purpose

This final rule updates 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 also responds to

section 1888(e)(4)(H) of the Act, which requires the Secretary to provide for publication of certain specified information relating to the payment update (see section II.C. of this final rule) in the **Federal Register**, before the August 1 that precedes the start of each FY. This final rule also revises the definition of group therapy under the SNF PPS and implements a subregulatory process for updating ICD-10 code lists used under the PDPM. Finally, this rule updates requirements for 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 (e)(5) of the Act, the federal rates in this final rule reflect an update to the rates that we published in the SNF PPS final rule for FY 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 revising the definition of group therapy under the SNF PPS and implementing a subregulatory process for updating ICD-10 code lists used under the PDPM.

This final rule updates requirements for the SNF QRP, including the adoption of two Transfer of Health Information quality measures and standardized patient assessment data elements that SNFs would be required to begin reporting with respect to admissions and discharges that occur on or after October 1, 2020. We also are finalizing our proposal to exclude baseline nursing home residents from the Discharge to Community Measure. Further, we also are finalizing our proposal to publicly display 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 also are finalizing our proposal to revise references in the regulations text to reflect enhancements to the system used for the submission

of data. Finally, we requested information on quality measures and standardized resident assessment data elements under consideration for future years, and we have summarized the information we received. In contrast, we are not finalizing our proposal to expand data collection for SNF QRP quality measures to all SNF residents, regardless of their payer.

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

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 final rule is an estimated increase of \$851 million in aggregate payments to SNFs during FY 2020.
FY 2020 Updates to the SNF QRP	The overall annual cost for SNFs to submit data for the SNF QRP for the provisions in this final rule is \$29 million
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. 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 DEL (<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 rules were open for public comment at www.regulations.gov. We invited 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 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/SNFPayment/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 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) of the Act, which requires the Secretary to implement a QRP 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 (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 final rule will provide the required annual updates to the per diem payment rates for SNFs for FY 2020.

III. Analysis and Responses to Public Comments on the FY 2020 SNF PPS Proposed Rule

In response to the publication of the FY 2020 SNF PPS proposed rule, we received 63 public comments from individuals, providers, corporations, government agencies, private citizens, trade associations, and major organizations. The following are brief summaries of each

proposed provision, a summary of the public comments that we received related to that proposal, and our responses to the comments.

A. General Comments on the FY 2020 SNF PPS Proposed Rule

In addition to the comments we received on specific proposals contained within the proposed rule (which we address later in this final rule), commenters also submitted the following, more general, observations on the SNF PPS and SNF care generally, as well as on aspects of PDPM that were finalized in the FY 2019 SNF PPS final rule. A discussion of these comments, along with our responses, appears below.

Comment: Many commenters expressed their continued support for implementation of PDPM. Many commenters also offered suggestions and recommendations for how to improve aspects of PDPM finalized in the FY 2019 SNF PPS final rule. Several commenters raised concerns regarding the impact of PDPM on other payers, such as on Medicare Advantage plans and on Medicaid programs, as well as on other CMS payment models, such as the Bundled Payment for Care Initiative and Accountable Care Organizations. A few commenters requested clarification on how PDPM would align with a unified post-acute payment system. Finally, several commenters raised concerns with certain structural elements of PDPM finalized in the FY 2019 final rule, such as the data used in developing the case-mix indexes under PDPM, the use of section GG on the MDS, and the effect of the variable per diem adjustment, specifically that used under the NTA component, on care provision.

Response: We appreciate all of the comments we received supporting PDPM implementation. We also appreciate all of the comments and suggestions on ways to improve PDPM in the future, including comments regarding changes in the structural elements of PDPM, such as the variable per diem adjustment or use of section GG on the MDS. However, because we consider these comments to be outside the scope of the current rulemaking, we are not

addressing them in this final rule. We will consider all of these recommendations as we consider future rulemaking.

For comments on the impact of PDPM on other payers, we have worked with each of these groups to provide education and training to aid in understanding the impact of PDPM implementation on the respective group. Most notably, we have worked closely with states to aid in navigating the transition to PDPM, while maintaining support for legacy case-mix systems necessary for certain state Medicaid programs. With regard to the impact of PDPM on alternative payment models, we have worked with the teams responsible for these policies to provide education on how PDPM changes payment under the SNF PPS and will ensure that evaluating the impact of PDPM on these models is a component of our monitoring program after implementation.

In terms of how PDPM would align with a unified post-acute payment system, we believe that PDPM represents an important step in aligning the SNF PPS with other post-acute payment systems, in anticipation of a unified post-acute payment system. Many of the aspects of PDPM finalized in the FY 2019 final rule, such as the use of patient characteristics as the basis for payment, and our revision in this final rule to the definition of group therapy (as discussed in section III.D.1. of this final rule), better align SNF PPS payment policies with those used in other post-acute settings.

Comment: Many commenters suggested that CMS monitor closely the financial, clinical, and outcome-related impacts of PDPM implementation. Several commenters requested clarification on contingency plans in case of assessment and/or claims submission and processing errors in the early stages of PDPM implementation. A few commenters requested that CMS consider convening a stakeholder workgroup to review data derived from the aforementioned monitoring activities and consider ways of sharing the data collected with stakeholders.

Response: We agree with commenters that close, real-time monitoring will be essential once PDPM is implemented. We are developing a robust monitoring program that will incorporate data from patient assessments, claims, cost reports, and quality measurement programs to identify any adverse or positive trends associated with PDPM implementation. With respect to sharing this data or convening a stakeholder workgroup, we are still in the process of determining the best way to share the data collected during our monitoring activities and the best way to engage with stakeholders to ensure a collective understanding of the data collected.

Regarding contingency plans for any issues in assessment or claims submission and/or processing after PDPM is implemented, CMS and its contractors intend to put adequate risk mitigation strategies in place to identify potential risk areas pre-emptively and ensure adequate testing to eliminate such risk. If any issues are identified after PDPM is implemented, we request that stakeholders alert us as soon as possible, so that the issue can be addressed.

Comment: A few commenters requested that CMS finalize the Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies proposed rule (80 FR 68126-68155), to ensure that hospitals provide SNFs with the necessary medical records and documentation used for both care planning and coding purposes in as timely a manner as possible. These commenters stated that the lack of such information represents a potentially serious program risk, as they often do not have the hospital information in as timely a manner as necessary for capturing such information on the MDS.

Response: We appreciate this comment and have shared with the appropriate CMS staff responsible for the proposed rule referenced above.

B. SNF PPS Rate Setting Methodology and FY 2020 Update

1. Federal Base Rates

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

2. SNF Market Basket Update

a. SNF Market Basket Index

Section 1888(e)(5)(A) of the Act requires us to establish a SNF market basket index that reflects changes over time in the prices of an appropriate mix of goods and services included in covered SNF services. Accordingly, we have developed a SNF market basket index that

encompasses the most commonly used cost categories for SNF routine services, ancillary services, and capital-related expenses. 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.2.d. of this final rule. For the FY 2020 proposed rule, the growth rate of the 2014-based SNF market basket was 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. However, as discussed in the FY 2020 proposed rule (84 FR 17624), our policy is that if more recent data become available (for example, a more recent estimate of the 2014-based SNF market basket or MFP adjustment), we would use such data, if appropriate, to determine the FY 2020 SNF market basket percentage change, labor-related share relative importance, forecast error adjustment, and MFP adjustment in the SNF PPS final rule. Since the proposed rule, we have updated the FY 2020 market basket percentage increase based on the IGI second quarter 2019 forecast, with historical data through first quarter 2019. The revised SNF market basket growth rate based on this updated data is 2.8 percent.

In section III.B.2.e. of this final 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.

b. **Use of the SNF Market Basket Percentage**

Section 1888(e)(5)(B) of the Act defines the SNF market basket percentage as the percentage change in the SNF market basket index from the midpoint of the previous FY to the midpoint of the current FY. For the federal rates set forth in this final rule, we use the percentage change in the SNF market basket index to compute the update factor for FY 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 final rule, the SNF market basket percentage is estimated to be 2.8 percent for FY 2020 based on IGI's second quarter 2019 forecast (with historical data through first quarter 2019). Finally, as discussed in section II.B.2. of this final rule, we no longer compute update factors to adjust a facility-specific portion of the SNF PPS rates, because the initial three-phase transition period from facility-specific to full federal rates that started with cost reporting periods beginning in July 1998 has expired.

c. Forecast Error Adjustment

As discussed in the June 10, 2003 supplemental proposed rule (68 FR 34768) and finalized in the August 4, 2003 final rule (68 FR 46057 through 46059), § 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 2.8 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 (2014-based index).

**Based on the second quarter 2019 IGI forecast, with historical data through the first quarter 2019 (2014-based index).

d. 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 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>.

(1) 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.

In the FY 2020 proposed rule, the MFP adjustment, calculated as the 10-year moving average of changes in MFP for the period ending September 30, 2020, was estimated to be 0.5 percent based on IGI's first quarter 2019 forecast. However, in the FY 2020 proposed rule (84 FR 17624), we stated that if more recent data became available (for example, a more recent estimate of the 2014-based SNF market basket or MFP adjustment), we would use such data, if appropriate, to determine the FY 2020 SNF market basket percentage change, labor-related share relative importance, forecast error adjustment, and MFP adjustment in the final rule. Since that time, we have updated the FY 2020 MFP adjustment based on the IGI second quarter 2019 forecast. The revised MFP adjustment based on updated data is 0.4 percent.

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 second quarter 2019 forecast of the SNF market basket percentage, which is estimated to be 2.8 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 which, as discussed above, is 0.4 percent. The resulting MFP-adjusted SNF market basket update is equal to 2.4 percent, or 2.8 percent less 0.4 percentage point.

e. Market Basket Update Factor for FY 2020

Sections 1888(e)(4)(E)(ii)(IV) and (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 2.8 percent.

As further explained in section III.B.2.c. of this final rule, as applicable, we adjust the market basket percentage change by the forecast error from the most recently available FY for which there is final data and apply this adjustment whenever the difference between the forecasted and actual percentage change in the market basket exceeds a 0.5 percentage point threshold. Since the 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 2.8 percent is not 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) which is 0.4 percent, as described in section III.B.2.d. of this final rule. The resulting net SNF market basket update would equal 2.4 percent, or 2.8 percent less the 0.4 percentage point MFP adjustment.

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.

As discussed above and in the proposed rule, we proposed 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 reflected a market basket increase factor of 3.0 percent, less a 0.5 percentage point MFP adjustment. However, as noted previously in this final rule, based on updated data, we are revising the FY 2020 SNF market basket update factor used in our determination of the FY 2020 SNF PPS unadjusted federal per diem rates, to 2.4 percent, which reflects a revised market basket percentage increase of 2.8 percent, less the revised 0.4 percentage point MFP adjustment.

We did not receive any comments regarding the calculation of the SNF market basket percentage increase or the MFP adjustment. Accordingly, for the reasons discussed in this final rule and in the FY 2020 SNF PPS proposed rule, we are finalizing the SNF market basket update factor of 2.4 percent, which reflects the updated SNF market basket percentage increase of 2.8 percent less the updated MFP adjustment of 0.4 percentage point.

f. **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 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	\$60.75	\$56.55	\$22.68	\$105.92	\$79.91	\$94.84

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

Rate Component	PT	OT	SLP	Nursing	NTA	Non-Case-Mix
Per Diem Amount	\$69.25	\$63.60	\$28.57	\$101.20	\$76.34	\$96.59

Commenters submitted the following comments related to the proposed rule's discussion of the Unadjusted Federal Per Diem rates for FY 2020. A discussion of these comments, along with our responses, appears below.

Comment: We received a number of comments in relation to applying the FY 2020 SNF market basket update factor in the determination of the FY 2020 unadjusted federal per diem rates, with most commenters supporting its application in determining the FY 2020 unadjusted per diem rates, while a few commenters opposed its application. In their March 2019 report

(available at http://www.medpac.gov/docs/default-source/reports/mar19_medpac_ch8_sec.pdf)

and in their comment on the FY 2020 SNF PPS proposed rule, MedPAC recommended that we eliminate the market basket update for SNFs altogether for FY 2020.

Response: We appreciate all of the comments received on the proposed market basket update for FY 2020. In response to those comments opposing the application of the FY 2020 market basket update factor in determining the FY 2020 unadjusted federal per diem rates, specifically MedPAC's proposal to eliminate the market basket update for SNFs, we are required to update the unadjusted federal per diem rates for FY 2020 by the SNF market basket percentage change in accordance with sections 1888(e)(4)(E)(ii)(IV) and (e)(5)(B) of the Act.

Comment: Several commenters raised concerns regarding the calculation of the proposed unadjusted federal per diem rates. These commenters believe that the unadjusted federal per diem rates were calculated using an increase factor greater than the proposed 2.5 percent and requested clarification on exactly how the unadjusted federal per diem rates for FY 2020 were calculated.

Response: We appreciate the commenters highlighting this concern regarding the calculation of the unadjusted federal per diem rates for FY 2020, but we believe the commenters did not account for the effect of an additional factor used in calculating the FY 2020 unadjusted federal per diem rates.

As discussed in the FY 2020 proposed rule (84 FR 17630), section 1888(e)(4)(G)(ii) of the Act requires that we apply the wage index adjustment 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. To accomplish this, as in prior years, we multiply 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. In the FY 2020 proposed rule, this wage adjustment budget neutrality factor was 1.0060. As noted below, due to an update in the data used for this calculation, this adjustment factor has been revised to be 1.0002.

Comment: One commenter raised concerns with how the base rates used under the SNF PPS, which have been adjusted by the SNF market basket each year, are based on cost reports from 1995. The commenters requested that CMS update the cost reporting base year used in deriving the unadjusted federal rates.

Response: We appreciate the commenter's suggestion regarding updating the cost reporting base year used for deriving the unadjusted federal per diem rates. However, section 1888(e)(4)(A) of the Act requires that we use the "allowable costs of extended care services (excluding exception payments) for the facility for cost reporting periods beginning in 1995." As such, we do not have the statutory authority to update the cost reporting base year used to derive the SNF PPS federal per diem rates.

Comment: Two commenters requested that CMS consider a cost of living adjustment, or COLA, for Hawaii and Alaska, stating that the absence of a COLA differentiates SNFs from hospitals, which do receive a COLA on non-labor costs. These commenters stated that providing care in these states is more expensive than others due to their unique circumstances.

Response: While the law specifically authorizes a COLA for Hawaii and Alaska for hospitals, it does not provide such an adjustment for SNFs in these states. Specifically, section 1886(d)(5)(H) of the Act authorizes the Secretary to make appropriate adjustments to reflect the unique circumstances of hospitals located in Alaska and Hawaii.

Accordingly, after considering the comments received, for the reasons specified in this final rule and in the FY 2020 SNF PPS proposed rule, **we are finalizing the unadjusted federal per diem rates set forth above,** which were derived in accordance with the methodology proposed

in the FY 2020 SNF PPS proposed rule (84 FR 17624 through 17625) (as discussed above), using the revised SNF market basket update of 2.4 percent and the revised wage index budget neutrality factor of 1.0002 (as discussed later in this preamble).

3. Case-Mix Adjustment

Under section 1888(e)(4)(G)(i) of the Act, the federal rate also incorporates an adjustment to account for facility case-mix, using a classification system that accounts for the relative resource utilization of different patient types. The statute specifies that the adjustment is to reflect both a resident classification system that the Secretary establishes to account for the relative resource use of different patient types, as well as resident assessment data and other data that the Secretary considers appropriate. In the 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 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 III.C.1. of this final rule, the clinical orientation of the case-mix classification system supports the SNF PPS's use of an administrative presumption that considers a beneficiary's initial case-mix classification to assist in making certain SNF level of care determinations. Further, because the MDS is used as a basis for payment, as well as a clinical assessment, we have provided

extensive training on proper coding and the timeframes for MDS completion in our Resident Assessment Instrument (RAI) Manual. As we have stated in prior rules, for an MDS to be considered valid for use in determining payment, the MDS assessment should 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) of the Act, 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 final rule reflect the use of the PDPM case-mix classification system from October 1, 2019, through September 30, 2020. In the FY 2020 SNF PPS proposed rule (84 FR 17627 through 17628), we listed the proposed case-mix adjusted PDPM payment rates for FY 2020, provided separately for urban and rural SNFs, in Tables A6 and A7 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.” 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 the proposed rule, we proposed 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. We stated in the proposed rule that 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 the proposed rule is that, in the proposed rule, we updated 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, was provided in Table 5 of the proposed rule (84 FR 17626). We 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 standardization and budget neutrality multipliers for this final rule are set forth in Table 5.

TABLE 5: 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

We did not receive any comments regarding our proposed calculation of the PDPM standardization and budget neutrality multipliers. Accordingly, for the reasons discussed in this final rule and in the FY 2020 SNF PPS proposed rule, we are finalizing the standardization and budget neutrality multipliers, as proposed, without modification, calculated based on FY 2018 data as set forth in Table 5. The CMIs provided in Tables 6 and 7 of this final rule reflect the use of the final multipliers in Table 5, which are based on FY 2018 data.

We stated in the proposed rule that given the differences between RUG-IV and PDPM in terms of patient classification and billing, it was 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 stated in the proposed rule that we were modifying the format of Tables A6 and A7 from what we have used for similar tables in prior SNF PPS rulemaking, such as Tables A6 and A7 of the FY 2019 SNF PPS final rule (83 FR 39170 through 39172). We stated in the proposed rule that Column 1 of modified Tables A6 and A7 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. We received no comments on the revised format of these tables.

Tables A6 and A7 reflect the final PDPM case-mix adjusted rates and case-mix indexes for FY 2020. Tables A6 and A7 do not reflect adjustments which may be made to the SNF PPS rates as a result of either the SNF QRP, discussed in section III.E.1. of this final rule, or the SNF VBP program, discussed in section III.E.2. of this final rule, or other adjustments, such as the

variable per diem adjustment. Further, we used 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	\$92.95	1.49	\$84.26	0.68	\$15.42	ES3	4.06	\$430.04	3.24	\$258.91
B	1.70	\$103.28	1.63	\$92.18	1.82	\$41.28	ES2	3.07	\$325.17	2.53	\$202.17
C	1.88	\$114.21	1.69	\$95.57	2.67	\$60.56	ES1	2.93	\$310.35	1.84	\$147.03
D	1.92	\$116.64	1.53	\$86.52	1.46	\$33.11	HDE2	2.40	\$254.21	1.33	\$106.28
E	1.42	\$86.27	1.41	\$79.74	2.34	\$53.07	HDE1	1.99	\$210.78	0.96	\$76.71
F	1.61	\$97.81	1.60	\$90.48	2.98	\$67.59	HBC2	2.24	\$237.26	0.72	\$57.54
G	1.67	\$101.45	1.64	\$92.74	2.04	\$46.27	HBC1	1.86	\$197.01	-	-
H	1.16	\$70.47	1.15	\$65.03	2.86	\$64.86	LDE2	2.08	\$220.31	-	-
I	1.13	\$68.65	1.18	\$66.73	3.53	\$80.06	LDE1	1.73	\$183.24	-	-
J	1.42	\$86.27	1.45	\$82.00	2.99	\$67.81	LBC2	1.72	\$182.18	-	-
K	1.52	\$92.34	1.54	\$87.09	3.70	\$83.92	LBC1	1.43	\$151.47	-	-
L	1.09	\$66.22	1.11	\$62.77	4.21	\$95.48	CDE2	1.87	\$198.07	-	-
M	1.27	\$77.15	1.30	\$73.52	-	-	CDE1	1.62	\$171.59	-	-
N	1.48	\$89.91	1.50	\$84.83	-	-	CBC2	1.55	\$164.18	-	-
O	1.55	\$94.16	1.55	\$87.65	-	-	CA2	1.09	\$115.45	-	-
P	1.08	\$65.61	1.09	\$61.64	-	-	CBC1	1.34	\$141.93	-	-
Q	-	-	-	-	-	-	CA1	0.94	\$99.56	-	-
R	-	-	-	-	-	-	BAB2	1.04	\$110.16	-	-
S	-	-	-	-	-	-	BAB1	0.99	\$104.86	-	-
T	-	-	-	-	-	-	PDE2	1.57	\$166.29	-	-
U	-	-	-	-	-	-	PDE1	1.47	\$155.70	-	-
V	-	-	-	-	-	-	PBC2	1.22	\$129.22	-	-
W	-	-	-	-	-	-	PA2	0.71	\$75.20	-	-
X	-	-	-	-	-	-	PBC1	1.13	\$119.69	-	-
Y	-	-	-	-	-	-	PA1	0.66	\$69.91	-	-

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	\$105.95	1.49	\$94.76	0.68	\$19.43	ES3	4.06	\$410.87	3.24	\$247.34
B	1.70	\$117.73	1.63	\$103.67	1.82	\$52.00	ES2	3.07	\$310.68	2.53	\$193.14
C	1.88	\$130.19	1.69	\$107.48	2.67	\$76.28	ES1	2.93	\$296.52	1.84	\$140.47
D	1.92	\$132.96	1.53	\$97.31	1.46	\$41.71	HDE2	2.40	\$242.88	1.33	\$101.53
E	1.42	\$98.34	1.41	\$89.68	2.34	\$66.85	HDE1	1.99	\$201.39	0.96	\$73.29
F	1.61	\$111.49	1.60	\$101.76	2.98	\$85.14	HBC2	2.24	\$226.69	0.72	\$54.96
G	1.67	\$115.65	1.64	\$104.30	2.04	\$58.28	HBC1	1.86	\$188.23	-	-
H	1.16	\$80.33	1.15	\$73.14	2.86	\$81.71	LDE2	2.08	\$210.50	-	-
I	1.13	\$78.25	1.18	\$75.05	3.53	\$100.85	LDE1	1.73	\$175.08	-	-
J	1.42	\$98.34	1.45	\$92.22	2.99	\$85.42	LBC2	1.72	\$174.06	-	-
K	1.52	\$105.26	1.54	\$97.94	3.70	\$105.71	LBC1	1.43	\$144.72	-	-
L	1.09	\$75.48	1.11	\$70.60	4.21	\$120.28	CDE2	1.87	\$189.24	-	-
M	1.27	\$87.95	1.30	\$82.68	-	-	CDE1	1.62	\$163.94	-	-
N	1.48	\$102.49	1.50	\$95.40	-	-	CBC2	1.55	\$156.86	-	-
O	1.55	\$107.34	1.55	\$98.58	-	-	CA2	1.09	\$110.31	-	-
P	1.08	\$74.79	1.09	\$69.32	-	-	CBC1	1.34	\$135.61	-	-
Q	-	-	-	-	-	-	CA1	0.94	\$95.13	-	-
R	-	-	-	-	-	-	BAB2	1.04	\$105.25	-	-
S	-	-	-	-	-	-	BAB1	0.99	\$100.19	-	-
T	-	-	-	-	-	-	PDE2	1.57	\$158.88	-	-
U	-	-	-	-	-	-	PDE1	1.47	\$148.76	-	-
V	-	-	-	-	-	-	PBC2	1.22	\$123.46	-	-
W	-	-	-	-	-	-	PA2	0.71	\$71.85	-	-
X	-	-	-	-	-	-	PBC1	1.13	\$114.36	-	-
Y	-	-	-	-	-	-	PA1	0.66	\$66.79	-	-

4. Wage Index Adjustment

Section 1888(e)(4)(G)(ii) of the Act requires that we adjust the federal rates to account for differences in area wage levels, using a wage index that the Secretary determines appropriate. Since the inception of the SNF PPS, we have used hospital inpatient wage data in developing a wage index to be applied to SNFs. We proposed to continue this practice for FY 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 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 believe this undertaking is feasible at this time.

In addition, we proposed to continue to use the same methodology discussed in the SNF PPS final rule for FY 2008 (72 FR 43423) to address those geographic areas in which there are

no hospitals, and thus, no hospital wage index data on which to base the calculation of the FY 2020 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 stated 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 stated 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 stated 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.

We note that after the publication of the FY 2020 SNF PPS proposed rule, we were made aware of a minor calculation error in the file used to compute the SNF wage index values. Specifically, the wage and hour data for CBSA 31084 were inadvertently doubled. This caused an error in the national average hourly wage, which factors into the calculation of all wage index values. We have changed the programming logic to correct this error. In addition, we corrected the classification of one provider in North Carolina that was erroneously identified as being in an urban CBSA. We also standardized our procedures for rounding, to ensure consistency. The correction to the proposed rule wage index data was not completed until after the comment period closed on June 18, 2019. This final rule reflects the corrected and updated wage index.

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/SNFPPS/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 in the June 28, 2010 **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.

We stated in the proposed rule that, 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.

In the FY 2020 SNF PPS proposed rule, the labor-related share calculation was based on IGI's first quarter 2019 forecast with historical data through fourth quarter 2018. However, as discussed in the FY 2020 SNF PPS proposed rule (84 FR 17624), our policy is if more recent data become available (for example, a more recent estimate of the 2014-based SNF market basket or MFP adjustment), we would use such data, if appropriate, to determine the FY 2020 SNF market basket percentage change, labor-related share relative importance, forecast error adjustment, and MFP adjustment in the final rule. Since that time, we revised the FY 2020 labor-related share calculation to reflect the IGI second quarter 2019 forecast, with historical data through first quarter 2019. Table 8 summarizes the final, revised labor-related share for FY 2020, based on the updated data, 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 19:2 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	2.6
Capital-related (.391)	2.9	2.9
Total	70.5	70.9

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

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

In the proposed rule (84 FR 17630), we stated that in order to calculate the labor portion of the case-mix adjusted per diem rate, we 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, as we discussed in the proposed rule (84 FR 17630), 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.

We note that in the FY 2020 SNF PPS proposed rule, the budget neutrality factor calculation was based on the wage and cost data available at the time of the proposed rule. As a result of correcting the wage index error discussed above, the budget neutrality factor that was calculated for the proposed rule has been revised. The proposed FY 2020 budget neutrality factor was 1.0060. The revised and final FY 2020 budget neutrality factor, which was used in calculating the final unadjusted FY 2020 federal per diem rates, is 1.0002.

Commenters submitted the following comments related to our proposed calculation of the SNF wage index. A discussion of these comments, along with our responses, appears below.

Comment: Several commenters raised concerns with the use of the inpatient hospital wage index in lieu of a SNF-specific wage index. These commenters provided suggested revisions to the manner in which CMS uses the inpatient hospital wage index under the SNF PPS. One commenter suggested that CMS apply the average state wage index in areas where all of the hospitals within that CBSA have been reclassified under the hospital wage index to a

different CBSA, similar to how the average wage index is used in areas where no hospitals exist within a CBSA. A few commenters suggested that CMS consider modifying the current hospital wage data that are used to construct the SNF PPS wage index, in order to reflect more closely the SNF environment, by trimming hospital wage data to reflect positions staffed in nursing homes, as well as using an occupational mix adjustment specific to SNFs and/or rural floor under the SNF PPS. A few commenters also requested that CMS develop a SNF-specific wage index, which would allow for the possibility of a reclassification methodology under the SNF PPS.

Response: We appreciate all of the suggestions and comments on the SNF PPS wage index. With regard to the suggestion that CMS develop a SNF-specific wage index, which would allow for the possibility of a reclassification methodology under the SNF PPS, as we discussed in the FY 2020 SNF PPS proposed rule (84 FR 17628) and in prior rules (most recently in the FY 2019 SNF PPS final rule (83 FR 39177 through 39178)), section 315 of BIPA 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, the development of a SNF-specific wage index 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. In addition, 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 believe this undertaking is feasible at this time. While we continue to review all available data and contemplate potential methodological approaches for a SNF-specific wage index in the future, we continue to believe that in the absence of the appropriate SNF-specific wage data, using the pre-reclassified, pre-rural floor hospital inpatient wage data (without the occupational mix adjustment) is appropriate and reasonable for the SNF PPS.

With regard to those comments on modifying the current hospital wage data that are used to construct the SNF PPS wage index, in order to reflect more closely the SNF environment, by trimming hospital wage data to reflect positions staffed in nursing homes, applying an occupational mix adjustment, and other such suggestions, we believe it would be appropriate to consider such changes in future rulemaking. However, while we consider whether or not such approaches would improve the SNF PPS wage index, we would note that other provider types also use the hospital wage index as the basis for their associated wage index. As such, we believe that such a recommendation should be part of a broader discussion on wage index reform across Medicare payment systems.

With regard to using an occupational mix adjustment for the SNF PPS wage index, as discussed above and in the FY 2020 SNF PPS proposed rule (84 FR 17628), 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 hospital occupational wage data excludes any wage data related to SNFs. Therefore, we believe that using the updated hospital wage data exclusive of the IPPS occupational mix adjustment continues to be appropriate for SNF payments. With regard to developing a SNF-specific occupational mix adjustment, we appreciate this suggestion and may consider this in future rulemaking.

With regard to implementing a rural floor under the SNF PPS, we do not believe it would be prudent at this time to adopt such a policy, particularly because MedPAC has recommended eliminating the rural floor policy from the calculation of the IPPS wage index (see, for example, Chapter 3 of MedPAC's March 2013 Report to Congress on Medicare Payment Policy, available at http://www.medpac.gov/docs/default-source/reports/mar13_ch03.pdf, which notes on page 65 that, in 2007, MedPAC had recommended eliminating these special wage index adjustments and adopting a new wage index system to avoid geographic inequities that can occur due to current wage index policies (Medicare Payment Advisory Commission 2007b)). If we adopted the rural floor policy at this time, the SNF PPS wage index could become vulnerable to problems similar to those MedPAC identified in its March 2013 Report to Congress.

Finally, with regard to the suggestion that CMS use the average state wage index for areas where all of the hospitals within a CBSA have reclassified under the IPPS out of the CBSA to a different CBSA, we believe that such circumstances are different from those in which there are no hospitals located within the CBSA, specifically CBSA 25980, Hinesville-Fort Stewart, GA, where we use the average wage index for all urban areas in the state. In the circumstance where all hospitals in a CBSA have reclassified under the IPPS to a different CBSA, there still are hospitals geographically located in the CBSA and we would have hospital data for the associated CBSA, even if the hospitals subsequently reclassify out of the CBSA. Therefore, we would have data upon which to base our calculation of the SNF PPS wage index for that CBSA, and we think it would be appropriate to use that data to determine the SNF PPS wage index as we do in other CBSAs.

After consideration of the comments received, for the reasons discussed in this final rule and in the FY 2020 SNF PPS proposed rule, we are finalizing, without modification, our proposed policies discussed above relating to the wage index and the labor-related share. 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/SNFPPS/WageIndex.html>

5. 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. In the FY 2020 SNF PPS proposed rule, we solicited 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.

Commenters submitted the following comments related to the wage index comment solicitation. A discussion of these comments, along with our responses, appears below.

Comment: Several commenters raised concerns with the wage index related proposals contained in the FY 2020 Inpatient Prospective Payment System proposed rule, specifically the proposal related to those hospitals whose wage indexes are in the bottom 25 percent of all wage index values. Several commenters also raised issues with the manner in which the hospital wage index was calculated. These commenters also highlighted discrepancies between the SNF PPS wage index values posted on the CMS website and those calculated using public use files made available by CMS. A few commenters stated concerns with the improper exclusion of seven hospitals in California. One commenter stated that Part B wages should be removed from the calculation of the hospital wage index.

Response: We appreciate these comments on the inpatient hospital wage index and associated proposed changes and will pass these comments to our colleagues responsible for the hospital wage index. With respect to the highlighted discrepancies between the posted proposed

SNF PPS wage index values and those calculated using the public use file, as stated above, there was a minor error in the file used to compute the proposed SNF wage index values. We have corrected this error in computing the SNF wage index values and payment rates for this final rule.

Comment: One commenter stated that CMS has the statutory authority to implement geographically-specific updates associated with rising state and/or regional minimum wage standards. The commenter requested that such updates be made at the Core-Based Statistical Area (CBSA) levels.

Response: With regard to rising minimum wage standards, we would note that such increases will likely be reflected in future data used to create the SNF wage index, as these changes to state minimum wage standards would be reflected in increased wages to SNF staff. Therefore, we already incorporate such standards into the calculation of the SNF PPS wage index to the extent that these standards have an impact on facility wages.

6. 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 III.E.2. of this final rule for a further discussion of our policies for the SNF VBP Program.

7. Adjusted Rate Computation Example

The following tables provide examples generally illustrating payment calculations 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 \$19,975.62.

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	\$89.91	1.00	\$89.91
OT	TN	\$84.83	1.00	\$84.83
SLP	SH	\$64.86	-	\$64.86
Nursing	CBC2	\$164.18	-	\$164.18
NTA	NC	\$147.03	3.00	\$441.09
Non-Case-Mix	-	\$94.84	-	\$94.84
Total PDPM Case-Mix Adj. Per Diem				\$939.71

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	\$939.71	\$666.25	0.9839	\$655.53	\$273.46	\$928.98

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	\$928.98
2	3.0	1.0	\$928.98
3	3.0	1.0	\$928.98
4	1.0	1.0	\$638.28
5	1.0	1.0	\$638.28
6	1.0	1.0	\$638.28
7	1.0	1.0	\$638.28
8	1.0	1.0	\$638.28
9	1.0	1.0	\$638.28
10	1.0	1.0	\$638.28
11	1.0	1.0	\$638.28
12	1.0	1.0	\$638.28
13	1.0	1.0	\$638.28
14	1.0	1.0	\$638.28
15	1.0	1.0	\$638.28
16	1.0	1.0	\$638.28
17	1.0	1.0	\$638.28
18	1.0	1.0	\$638.28
19	1.0	1.0	\$638.28
20	1.0	1.0	\$638.28
21	1.0	0.98	\$634.83
22	1.0	0.98	\$634.83
23	1.0	0.98	\$634.83
24	1.0	0.98	\$634.83
25	1.0	0.98	\$634.83
26	1.0	0.98	\$634.83
27	1.0	0.98	\$634.83
28	1.0	0.96	\$631.37
29	1.0	0.96	\$631.37
30	1.0	0.96	\$631.37
Total Payment			\$19,975.62

C. Additional Aspects of the SNF PPS

1. SNF Level of Care--Administrative Presumption

The establishment of the SNF PPS did not change Medicare's fundamental requirements for SNF coverage. However, because the case-mix classification is based, in part, on the

beneficiary's need for skilled nursing care and therapy, we have attempted, where possible, to coordinate claims review procedures with the existing resident assessment process and case-mix classification system discussed in section III.B.3. of this final rule. This approach includes an administrative presumption that utilizes a beneficiary's correct assignment, at the outset of the SNF stay, of 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. We also 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 initial Medicare 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 initial Medicare assessment (as discussed further in section III.D.3 of this final rule). 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 39252, 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.

Commenters submitted the following comments related to the proposed rule’s discussion of the administrative level of care presumption. A discussion of these comments, along with our responses, appears below.

Comment: Commenters expressed support for CMS’ 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” (84 FR 17632). One commenter specifically endorsed CMS’ longstanding position that under PDPM, SNFs are still required to make decisions related to level of care appropriately and in a timely manner and to monitor for changes in patients’ conditions related to the continuing need for Part A SNF benefits after the assessment reference date of the initial assessment.

Response: We appreciate the support for our position, and note that our ongoing review of the administrative presumption will include careful monitoring of the newly-designated classifiers under the PDPM to ensure that they are not inappropriately capturing significant numbers of nonskilled cases in actual practice. In that context, we have repeatedly noted--most recently, in the FY 2019 SNF PPS final rule (83 FR 39251)--that the actual purpose of the level of care presumption has always been to afford a streamlined and simplified administrative procedure for readily identifying those beneficiaries with the greatest likelihood of meeting the level of care criteria that in no way serves to disadvantage other beneficiaries who may also meet the level of care criteria. Accordingly, in view of the presumption’s intended role of identifying

only the most clearly qualified cases, once a particular classifier has been found in actual practice to capture a significant number of nonskilled cases, we believe that it would be inappropriate to continue to designate such a classifier for use in triggering the coverage that the presumption provides.

2. 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 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 the proposed rule, we specifically invited public comments identifying HCPCS codes in any of these four service categories (chemotherapy items, chemotherapy administration services, radioisotope services, and customized prosthetic devices) representing recent medical advances that might meet our criteria for exclusion from SNF consolidated billing. We stated in the proposed rule that we may consider excluding a particular service if it meets our criteria for exclusion as specified above. We requested that commenters 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, we stated in the proposed rule that, 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.

Commenters submitted the following comments related to the proposed rule's discussion of consolidated billing. A discussion of these comments, along with our responses, appears below.

Comment: One commenter expressed support for the overall concept of consolidated billing, but cautioned that problems in its practical application can create difficulties for suppliers in obtaining payment for those services that are subject to this provision. The commenter noted that when a MAC denies separate payment to a supplier for a bundled SNF service, the denial notice may not specify the particular SNF involved; even after the supplier has identified the SNF in question, the latter may be reluctant to pay the supplier, especially if the SNF itself did not directly order the service. The commenter suggested that the consolidated billing edits should deny separate payment to the supplier only for those services that are directly ordered by the practitioner who is responsible for the patient in the SNF.

Response: Sections 1862(a)(18) and 1866(a)(1)(H)(ii) of the Act specifically require the SNF itself to be responsible for furnishing the entire range of covered SNF services (the bundled services)--either directly with its own resources, or under an "arrangement" with an outside supplier in which the supplier's payment would come from the SNF (rather than from Part B or the beneficiary). Further, as noted in Section 70.4 of the Medicare Benefit Policy Manual, Chapter 8 (available online at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c08.pdf>), while

... the specific details of the ensuing payment arrangement between the SNF and the outside supplier (such as the actual payment amount and timeframe) represent a private, "marketplace" transaction that is negotiated between the parties themselves ... in order for the arrangement itself to be valid, the SNF must, in fact, make payment to its supplier

for services rendered.

In that context, the Medicare Claims Processing Manual, Chapter 6 (available online at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c06.pdf>) discusses in Sections 10.4ff. the importance of establishing written agreements between SNFs and their suppliers--preferably before services are actually rendered--to ensure that both parties have arrived at a common understanding of the specific terms of payment and also to help resolve any disputes that may arise regarding them, and it describes some additional steps that both SNFs and suppliers can take to prevent problems from developing. For example, with reference to suppliers, Section 10.4.2 specifies that

. . . prior to furnishing services to a Medicare beneficiary, the supplier should routinely ascertain whether the beneficiary is currently receiving any comprehensive Medicare benefits (such as SNF or home health benefits) for which Medicare makes a bundled payment that could potentially include the supplier's services. If the supplier ascertains that a particular beneficiary is, in fact, a resident of an SNF with which the supplier does not have a valid arrangement in place, then the supplier should contact the SNF before actually furnishing any services to that beneficiary that are subject to the consolidated billing provision.

Notwithstanding such precautions, if a supplier nevertheless continues to encounter difficulties either in identifying the particular SNF involved or in securing that SNF's compliance with the consolidated billing requirement, the supplier's appropriate contact at that point would be with its servicing MAC, which is responsible for providing technical assistance and support to the entities that it serves. In addition, the Medicare fee-for-service operations component of the servicing CMS Regional Office is available to assist as needed in helping to resolve such situations.

Comment: Commenters urged CMS to create an exclusion from consolidated billing for clotting factor and non-factor medication therapies for patients with hemophilia, similar to the existing exclusions for chemotherapy and its administration, radioisotope services, and certain

customized prosthetic devices.

Response: We note that the item/service categories cited by the commenters (chemotherapy and its administration, radioisotope services, and certain customized prosthetic devices) are in statute at section 1888(e)(2)(A)(iii) of the Act (as enacted through section 103 of the BBRA). As we indicated previously in the FY 2012 SNF PPS final rule (76 FR 48531), hemophilia treatments are outside the particular service categories that the statute authorizes for exclusion, and establishing an exclusion category for hemophilia treatment services, or any other service categories that are not specified in the statute, would require legislation by Congress to amend this statutory provision. Thus, we decline to adopt the commenter's suggestion.

Comment: In terms of considering new chemotherapy drugs for exclusion, one commenter suggested that CMS should focus specifically on their cost, noting that such drugs do not always have their own HCPCS code. Another commenter expressed support for expanding the list of chemotherapy exclusions from consolidated billing as helping to “ensure that life-saving treatment is not interoperated during a patient's transition to sub-acute rehab,” but suggested that “rather than focusing on specific HCPCS for the expansion list,” CMS should instead “. . . set a dollar amount ceiling on Medicare approved chemotherapy medications and administration” in order to “. . . help reduce burden on providers and patients involved in this important care transition.” Still another commenter reiterated a recommendation from previous years to exclude the oral chemotherapy drug REVLIMID®.

Response: We note that as enacted by section 103 of the BBRA, section 1888(e)(2)(A)(iii) of the Act does not authorize or provide for setting an overall cap on chemotherapy expenditures in this context, and instead establishes the existing approach of designating by HCPCS code those individual “high-cost, low probability” chemotherapy items and services that qualify for exclusion. Accordingly, as we noted previously in the FY 2016

SNF PPS final rule (80 FR 46407), we are unable to designate a chemotherapy drug for exclusion from consolidated billing prior to the point at which it is actually assigned its own J code. We further explained in the FY 2015 SNF PPS final rule (79 FR 45642) that

... the assignment of such a code has been an essential element of identifying certain chemotherapy drugs for exclusion ever since the BBRA first created the statutory exclusion in 1999, as reflected in the drafting of the statutory provision itself as well as in our periodic solicitation of “codes” that might meet the criteria for exclusion.

Regarding the oral chemotherapy drug REVLIMID[®], we note that this drug has been recommended for exclusion during several previous rulemaking cycles--most recently, in the one for FY 2019, when commenters recommended its exclusion along with three other Part-D-only oral chemotherapy drugs: ZYTIGA[®], ERLEADA[®], and GLEEVEC[®]. In the FY 2019 SNF PPS final rule (83 FR 39181 through 39182), we stated that because the particular drugs at issue here would not be covered under Part B, the applicable provisions at section 1888(e)(2)(A) of the Act may not provide a basis for excluding them from consolidated billing (emphasis added), but we also cited “the need for further consideration of this issue.” After further consideration, we continue to believe that the applicable provisions at section 1888(e)(2)(A) of the Act do not provide a basis for excluding Part-D-only chemotherapy drugs from consolidated billing. While the chemotherapy item exclusion itself (at section 1888(e)(2)(A)(iii)(II) of the Act) contains no language that would serve to restrict its scope to only those items that are payable under Part B, such restrictive language is, in fact, set forth more broadly in section 1888(e)(2)(A)(i) of the Act, which defines the “covered skilled nursing facility services” that are included in the SNF PPS per diem rate. Under section 1888(e)(1) of the Act, the payment for all costs of “covered skilled nursing facility services” furnished by a SNF is equal to (and thus included in) the SNF PPS adjusted per diem rate. Section 1888(e)(2)(A)(i) of the Act, in turn, defines the term “covered skilled nursing facility services” in subclause (I) as Part A post-hospital extended care services

(SNF services) as defined in section 1861(i) of the Act, and in subclause (II) as “all items and services (other than items and services described in clauses (ii), (iii), and (iv)) for which payment may be made under Part B” and which are furnished during the course of a Medicare-covered SNF stay (emphasis added). Accordingly, while therapeutic drugs such as the ones at issue here would fall within the scope of the Part A SNF bundle as referenced in subclause (I) above, the only items and services that potentially could be carved out from that bundle under subclause (II) above would be those that otherwise would be separately payable under Part B. Further, as noted in the FY 2019 SNF PPS final rule (83 FR 39181), while section 1861(s)(2)(Q) of the Act does include a specific Part B benefit category for oral chemotherapy drugs, coverage under that benefit is restricted to those with the same indication and active ingredient(s) as a covered non-oral anti-cancer drug, which is not the case for the specific drugs in question. Moreover, as noted in the FY 2006 SNF PPS final rule (70 FR 45049), expanding the existing statutory drug coverage available under Part B to include such drugs is not within our authority. In this context, we further note that section 410 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173, enacted December 8, 2003)--the same legislation that created the Part D drug benefit--also amended section 1888(e)(2)(A) of the Act by adding a new subclause (iv) that excluded certain Part B Rural Health Clinic and Federally Qualified Health Center services from consolidated billing. At the same time, the accompanying legislative history (House Ways and Means Comm. Rep. No. 108-178, Part 2 at 209) specifically reaffirmed the Part-B-only nature of the consolidated billing exclusions by noting that “Certain services and items provided a SNF resident . . . are excluded from the SNF PPS and paid separately under Part B” (emphasis added). Similar language also appears in the MMA’s Conference Report (H. Conf. Rep. No. 108-391 at 640-41). Finally, it is also worth bearing in mind in this context that the PDPM will introduce for the first time a separate SNF payment

component specifically for non-therapy ancillary (NTA) services. As we noted in the FY 2019 SNF PPS final rule (83 FR 39180), in accounting more accurately for the costs of NTA services such as drugs, the PDPM model has the potential to ameliorate some of the concerns about the adequacy of payment for drugs furnished in the SNF setting.

3. Payment for SNF-Level Swing-Bed Services

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

A commenter submitted the following comment related to the proposed rule's discussion of payment for SNF-level swing-bed services. A discussion of that comment, along with our response, appears below.

Comment: One commenter suggested that exempting the swing-bed services of CAHs from the SNF PPS creates a discrepancy in payment for comparable services between the CAH and any area SNFs which are not so exempted, to the SNF's disadvantage. The commenter urged CMS to seek statutory authority either to pay for CAH swing-bed services under the SNF PPS, or to adjust Medicare payments for those rural SNFs located in the same geographic area as a swing-bed CAH.

Response: We note that as originally enacted in section 4432 of the BBA 1997, the SNF PPS applied uniformly to all providers of extended care services under Part A, including SNFs themselves along with swing-bed CAHs as well as rural (non-CAH) swing-bed hospitals. However, the Congress subsequently enacted legislation in section 203 of the BIPA that specifically excluded swing-bed CAHs from the SNF PPS (see §1888)(e)(7)(C) of the Act), thus establishing that swing-bed CAHs are to be exempted from the SNF PPS while leaving this payment methodology in place for the other facilities, including rural SNFs. Accordingly, CMS cannot adjust Medicare payments for rural SNFs located in the same geographic area as a swing-bed CAH to provide for similar payments.

D. Issues Relating to PDPM Implementation

1. 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, as we noted in the FY 2020 SNF PPS proposed rule (84 FR 17634), 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. We stated that, 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. We stated in the proposed rule that 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, we stated that 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, we stated in the proposed rule that 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 the FY 2020 SNF PPS proposed rule (84 FR 17634), we proposed to adopt a new definition of group therapy for use under PDPM, effective October 1, 2019, as further discussed below. As discussed in the FY 2020 SNF PPS proposed rule, in an effort to support CMS' crosssetting initiatives under the IMPACT Act and Meaningful Measures Initiative, we 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-ServicePayment/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.

As discussed in the FY 2020 SNF PPS proposed rule (84 FR 17634), 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, we stated that 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. Thus, for the reasons discussed previously and in the FY 2020 SNF PPS proposed rule (84 FR 17634), we proposed 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 stated in the proposed rule that 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.

In the FY 2020 SNF PPS proposed rule (84 FR 17635), we stated that 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 stated that 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 SNF PPS 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.

Commenters submitted the following comments related to the proposed rule's discussion of the Revised Group Therapy Definition. A discussion of these comments, along with our responses, appears below.

Comment: The majority of the comments received supported changing the definition of group therapy to treatment by a qualified therapist or therapy assistant of two to six patients at the same time who are performing the same or similar activities. Several commenters noted agreement that the increased flexibility afforded by the revised definition will offer therapists more clinical flexibility when determining what mode of therapy would best suit their patients. Other commenters stated that the revised definition would allow smaller SNFs with fewer patients to treat a smaller group in a therapy session (for example, two patients) and that they believe they were unable to provide this when group therapy was defined as four patients.

Commenters approved of the standardization across post-acute care settings and appreciated the synchronization between the Inpatient Rehabilitation Facility (IRF) definition and the proposed SNF definition of group therapy. Additionally, one commenter pointed out that the increased latitude in the provision of group therapy will better allow patients to gradually progress from one-to-one treatment into a family or community setting which better simulates a typical living environment and will better provide a transition model from the short term SNF stay. Several of the commenters who supported the proposal noted that individual therapy is still the most preferred mode of therapy to provide to SNF patients and expressed that although they were in agreement with the change in definition of group therapy, their support should not be conflated with any thought that individual therapy isn't the most appropriate mode of therapy.

Response: We are pleased that so many commenters supported the change to the definition of group therapy in the SNF setting. We agree that the increased flexibility for therapists to determine the appropriate number of patients in a group is appropriate and will allow therapists to better meet the clinical needs of their patients. Further, we believe that this change is a positive part of CMS' mission to reduce administrative burden on providers by utilizing the same or similar definitions across settings. We agree with the commenter who discussed that the ability to use different modes of therapy may better simulate real-life situations for many patients. We do, however, believe that, as with all clinical situations, there should not be a one-size-fits-all approach--which is entirely consistent with our emphasis on the critical importance of addressing each patient's specific condition and individualized treatment needs. While utilizing different modes of therapy may be a good way to transition some patients back to their home environments, it may be inappropriate for other patients. We continue to believe and agree with the commenters who stated that individual therapy is the most preferred mode of therapy to use in the SNF. While group therapy can play an important role in SNF patient care

for certain patients or for certain conditions, it is primarily a supplement to individual therapy, and we continue to maintain that a therapist providing one-to-one care with his or her full attention on one patient should be considered the primary mode of therapy and standard of care.

Comment: One commenter requested further clarification regarding documentation requirements described in the proposed rule. This commenter questioned whether documentation requires a new plan of care to incorporate group therapy after an evaluation.

Response: We note that there are no new documentation requirements regarding group therapy. In the proposed rule, we simply reiterated existing CMS policy pertaining to documentation. 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.

If there is a change in the need for group therapy after a plan of care is completed, we would expect that this would be reflected in the medical record with whatever progress notes a facility requires to adequately capture the clinical status of a patient.

Comment: Many commenters discussed the increased value in providing all different modes of therapy (that is, individual, concurrent, and group therapy) to patients based on their different clinical needs. They believe that in the strictest sense, the definition of group therapy in the SNF setting is for payment purposes rather than clinical purposes and that ultimately

clinicians should be the ones to determine which mode of therapy is in the best interest of each patient.

Response: We agree that the ability to provide different modes of therapy increases the possibility that patients will receive therapy that is most appropriate for their individual needs based on the sound clinical judgment of SNF therapists and therapy assistants. We also agree that clinicians should be the ultimate deciders of which mode of therapy is appropriate for each patient, but as we stated previously, we continue to maintain that individual therapy should be the primary mode of therapy and the standard of care for SNF patients. Furthermore, we believe the implementation of PDPM will bring with it incentives to provide less therapy in general because payment will no longer be based on the volume of service provided, and for the sake of patients and their needs, we have placed some limits on the size of the group to help assure that patients are not placed in groups that are too large and that patients continue to receive the individualized care that is the most appropriate for them. Thus, even though the proposed definition of group therapy is technically being used for payment purposes, the proposed definition is also based on clinical considerations, as we believe it is necessary to assure that patients are receiving the best clinical care possible.

Comment: Several commenters pointed out that because the definition of group therapy will change simultaneously with the implementation of PDPM, there cannot be a direct comparison between group therapy utilization under RUG-IV and group therapy under PDPM. They noted that, under RUG-IV, when the definition of group therapy was exactly four patients, it was possible that patients who might have benefitted from group therapy but whose sessions did not qualify for the strict definition would have received individual or concurrent therapy in its place. These commenters cautioned CMS against assuming a correlation between an increase in group therapy usage and the implementation of PDPM. Further, one commenter suggested that

CMS delay the change in definition of group therapy for at least 3 years until the impact of the PDPM transition has been adequately monitored and analyzed.

Response: We recognize that the simultaneous implementation of PDPM and the change to the definition of group therapy means that it will be difficult to compare RUG-IV and PDPM in terms of the impact of the PDPM on group therapy utilization. However, we think it is important and appropriate to move forward with the change in definition. This change will benefit SNF patients by providing therapists with increased flexibility to determine the size of groups thereby enhancing the therapists' ability to accommodate the needs of different patients with different conditions. We do not believe a delay in implementation of the definition change is an appropriate solution. Given the significant behavioral changes that may be seen under PDPM, specifically a reduction in therapy provision generally and an increase in use of group therapy, we put in place several safeguards or monitoring mechanisms, such as the required PPS discharge assessment that will record the amount of therapy provided during a SNF stay as well as act as a tool that will calculate the percentage of group therapy provided. We continue to expect that therapists will use clinical judgment to determine the appropriate frequency, duration, and modality of therapy services for SNF patients and will do so based on sound clinical reasoning and not financial motives. We also expect that these therapists will document the use of group therapy for each patient they treat in a group in a way that clearly shows that group therapy is the most appropriate mode of therapy to be used in each case. Finally, we plan to monitor closely how the provision of therapy changes under PDPM and may consider additional policy development in the future to address any adverse trends we identify.

Comment: Several commenters did not support the proposal to change the definition of group therapy. These commenters believe that this definition goes against the long held CMS belief that individual therapists cannot supervise large groups of patients and that small groups of

two or three patients do not provide an adequate opportunity for patients to interact with each other to maximize the benefit of a group. This group of commenters urged CMS to keep the current definition of group therapy. These commenters also expressed concern that the revised definition of group therapy will incentivize SNFs to provide more group therapy, possibly to the detriment of their patients. In general, these commenters are concerned that with the PDPM changes, SNFs already have too many incentives to provide group therapy in place of individual therapy and that the change in the definition of group therapy is one more factor that will result in care decisions being made for financial reasons rather than clinical reasons. They stated that PDPM will incentivize SNFs to provide less therapy in general and the additional change to group therapy will inhibit SNFs from providing the individualized therapy that the majority of SNF patients require. These commenters requested that CMS closely monitor the 25 percent combined cap on group and concurrent therapy that will go into effect upon implementation of PDPM to protect patients from receiving inappropriate amounts of group and concurrent therapy and to consider adding a penalty to providers who do not comply with the limit.

Response: We appreciate the concern that the commenters expressed with regard to the change in definition of group therapy. We are aware that in the past, we maintained the position that large groups were difficult to supervise and could make it difficult for patients to engage with one another and that small groups did not offer adequate opportunity to effectively interact or maximize the benefit of the group. However, as we discussed in the FY 2020 SNF PPS proposed rule (84 FR 17634), we reviewed the usage of group therapy sizes in the IRF setting and we found that therapists are capable of using their clinical judgment to determine whether a group is too large or small and can manage groups of various sizes, and we expect therapists to adequately document the basis for their clinical decisions. Additionally, as we stated in the proposed rule, groups of various sizes can provide psycho-social benefits to patients, and thus we

believe the increased flexibility provided to therapists to furnish therapy through different size groups will be clinically beneficial to patients.

We understand that in some SNFs, staffing issues may make it difficult to adequately and effectively supervise larger groups. However, there are many cases where this is not an issue and we do not want to prohibit SNFs from providing valuable therapy in larger groups if they can appropriately staff them. Additionally, these larger groups are an opportunity to utilize therapy students as extra sets of hands, eyes, and observers and can work as a way to offer therapy students valuable teaching and patient care time to assist them in maximal learning. Conversely, we do not want to prevent SNFs that have fewer patients with similar or the same needs from providing group therapy in smaller groups because the definition is currently set at four patients.

We recognize that the change in the way we are paying for therapy under PDPM may incentivize providers to furnish more group therapy for financial, rather than clinical reasons, and for this reason, we put the 25 percent combined cap into place effective October 1, 2019 as a limit on the amount of group and concurrent therapy that may be provided under PDPM.

Ultimately though, we expect the decision on group size (within the revised definition) will be made by qualified therapists and therapy assistants and we expect their judgment on this matter to be based on sound clinical rationale and not financial gain. We believe that the judgment of the therapists and therapy assistants will allow for appropriate decision making regarding the number of group participants, and the combined 25 percent cap on group and concurrent therapy will help prevent an overutilization of group therapy under PDPM. We plan to implement a robust monitoring program to assess compliance with the 25 percent cap, and based on our findings, we may propose taking additional action in future rulemaking.

Comment: Several commenters expressed concern that the definition of group therapy as two to six patients will give providers an incentive to place the maximum number of patients in a group in order to exploit the financial incentives that would accompany doing so. One commenter expressed concern that corporate rehabilitation companies will disregard the clinical judgment of their therapists and therapy assistants and pressure them into providing groups of five or six at all times for financial gain. This commenter also stated the concern that rehabilitation companies may relax their standards for what is considered a group and pressure their therapists into providing groups that are less than clinically sound.

Response: We appreciate the commenters' concern that the proposed change in the definition of group therapy may give providers an incentive to place the maximum number of patients in a group for financial reasons. We also appreciate the concern of the commenter who stated that it is possible that corporate rehabilitation companies will pressure therapists into providing group therapy in groups with as many patients as possible and that this might not be appropriate as group therapy at all times. As we have stated previously, therapists treating SNF patients should use their own clinical judgment to determine the appropriate frequency, duration, and modality of therapy services and the size of a therapy group based on the individual needs of each patient. Financial motives should not override the clinical judgment of a therapist or therapy assistant or pressure a therapist or therapy assistant to provide less than appropriate therapy, including putting patients in large groups that are not clinically appropriate for those patients.

Comment: Several commenters suggested that CMS consider revising the definition of group therapy to two to four patients doing the same or similar activity. These commenters explained that doing so would still provide therapists an appropriate level of clinical flexibility

while preventing SNFs from including a very large number of patients in a group only for financial reasons.

Response: We appreciate the suggestion of revising the definition of a group to two to four patients. If, after monitoring the provision of group therapy under the PDPM, we believe this policy would be more appropriate in the SNF setting, we will consider it for future rule-making. As stated above and the in the FY 2020 SNF PPS proposed rule (84 FR 17634), we believe that defining group therapy as therapy provided to groups of 2 to 6 patients at the same time who are performing the same or similar activities would provide therapists with an appropriate amount of flexibility to meet the clinical needs of their patients without compromising the therapist's ability to manage groups and the patient's ability to interact effectively and benefit from the group. We expect that therapists will use their professional judgment to determine the most appropriate group size within the bounds of that definition to maximize the benefit to each patient in the group session.

Comment: Several commenters noted that revising the definition of group therapy to better align with other post-acute care settings is "misguided". These commenters stated that the post-acute care settings provide different levels of care and that the IRF setting, specifically, is meant to provide a more intense level of therapy than other settings, and that it would be flawed to try to synchronize the definition of group therapy across these settings that have different coverage requirements and patients with different acuity levels.

Response: We disagree with the notion that the change in the definition of group therapy to better align with other post-acute settings is "misguided." Anecdotally, providers have stated that the acuity of SNF patients has increased over the years and that the level of care and therapy they require is comparable to that of IRF residents. Additionally, under RUG-IV, the majority of SNF therapy patients have been placed in the Ultra High therapy group, receiving at least 720

minutes of therapy a week. We do not believe that this level of therapy is very different from the intense level of therapy that is occurring in IRFs. We acknowledge that the higher acuity and need for an intense level of therapy does not apply to all SNF patients, but we expect the therapists and assistants who will be providing the group therapy will determine the appropriate intensity of therapy for each patient. Additionally, we continue to maintain that synchronization of the group therapy definition between settings will ease provider burden and help achieve CMS' goal of cross-setting alignment in this aspect.

Comment: Several commenters expressed concern that PDPM will inadvertently cause therapy students to lose out on opportunities for supervision and training. These commenters are concerned that maintaining compliance with the 25 percent combined limit on concurrent and group therapy may encourage therapists and assistants to forego supervising therapy students because doing so would add additional burden to their facilities. These commenters stated that this would affect the ability of students to get the valuable clinical training required to adequately treat geriatric patients in the SNF setting. One commenter explained that the current policy of considering a student clinician as an extension of the therapist or assistant who is training the student, as described in the FY 2012 final rule (76 FR 48511), (that is, the time the student spends with a patient is coded as if it were the supervising therapist or therapy assistant alone providing the therapy) should not be necessary under PDPM as it is under RUG-IV. This commenter stated that, because under the PDPM therapy minutes are no longer the primary driver for payment, this should not be a necessary aspect of the policy. One commenter recommended that CMS apply the 25 percent group and concurrent therapy limit at the facility level rather than individual level, and stated that doing this would not only maintain consistency of data comparison between RUG-IV and PDPM but also reduce the concerns with student supervision described above by creating a more flexible environment for treatment. Several

commenters requested reiteration of CMS guidance regarding appropriate and effective use of student clinicians for group therapy.

Response: We do not agree with the comment that our policy under which the therapy student acts as an extension of the supervising therapist is no longer necessary under PDPM, as it is under RUG-IV, due to the discontinued use of therapy minutes as a primary driver of payment under PDPM. First, therapy minutes are still used under PDPM as part of calculating compliance with the cap on concurrent and group therapy. As such, maintaining this policy will ensure that therapy student time is reflected accurately and consistently with how it is reported under RUG-IV, to ensure an appropriate comparison between the two models. Additionally, we believe it is appropriate to maintain this policy under PDPM because it reflects the responsibility of the supervising therapist for the actions and treatments furnished by the student.

Further, we do not agree that PDPM will cause SNFs not to offer therapy students adequate supervision and training. Specifically, we do not agree that the combined 25 percent limit on group and concurrent therapy will create an extra burden that impedes therapists and therapy assistants from supervising students, and we believe that SNF therapists and therapy assistants will continue to be able to teach, train, and supervise therapy students in the same way under PDPM as they have in the past. As we have discussed previously (84 FR 17634), our data show that group therapy represents a very small proportion of therapy provided to SNF patients. Thus, the 25 percent limit on group and concurrent therapy should not adversely affect opportunities for student supervision and training. As stated in the FY 2019 SNF PPS final rule (83 FR 39242):

...as mentioned above, our most recent (FY 2017) data show that individual therapy was provided 99.77 percent of the time, meaning that group and concurrent therapy combined was reported as having been provided 0.23 percent of the time. It concerns us that commenters have stated that they are providing so much concurrent therapy with students that the 25 percent cap would be too low for them, because this would suggest that either the comments were provided mistakenly or that facilities are falsely reporting concurrent

therapy as individual therapy. While we agree with commenters that the opportunity to supervise student therapists in SNFs is valuable to the education of future therapists and assistants, our data indicate that a 25 percent combined cap on group and concurrent therapy should not deter facilities from taking more therapy students.

We do not agree with the suggestion to apply the 25 percent limit on group and concurrent therapy at a facility level. The notion that doing so would maintain consistency of data comparison between RUG-IV and PDPM is incorrect since we currently monitor data at the patient level under RUG-IV, not at the facility level. We also do not believe that we should apply the 25 percent limit at the facility level because, if we were to apply the 25 percent limit at a facility level, a large number of patients may receive 100 percent group or concurrent therapy and we do not believe that would be clinically appropriate. As we have stated previously, we believe that individual therapy is the preferred mode of therapy. The 25 percent limit on group and concurrent therapy underscores this. Anecdotally, we have been told by an industry group that they would advise their facilities to give as much group and concurrent therapy as possible based on the limit we set for group and concurrent therapy, so that if the limit were 50 percent, they would advise their facilities to give 50 percent group and concurrent therapy. This group informed us that they plan to advise their facilities to furnish 25 percent of all therapy as group and concurrent therapy. We note that we do not believe it would be appropriate to automatically provide the maximum amount of group and concurrent therapy permitted under the percent cap set by Medicare without considering the individual clinical needs of each patient. As we stated previously, we expect therapists to determine the frequency, duration, and modality of therapy based on sound clinical reasoning and the individual needs of each patient. Further, as we stated above and in the FY 2020 SNF PPS proposed rule (84 FR 17635), we continue to believe that individual therapy is the preferred mode of therapy provision and should be considered the standard of care in therapy services provided to SNF residents. Regarding our guidance addressing the most appropriate use of student clinicians for group therapy, we have updated the

MDS RAI manual in Chapter 3 Section O to include in it a revised explanation of how the time during which therapy students furnish either concurrent or group therapy should be captured on the MDS; however, we continue to believe the most appropriate ways to receive guidance on how to best incorporate students in the group and concurrent therapy process would come from the therapy associations and clinical departments of SNFs, as has been done in the past.

Comment: Several commenters requested that CMS discuss whether there will be a penalty for facilities that exceed the 25 percent concurrent and group therapy limit in the future. Commenters explained that the non-fatal warning is not a strong enough incentive for facilities to comply with the limit.

Response: We plan on monitoring the usage of group and concurrent therapy as well as looking at clinical outcomes. If the results of our monitoring efforts indicate substantial non-compliance with the 25 percent limit, we may consider taking additional action in future rulemaking. However, we expect that providers will pay close attention to the warning provided on their validation reports and be aware that we are monitoring their use of group and concurrent therapy as well.

After considering the comments above, for the reasons set forth in this final rule and in the FY 2020 SNF PPS proposed rule, we are finalizing our revision to the definition of group therapy as proposed without modification. Effective October 1, 2019, under the SNF PPS, group therapy will be defined 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.

2. 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.

We stated in the FY 2020 SNF PPS proposed rule (84 FR 17635) that 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 proposed 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, we stated in the proposed rule that, 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.

As discussed in the proposed rule (84 FR 17635), 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. We stated that 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 above-referenced subregulatory process. By contrast, we stated that 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, we stated that 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 example, 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, we explained in the proposed rule that 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. One such instance would be when 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 stated that 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 proposed 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 proposed 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. We stated that all changes would be included in these documents, with substantive changes being included only after being finalized through notice and comment rulemaking.

As discussed in the proposed rule (84 FR 17635 through 17636), 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 stated that 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, we explained in the proposed rule (84 FR 17636) that 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 used in determining the applicability of the consolidated billing (CB) provision of the SNF PPS to a given service, as discussed in section III.C.2 of this final rule. 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 essentially describe the same overall set of services that are excluded from CB. No additional service categories are added by these routine updates; that is, these updates are necessary because of changes to the coding system, not because the basic service categories that are excluded from CB are themselves being redefined. We stated in the proposed rule that 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, we explained in the proposed rule (84 FR 17636) that 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 stated that we believe the subregulatory process proposed in the proposed rule is appropriate because it is also consistent with processes used in another Medicare setting.

We proposed (84 FR 17636) that this subregulatory process for updating the ICD-10 codes used under the PDPM would take effect beginning with the updates for FY 2020. We

further stated that the proposed ICD-10 code mappings and lists for use under the PDPM were available for download from the SNF PPS Web site (<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/PDPM.html>). We stated that 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. Furthermore, we explained in the proposed rule that 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 described above.

Commenters submitted the following comments related to the proposed rule's discussion of Updating ICD-10 Code Mappings and Lists. A discussion of these comments, along with our responses, appears below.

Comment: The majority of commenters expressed support for the proposed subregulatory process for updating ICD-10 mappings. Several commenters noted that the proposed method would support the timely implementation of changes in coding, while ensuring additional consideration is given to substantive changes that amount to a change in policy. Only one commenter stated a preference for notice and comment rulemaking for all changes.

Response: We agree with the majority of commenters that the proposed subregulatory method is the best way to ensure the timely implementation of nonsubstantive changes in ICD coding under the PDPM. With regard to the comment that we utilize notice and comment rulemaking to implement all changes to ICD-10 code mappings and lists under the PDPM, we believe that this could represent a potential program vulnerability, as SNF providers would be prevented from utilizing valid ICD-10 codes under the SNF PPS pending the completion of the notice and comment rulemaking process and, moreover, could be compelled to utilize ICD-10

codes that are no longer valid due to our inability to ensure timely updates to our code mappings and lists when ICD-10 code revisions occur.

Comment: A commenter requested additional guidance on what constitutes a “substantive” change for the purposes of the proposed subregulatory process to update the ICD-10 code mappings and lists associated with the SNF PDPM.

Response: A “substantive” change would be any change to the mappings and lists that goes beyond the intention of maintaining consistency with the most current ICD-10 medical code data set. Any change that constitutes a change in policy, including changes to PDPM clinical category assignments or to the assignment of a code to the comorbidities list, would be considered a substantive change. For instance, consider a hypothetical code XYZ, which is mapped to a comorbid condition on our comorbidities list. In a revision to the ICD-10 codes, code XYZ is split into two separate codes, XYZ.1 and XYZ.2, providing additional detail. We would consider it a non-substantive change to update the mappings and lists to reflect the two new codes instead of the previous single code, and we would make this change to the mappings and lists through the proposed subregulatory process. On the other hand, if we believe the new code XYZ.2 is not predictive of SNF costs of care and wish to remove the new code XYZ.2 from the mappings and lists of PDPM comorbidities, this would be a substantive change, because it changes a policy: conditions previously included on the comorbidities list under the old code XYZ would no longer be included on the comorbidities list if we chose to remove XYZ.2. Therefore, removing the new XYZ.2 code from the mappings and lists would represent a substantive change. We would only make such a change through notice and comment rulemaking.

Comment: A commenter noted that the proposed rule does not clearly state whether non-substantive changes will be made according to the same schedule followed by the ICD-10

Coordination and Maintenance Committee, which updates ICD-10 medical code data sets in June of each year that then become effective in October 1 or April 1 of that year. The commenter stated that a predictable schedule for updates is necessary given the importance of ICD-10 codes and the associated mappings to the determination of patient classification and the calculation of per diem rates under PDPM. The commenter requested further clarification on when providers can expect non-substantive changes to be made according to the subregulatory process.

Response: The schedule for non-substantive CMS updates to the PDPM mappings and lists via the proposed subregulatory process will roughly follow the same schedule currently followed by the ICD-10 Coordination and Maintenance Committee in releasing updates to the ICD-10 medical code data sets in June. Once we receive the revised ICD-10 code lists from the committee, we will publish revised PDPM mappings and lists associated with the revised code lists shortly thereafter. Further, the revised PDPM mappings and lists would be effective at the same time as when the revised ICD-10 codes are effective. For example, if the revised codes are effective October 1 of a given year, then the revised PDPM mappings and lists based on these codes would also be effective October 1.

Comment: Several commenters made specific suggestions regarding how CMS should present changes made through the subregulatory process on the CMS website to ensure that stakeholders are aware of the changes. Commenters suggested that CMS should ensure the updates are communicated in a timely manner, easy to locate on the website, dated so providers are able to easily identify the most current files, and include a summary of what changes were made. Commenters also requested that updates include specific effective dates for the change, with such effective dates being reasonable for SNF staff to implement.

Response: We agree with these suggestions and note that we have established website maintenance and design practices that already incorporate the majority of the recommendations

for presenting changes to the information uploaded on the website. The updates to the ICD-10 mappings and lists will be posted in a timely manner, easy to locate, dated, and accompanied by summaries of the changes and the specified effective dates.

Comment: Two commenters suggested that CMS send a monthly or quarterly newsletter announcing any changes made to the ICD-10 mappings and lists.

Response: We currently issue the Medicare Learning Network (MLN) newsletter and will issue an MLN article alerting providers and stakeholders to any update to the ICD-10 mappings and lists.

Comment: A commenter suggested that education and resources should be made available to all members of the interdisciplinary team, including therapy practitioners, to understand the implications of coding on patient categories and payment.

Response: We currently provide a number of educational materials on the PDPM website (<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/PDPM.html>) including FAQs and fact sheets concerning PDPM patient classification and payment categories. We will update such materials on an ongoing basis to best serve the needs of providers.

Comment: Some commenters commented on an aspect of the PDPM established in the FY 2019 SNF PPS final rule (83 FR 39162), specifically, the use of ICD-10 codes in section I0020B to assign patients to clinical categories used for categorization in the PT, OT, and SLP components. Commenters noted a possible discrepancy between the American Health Information Management Association (AHIMA) guidance and MDS guidance with regard to how to code the “principal diagnosis” in I0020B. Commenters requested that CMS work with AHIMA or other professional coding organizations to ensure that coding instructions for the MDS are consistent with all relevant ICD-10 coding rules and guidelines.

Response: We appreciate these comments and will work to ensure that any guidance provided to SNFs on ICD-10 coding practice aligns with best practices in this field.

Comment: A commenter encouraged CMS to ensure that, for SNFs, the subregulatory process to update ICD-10 mappings and lists aligns with the process used in the context of the Inpatient Rehabilitation Facility (IRF) PPS, where the commenter understands providers globally have accepted the changes.

Response: We agree and believe the proposed subregulatory update process for SNFs aligns with the process used in the IRF PPS to update the tier comorbidities list and the code lists used for the IRF presumptive compliance methodology. As we noted in the proposed rule, the subregulatory update process used in the IRF PPS was one of the models we used to develop the proposed subregulatory process for updating ICD-10 code mappings and lists in the SNF PDPM.

Comment: A commenter noted that, in addition to annual implementation of new and revised ICD-10-CM codes, the conventions and instructional notes in the ICD-10-CM code set and the ICD-10-CM Official Guidelines for Coding and Reporting are also updated on October 1 of each year. The commenter stated that compliance with the current ICD-10-CM codes, conventions, instructions, and the Official Guidelines for Coding and Reporting is required for all healthcare settings under the Health Insurance Portability and Accountability Act (HIPAA). The commenter recommends that CMS ensure any appropriate updates to the ICD-10-CM codes associated with PDPM clinical categories and comorbidity lists that are necessitated by changes to the ICD-10-CM conventions, instructions, or guidelines are included in the proposed subregulatory process.

Response: We agree and will ensure that any appropriate updates to the ICD-10-CM codes associated with PDPM clinical categories and comorbidity lists that are necessitated by changes to the ICD-10-CM conventions, instructions, or guidelines are included in the proposed

subregulatory update process.

Comment: Some commenters provided specific recommendations on revisions to the current mappings available on the CMS website, such as changes in code assignments to clinical categories and the comorbidities list, additional comorbidities, and other such changes.

Response: We appreciate the commenters' suggestions for changes in the current ICD-10 mappings and lists. However, because we consider these suggestions to be outside the scope of the current rulemaking, we are not addressing them in this final rule. We will certainly consider these suggestions as part of our future rulemaking efforts, or for inclusion in our updated mappings in case certain suggestions may be characterized as non-substantive in nature.

After consideration of the comments received, for the reasons discussed in this final rule and in the FY 2020 SNF PPS proposed rule, we are finalizing as proposed, without modification, the process discussed above for updating the ICD-10 code mappings and lists associated with PDPM. As proposed, the subregulatory process for updating the ICD-10 codes used under the PDPM will take effect beginning with the updates for FY 2020. When the proposed rule was issued, the ICD-10 code mappings and lists available for download from the SNF PPS Web site (<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/PDPM.html>). reflected 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, and we stated that these would constitute the baseline for any future updates to the mappings and lists using the update process finalized in this rule. Effective October 1, 2019, these baseline mappings and lists will be updated to incorporate, as appropriate under the process finalized in this rule, updates to the ICD-10 code sets issued by the ICD-10 Coordination and Maintenance Committee in June 2019 to be effective October 1, 2019. We plan to post these updated mappings and lists on our

website prior to October 1, 2019 (and after issuance of this final rule) so that the public can access them prior to the effective date.

3. Revisions to the Regulations Text

We proposed 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 proposed 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 noted 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 proposed to include a conforming revision in § 413.343(b) that we stated was intended to clarify that the 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 proposed to replace the phrase “patient assessments” in § 413.343(b) with the phrase “an initial patient assessment.” Accordingly, we proposed 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 proposed 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 stated that we believe 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 proposed 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 proposed to replace the phrase “the 5-day assessment” with “the initial patient assessment.” We also noted 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.

Commenters submitted the following comments related to the proposed rule’s discussion of the revisions to the regulations text. A discussion of these comments, along with our responses, appears below.

Comment: Some commenters expressed concern that the term “initial patient assessment” is somewhat similar to (and, thus, might be confused with) the interim payment assessment, or IPA, and suggested a number of other names for the 5-day assessment as possible alternatives,

such as the “initial Medicare assessment.” Some commenters noted confusion over the proposed rule’s discussion of this 8-day timeframe (84 FR 17636) as representing the deadline for the assessment’s “completion.” Others cited the proposed rule’s discussion of the SNF’s responsibility to continually monitor and document patient status and to recognize those situations that warrant a decision to complete an IPA in order to account appropriately for a change in status (84 FR 17636), and requested clarification regarding how this responsibility comports with the optional nature of the IPA. One of those commenters characterized the IPA as relating specifically to resetting the SNF’s Part A per diem payment rate and suggested that the regulations text in proposed § 413.343(b)--which specifies performing such other IPAs as the SNF determines are necessary “to account for changes in patient care needs”--is inappropriate in those instances where such changes would have no impact on payment. The commenter recommended deleting that phrase from the regulations text, noting that a Significant Change in Status Assessment (SCSA) is already required in those situations that meet the applicable SCSA criteria.

Response: Although we proposed in the FY 2020 SNF PPS proposed rule (84 FR 17636) to replace the phrase “5-day assessment” with “initial patient assessment,” to help distinguish that assessment more clearly from the IPA, we will henceforth refer to the 5-day assessment as the “initial Medicare assessment.” Further, we wish to resolve any confusion that the proposed rule’s preamble language may have inadvertently created in referring to the 8th day of posthospital SNF care as the deadline for “completing” this assessment. As explained in the longstanding instructions in section 2.9 of the RAI Version 3.0 Manual, the initial Medicare assessment itself need not actually be completed by the 8th day; rather, the assessment reference date (ARD) for this assessment must be set for a date that is no later than the 8th day of posthospital SNF care (in other words, the facility cannot designate Day 9 or later as this

assessment's ARD). In fact, it is the parameters for setting the ARD that the existing regulations text at 42 CFR 413.343(b) has always referenced when requiring a given assessment's "performance" in by a specified day. In order to convey that policy more directly and forestall additional confusion on this point, we are further revising the proposed regulations text at 42 CFR 413.343(b) to require the performance of an initial Medicare assessment "with an assessment reference date that is set for no later than the 8th day of posthospital SNF care." To ensure consistency, we are also making a conforming revision in the introductory paragraph of the regulations text at 42 CFR 409.30, by specifying that the ARD for this assessment "must be set for" (rather than "must occur") no later than the 8th day of posthospital SNF care. As specified in section 2.9 of the RAI Version 3.0 Manual, the actual completion date (Item Z0500B) for this assessment is ". . . within 14 days after the ARD (ARD + 14 days)." Finally, regarding the request for clarification about the optional nature of the IPA, we note that while an SNF's decision to complete the IPA itself is indeed optional, the SNF's underlying responsibility to remain fully aware of (and respond appropriately to) any changes in its resident's condition is in no way discretionary. Moreover, the discussion of the IPA in the FY 2019 SNF PPS final rule (83 FR 39233) clearly envisions a role for this assessment that is not strictly limited to payment alone: "We continue to believe that it is necessary for SNFs to continually monitor the clinical status of each and every patient in the facility regularly regardless of payment or assessment requirements and we believe that there should be a mechanism in place that would allow facilities to do this" (emphasis added). At the same time, in making the IPA optional, we recognized ". . . that providers may be best situated, as in the case of the Significant Change in Status Assessment, to determine when a change has occurred that should be reported through the IPA." (84 FR 39233) We believe this discussion clearly establishes the IPA as one of the vehicles that the SNF can utilize in the course of carrying out its ongoing patient monitoring

responsibilities. Further, we believe that deleting the longstanding regulations text regarding changes in patient care needs--which dates all the way back to the inception of the SNF PPS itself, as originally issued in the May 12, 1998 SNF PPS interim final rule (63 FR 26311)--could be misinterpreted as actually precluding SNFs that may wish to use the IPA in this manner from doing so. Accordingly, we are not adopting the commenter's recommended revision to § 413.343(b).

After considering the comments received, for the reasons specified in this final rule and the FY 2020 SNF PPS proposed rule, we are finalizing the proposed changes to the regulation text in §§ 413.343 and 409.30, with the modifications discussed above.

E. Other Issues

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

a. 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).

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

For a detailed discussion of the considerations we use 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).

Comment: Several commenters expressed general support for CMS' proposed changes to the SNF QRP. One commenter expressed general support of CMS efforts to improve the Quality Reporting Program while another commenter recognized that the changes are part of a multi-year process to reform patient assessment and quality reporting across multiple levels of care. Another commenter expressed appreciation for CMS transparency and responsiveness to stakeholder input during the development and testing of the proposed SNF QRP measures, measure refinement, and proposed Standardized Patient Assessment Data Elements (SPADEs) which they believe are much improved from earlier draft versions and reflect many of the concerns and recommendations we have previously offered. One commenter was concerned about specialty populations and suggested that CMS make appropriate modifications to the application of the QRP to special populations programs and via distinct reimbursement to state-recognized special populations programs to avoid unintended consequences for specialty populations such as those living with HIV/AIDS.

Response: We thank the commenters for their support and suggestions. While we consider general comments regarding specialty populations to be out of the scope of this final rule, we will take into consideration the impact of specialty populations in our future work.

c. **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).

While we did not solicit comments on currently adopted measures (with the exception of the Discharge to Community Measure discussed in section III.E.1.d.(3) of this rule and the policies regarding public display of Drug Regimen Review Conducted With Follow-Up for Identified Issues-Post Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP) measure data in section III.E.1.i. of this rule), we received several comments.

Comments: One commenter expressed concerns with the Drug Regimen Review Conducted With Follow-Up for Identified Issues—Post Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP) measure, believing that the measure does not identify where clinically significant recommendations originate, there is no measure of what is considered “good” when comparing rates at different facilities, and that facilities that place a

high value on regular drug regimen review conducted by a consultant pharmacist deserve to be recognized for their efforts to improve patient safety and adherence to medication regimens.

Another commenter does not support the 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) measure, preferring outcome-based measures based on measures currently used in Nursing Home Compare. The commenter suggested a number of alternative measures for interim use in the SNF QRP until more measures are developed. This commenter also expressed concerns with the use of the four functional outcome measures in the SNF QRP encouraging CMS to identify a timeline for NQF endorsement. One commenter recommended that CMS adopt a standard process for evaluating whether a measure should be retained in the SNF QRP or removed or retired from the SNF QRP.

Response: We appreciate the comments on our implemented measures, the Drug Regimen Review Conducted With Follow-Up for Identified Issues—Post Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP) and the Application of Percent of Long-Term Care Hospital (LTCH) Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631) and note that we did not propose changes to these measures, so comments are outside the scope of this rule. In Table 12, we have provided a list of measures that are currently adopted in the SNF QRP. For the eight factors used to evaluate whether a measure should be removed from the SNF QRP, we refer readers to § 413.360(b)(3) of our regulations.

d. **Adoption of Two New Quality Measures and Updated Specifications for a Third Quality Measure Beginning with the FY 2022 SNF QRP**

In the FY 2020 SNF PPS proposed rule (84 FR 17637 through 17643), we proposed 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 proposed to adopt were: (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 proposed to update the specifications for the Discharge to Community – PAC SNF QRP measure to exclude baseline nursing facility (NF) residents from the measure.

IV. (1) Transfer of Health Information to the Provider–Post-Acute Care (PAC) Measure

The Transfer of Health Information to the Provider–Post-Acute Care (PAC) Measure that we proposed to adopt beginning with the FY2022 SNF QRP 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.

(a) 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.

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}

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.

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.

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

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 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.

detailed transfer of medication information.^{32,33,34} Individuals in PAC settings may be 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

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.

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.

communication barriers delay resolving medication discrepancies during transitions of care.⁴¹ 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

(b) 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

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.

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.

developed after evaluation of data collected during two pilot tests we conducted in accordance with the CMS Measures Management System Blueprint.

Our measure development contractors constituted a TEP which met on September 27, 2016⁵², January 27, 2017⁵³, and August 3, 2017⁵⁴ 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

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.

⁵⁴ Ibid

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 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>.

(c) 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>.

(d) 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 previously, 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.

(e) 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, “Final 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 proposed for this measure, we refer readers to section III.E.1.h.(3) of this final rule.

Commenters submitted the following comments related to the proposed rule’s discussion of the SNF QRP Quality Measure Proposals beginning with the FY 2022 SNF QRP. A discussion of these comments, along with our responses, appears below. We also address comments on the proposed Transfer of Health Information to the Patient–Post-Acute Care measure (discussed further in a subsequent section of this final rule) in this section because commenters frequently addressed both Transfer of Health Information measures together.

Comment: The majority of commenters supported the adoption of both of the Transfer of Health Information measures. These commenters stated that the measures will help improve care coordination, patient safety, and care transitions.

Response: We thank commenters for their support of the Transfer of Health Information

measures.

Comment: One commenter suggested that other providers, such as outpatient physical therapists, should be included in the definition of a subsequent provider for the Transfer of Health Information to the Provider–Post-Acute Care measure.

Response: We appreciate the suggestion to expand the Transfer of Health Information to the Provider–Post-Acute Care measure outcome to assess the transfer of health information to other providers such as outpatient physical therapists. We recognize that sharing medication information with outpatient providers is important, and will take into consideration additional providers in future measure modifications. Through our measure development and pilot testing we learned that outpatient providers cannot always be readily identified by the PAC provider. For this process measure, which serves as a building block for improving the transfer of medication information, we specified providers who will be involved in the care of the patient and medication management after discharge and can be readily identified through the discharge location item on the MDS. The clear delineation of the recipient of the medication list in the measure specifications will improve measure reliability and validity.

Comment: One commenter recommended that the Transfer of Health Information to the Provider–Post-Acute Care measure be expanded to include the transfer of information that would help prevent infections and facilitate appropriate infection prevention and control interventions during care transitions in addition to the medication information in the finalized measures.

Response: The Transfer of Health Information to the Provider–Post-Acute Care measure focuses on the transfer of a reconciled medication list. The measure was designed after input from TEPs, public comment, and other stakeholders that suggested the quality measures focus on the transfer of the most critical pieces of information to support patient safety and care coordination. However, we acknowledge that the transfer of many other forms of health

information is important, and while the focus of this measure is on a reconciled medication list, we hope to expand our measures in the future.

Comment: Some commenters raised concerns about both of the Transfer of Health Information measures not being endorsed by the National Quality Forum (NQF). Some commenters recommended that CMS receive NQF approval before adoption.

Response: We agree that the NQF endorsement process is an important part of measure development. As discussed in the FY 2020 SNF PPS proposed rule (84 FR 17639 through 17640), we believe that the measures better address 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, than any endorsed measures. While 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), 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. We plan to submit the measure for NQF endorsement consideration as soon as feasible.

Comment: Several commenters believe that the Transfer of Health Information to the Provider and Transfer of Health Information to the Patient measures will add burden. One commenter stated that both measures will add burden with no added value and did not support the measures for that reason. Another commenter noted that there will be additional burden to collect and report data for these two measures in part because most PAC providers do not have access to EHRs or health information technology systems that facilitate their ability to

electronically share this information.

Response: We are very mindful of burden that may occur from the collection and reporting of these measures, as supported by the CMS Meaningful Measures and Patients over Paperwork initiatives. The timely and complete transfer of information focuses on the medication list, as suggested by our TEP, public comment, and SMEs. We would like to emphasize that both measures are comprised of one item only, and further, the activities associated with the measures align with existing requirements related to transferring information at the time of a discharge in order to safeguard patients. Additionally, TEP feedback and pilot test found that burden of reporting will not be significant. We believe that these measures will likely drive improvements in the transfer of medication information between providers and with patients, families, and caregivers.

Comment: A commenter stated there will be no additional data collection time or overall burden to SNFs as the Transfer of Health Information measures will use data already captured in the MDS.

Response: We agree that the Transfer of Health Information measures will not add additional burden in data collection over time as the data captured by these measures aligns with the standards of care for the discharge or transfer of a SNF resident and are a part of common practice.

Comment: In comments related to both Transfer of Health Information measures, some commenters raised concerns about documenting the transfer of a medication list in the event of an audit, noting that providers are simply required to attest to the transfer process taking place. One commenter stated that there are many ways to operationalize and document this process in the medical record; however, CMS has not indicated whether it would favor certain methods over others. A few commenters also noted that the form of the current reconciled medication list

is not specified, nor is the method or route that the medication list is provided (that is, verbal, paper copy), which presents its own documentation challenges in ensuring adequate supporting evidence is available in the event of an audit. For these reasons, some commenters requested that CMS provide additional clarity regarding its documentation expectations and to consider the least burdensome ways for providers to comply while meeting the needs of a potential audit. One commenter also questioned whether the Transfer of Health Information to the Provider and Transfer of Health Information to the Patient measures require that the facility prove receipt of the transferred information by the other provider or patient. Lastly, another commenter questioned if there are any potential penalties related to documentation that may be associated with the measures as part of QRP program.

Response: Both measures simply require a SNF to document that the transfer of medication information took place. The Transfer of Health Information measures serve as a check to ensure that a reconciled medication list is provided as the patient changes care settings. We would like to note that it is up to the provider to decide if they have transferred a medication list that may include the following information: known medication and other allergies, known drug sensitivities and reactions; each medication, including the name, strength, dose, route of medication administration, and/or the reason for holding a medication or when a medication should resume. Defining the completeness of that medication list is left to the discretion of the providers and patient who are coordinating this care. We interpret the comments on audits to be referring to data validation. While we do not have a data validation program in place at this time, we are exploring such a program akin to that of the hospital inpatient quality reporting program. For all measures and data collected for the SNF QRP, we monitor and evaluate our data to assess for coding patterns, errors, reliability, and soundness of the data. Through data monitoring, we are able to assess if measure outcomes are consistent with the information that is collected.

With respect to the comment asking about whether there are any penalties associated with the proposed Transfer of Health Information measures, our policy for the SNF QRP is that, as detailed in 42 CFR 413.360(b)(2), SNFs must submit 100 percent of the required data elements on at least 80 percent of the MDS assessments submitted to be in compliance with SNF QRP requirements for a program year. SNFs are penalized if they do not meet this threshold.

Comment: In comments related to both Transfer of Health Information measures, some commenters commented on requiring hospitals to provide SNFs with important information at discharge. One commenter recommended that the Transfer of Health Information Measures be applied to acute care hospitals to ensure two-way, or bi-directional transfer of information and to support interoperability. A few commenters encouraged CMS to finalize revisions to “Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies” (CMS–3317–P), which would require hospitals to transfer patient information, including diagnosis and other clinical information, to the patient’s next setting in a timely manner.

Response: We agree that the bi-directional transfer of health information between hospitals and PAC providers is important and will support efforts to improve interoperability. Further, we believe that these measures will bring greater attention to the importance of the transfer of health information across all settings, increasing the seamless exchange of information across the care continuum. The Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies proposed rule (CMS–3317–P) has not been finalized. CMS has issued an extension notice for the publication of the final rule, which extends the timeline for publication of the final rule until November 3, 2019 (please see <https://www.federalregister.gov/documents/2018/11/02/2018-23922/medicare-and-medicaid-programs-revisions-to-requirements-for-discharge-planning-for-hospitals>).

Comment: A few commenters noted concerns that the Transfer of Health Information to the Provider and Transfer of Health Information to the Patient measures are not indicative of provider quality and questioned the ability of the measures to improve patient outcomes. One commenter did not support the measures for this reason. One commenter noted that the measures assess whether a medication list was transferred and not whether that medication list was accurate and received by the subsequent provider.

Response: The Transfer of Health Information to the Provider–Post-Acute Care and Transfer of Health Information to the Patient–Post-Acute Care measures are process measures designed to address and improve an important aspect of care quality. Lack of timely transfer of medication information at transitions has been demonstrated to lead to increased risk of adverse events, medication errors, and hospitalizations. Because this measure would encourage the transfer of medication information, it would be expected to have a positive impact on these type of patient outcomes. Process measures hold a lot of value as they delineate negative and/or positive aspects of the health care process. This measure will capture the quality of the process of medication information transfer and help improve those processes. Process measures, such as these, are building blocks toward improved coordinated care and discharge planning, providing information that will improve shared decision making and coordination. When developing future measures, we will take into consideration suggestions about measures that assess the accuracy of the medication list and whether it was received by the subsequent provider.

Comment: A few commenters suggested that CMS work to identify interoperability solutions to facilitate coordinated care, improve outcomes and overall quality comparisons related to both Transfer of Health Information measures. One commenter added that this would decrease opportunities for errors by providing clinicians and patients secure access to the most up-to-date medication-related information. One commenter also suggests that if CMS is required

by the IMPACT Act to adopt these measures, that they do so as an interim step, within a defined timeframe, while interoperability solutions are explored and tested. A few commenters stated that while the rule acknowledges that information may be transferred verbally, on paper or electronically, CMS has not provided funding to nursing facilities to facilitate deployment of EMRs. These commenters suggested that meaningful use incentives be extended to SNFs and other post-acute care providers. One commenter stated that the use of existing clinical and interoperability standards should be considered in the development of these and future measures and that using standardized quality measures and standardized data will help enable interoperability and access to longitudinal information to facilitate coordinated care, improved outcomes, and overall quality comparisons and suggested that CMS leverage ongoing efforts to adopt data standards and implementation guides for certified EHRs (such as the USCDI). One commenter cites numerous CMS requirements and states that they are not sufficiently aligned for purposes of electronic exchange and, as a result, create significant provider burden as providers attempt to navigate and comply with these various requirements. The commenter recommends that CMS seek greater alignment between its various data collection requirements included in both finalized and proposed rules.

Response: We agree with the comments on the importance of interoperability solutions to support health information transfer. CMS and ONC are focused on improving interoperability and the timely sharing of information between providers, patients, families and caregivers. We believe that PAC provider health information exchange supports the goals of high quality, personalized, and efficient healthcare, care coordination and person-centered care, and supports real-time, data driven, clinical decision making.

To further support interoperability, we recently released the Data Element Library (DEL), a new public resource aimed at advancing interoperable health information exchange by enabling

users to view assessment questions and response options about demographics, medical problems, and other types of health evaluations and their associated health IT standards. All data elements adopted for use in the Quality Reporting programs (QRPs), and not limited to data collected under the IMPACT Act, will be included in the DEL. In the initial version of the DEL (<https://del.cms.gov/>), assessment questions and response options are mapped to LOINC and SNOMED, where feasible. We also recognize the importance of leveraging existing standards, obtaining input from standards setting organizations, and alignment across federal interoperability efforts. We acknowledge that meaningful use incentives have not been extended to SNFs and other PAC providers and we will share these comments with the appropriate CMS staff and other governmental agencies to ensure they are taken into account as we continue to encourage adoption of health information technology. The Transfer of Health Information measures may encourage the electronic transfer of medication information at transitions. These measures and related efforts may help accelerate interoperability solutions.

The Transfer of Health Information measures assess the process of medication transfer, which can occur through both electronic and non-electronic means. We would like to clarify that these measures are an interim step in improving coordinated care, and we also believe that other interoperable solutions should be explored. Finalizing these Transfer of Health Information measures will be a first step in measuring the transfer of this medication-related information.

Comment: One commenter suggested that we develop a future outcome measure related to the transfer of medication information.

Response: We appreciate the suggestion that we develop an outcome measure related to the transfer of medication information, and agree that an outcome would be the next step when modifying the Transfer of Health Information measures. We will take this comment into consideration as we commence future measure development activities.

Comment: In comments related to both the Transfer of Health Information to the Provider and Transfer of Health Information to the Patient measures, one commenter requested the definition of a reconciled medication list and quoted from an older version of measure specifications where a medication profile had been defined.

Response: We appreciate these comments. We can confirm that as we tested these measures and gathered consensus input by TEPs and public comments, the definition of what is a reconciled medication list has been modified to decrease burden and to align to common clinical practice. Defining the completeness of that reconciled medication list is left to the discretion of the providers and patient who are coordinating this care.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the Transfer of Health Information to the Provider–Post-Acute Care (PAC) Measure under section 1899B(c)(1)(E) of the Act beginning with the FY 2022 SNF QRP as proposed.

V. (2) Transfer of Health Information to the Patient–Post-Acute Care (PAC)
Measure Beginning with the FY 2022 SNF QRP

We proposed 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.

(a) 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.⁵⁵ 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.⁵⁶

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.^{57,58,59,60,61} 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.^{62,63} Upon discharge to home, individuals in PAC settings may be faced with numerous medication changes, new medication regimes, and follow-up

⁵⁵ 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>.

⁵⁶ RTI International analysis of Medicare claims data for index stays in SNF 2017. (RTI program reference: IB55).

⁵⁷ 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.

⁵⁸ 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.

⁵⁹ Bell, C. M., Brenner, 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.

⁶⁰ 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.

⁶¹ 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.

⁶² 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.

⁶³ 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.^{64,65,66} 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.^{67,68}

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.^{69, 70} 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.⁷¹

(b) 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 MMS Blueprint.

⁶⁴ 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.

⁶⁵ 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.

⁶⁶ 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.

⁶⁷ 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.

⁶⁸ 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.

⁶⁹ 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>.

⁷⁰ 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_ltc.pdf.

⁷¹ 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.

Our measure development contractors constituted a TEP which met on September 27, 2016⁷², January 27, 2017⁷³, and August 3, 2017⁷⁴ 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, and accepted comments that were submitted from March 19, 2018 to May 3, 2018. Several

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_Summary_Report_Final-June-2017.pdf.

⁷³ 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.

⁷⁴ Ibid

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>.

(c) 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>.

(d) 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.

(e) 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 proposed for this measure, we refer readers to section III.E.1.h.(3) of this final rule.

Commenters submitted the following comments related to the proposed rule’s discussion of the SNF QRP Quality Measure Proposals Beginning with the FY 2022 SNF QRP. A discussion of these comments, along with our responses, appears below. Comments that applied to both Transfer of Health Information measures are discussed in section III.E.1.d.(1) of this final rule.

Comment: One commenter suggested that CMS use the field’s experience with transferring information to patients and reporting on the Transfer of Health Information to the Patient–Post-Acute Care (PAC) Measure to disseminate best practices about how to best convey

the medication list and suggested this include formats and informational elements helpful to patients and families.

Response: We have interpreted “the field” to mean PAC providers. Facilities and clinicians should use clinical judgement to guide their practices around transferring information to patients and how to best convey the medication list, including identifying the best formats and informational elements. This may be determined by the patient’s individualized needs in response to their medical condition. CMS does not determine clinical best practices standards and facilities are advised to refer to other sources, such as professional guidelines.

Comment: A couple of comments suggested that the Transfer of Health Information to the Patient–Post-Acute Care (PAC) Measure require transfer of the medication list to both the patient and family or caregiver. One of these commenters also stated that the measure should assess whether the patient, family or caregiver understands the medication list and has had a chance to ask questions about it.

Response: We agree there are times when it is appropriate for the SNF to provide the medication list to the patient and family and this decision should be based on clinical judgement. However, because it is not always necessary or appropriate to provide the medication list to both the patient and family, we are not requiring this for the measure.

Comment: One comment suggested that CMS adopt standards around the Transfer of Health Information to Patient measure that ensures a consultant pharmacist is involved in patient-centered medication counseling.

Response: We understand that it is important for patient safety and outcomes that patients, their family and caregivers have good understanding of medications and how to take them and the role that pharmacists fulfill in this process. However, we believe that PAC providers should rely on their facility policies or standards of practice to determine who will

provide medication counseling to patients.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the Transfer of Health Information to the Patient–Post-Acute Care (PAC) Measure under section 1899B(c)(1)(E) of the Act beginning with the FY 2022 SNF QRP as proposed.

VI. (3) Update to the Discharge to Community – Post Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP) Measure

In the FY 2020 SNF PPS proposed rule (84 FR 17643) we proposed 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 for 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 proposed 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 “Final 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 invited public comment on this proposal and received several comments. A

discussion of these comments, along with our responses, appears below.

Comment: Several commenters supported the proposed exclusion of baseline NF residents from the Discharge to Community-PAC SNF QRP measure. Commenters referred to their recommendation of this exclusion in prior years and appreciated CMS' willingness to consider and implement stakeholder feedback. One commenter recommended also excluding individuals without viable means to return to the community, such as those who are homeless, dependent on shelters, or unable to find a safe discharge option. One commenter suggested that CMS instead consider other quality measures for NF residents, such as functional status measures, to determine whether residents receive the appropriate standard of care they need during a long-term NF stay.

Response: We thank the commenters for their support of the proposed exclusion of baseline nursing facility residents from this measure, and for recommending additional exclusions and measures for consideration for baseline NF residents. We will consider the commenters' suggestions and would also note that exclusions and risk adjustment require the presence of reliable and valid data sources.

Comment: MedPAC did not support the proposed exclusion of baseline NF residents from the Discharge to Community-PAC SNF QRP measure. They stated that assessing safe discharge to "home" without post-discharge readmissions or death was also important for the baseline NF resident population and that excluding these residents would hold nursing homes harmless for their readmissions and death. MedPAC suggested that CMS instead expand their definition of "return to the community" to include baseline nursing home residents returning to the nursing home where they live, as this represents their home or community. MedPAC was also concerned that providers that mostly treat long-term care residents could have most stays excluded from the measure, and consumers using these rates for provider selection may not

know that the measure would reflect only a small share of the provider's stays. Finally, MedPAC stated that providers should be held accountable for the quality of care they provide for as much of their Medicare patient population as feasible.

Response: We agree that providers should be accountable for quality of care for as much of their Medicare population as feasible; we endeavor to do this as much as possible, only specifying exclusions we believe are necessary for measure validity. We also believe that monitoring quality of care and outcomes is important for all PAC patients, including baseline NF residents who return to a NF after their PAC stay. We publicly report several long-stay resident quality measures on Nursing Home Compare including measures of hospitalization and emergency department visits.

Community is traditionally understood as representing non-institutional settings by policy makers, providers, and other stakeholders. Including long-term care NF in the definition of community would confuse this long-standing concept of community and would misalign with CMS' definition of community in patient assessment instruments. CMS conceptualized this measure using the traditional definition of "community" and specified the measure as a discharge to community measure, rather than a discharge to baseline residence measure.

Baseline NF residents represent an inherently different patient population with not only a significantly lower likelihood of discharge to community settings, but also a higher likelihood of post-discharge readmissions and death compared with PAC patients who did not live in a NF at baseline. The inherent differences in patient characteristics and PAC processes and goals of care for baseline NF residents and non-NF residents are significant enough that we do not believe risk adjustment using a NF flag would provide adequate control. While we acknowledge that a return to nursing home for baseline NF residents represents a return to their home, this outcome does not align with our measure concept. Thus, we have chosen to exclude baseline NF residents from

the measure. While we agree that the proposed exclusion could affect providers differentially since the mix of skilled and long-term care residents differs across nursing homes, we believe it is necessary for measure validity. We also appreciate the concern that consumers using the measures may not know that the measure does not reflect outcomes for baseline NF residents. We will consider strategies to convey this information to consumers.

Comment: One commenter requested that CMS provide the definition of “long-term” NF stay in the proposed measure exclusion, requesting further clarification in the measure specifications.

Response: We have further clarified the definition of long-term NF stay in the “Final 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>. A long-term NF stay is identified by the presence of a non-SNF PPS MDS assessment in the 180 days preceding the qualifying prior acute care admission and index SNF stay.

After consideration of the public comments, we are finalizing our proposal to exclude baseline NF residents from the Discharge to Community-PAC SNF QRP measure. This measure is now NQF-endorsed.

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

We sought 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.

In the FY 2020 SNF PPS proposed rule, we included a Request for Information (RFI) related to assessment and claims-based quality measures and standardized patient assessment data elements. We received various comments on this RFI, and appreciate the input provided by commenters.

Several commenters offered general support for the future measures, measure concepts, and SPADEs under consideration, however a few commenters questioned the detail on intent and process for selecting them.

- **Assessment-Based Quality Measures and Measure Concepts**

A few commenters offered support for the addition of assessment-based quality measures related to functional maintenance outcomes. With respect to quality measures related to opioid use and frequency, one commenter offered general support and another commenter suggested caution in developing opioid related quality measures to ensure that they do not result unintended consequences that leave patients without access to critical treatments for pain management. A few commenters offered general support for exchange of electronic health information and interoperability. One commenter suggested that CMS enhance its efforts to develop standards

and measures for data exchange and sharing across all care settings including post-acute care, to explore approaches to incentivize the adoption of EHRs across the care continuum, and to develop future measures and SPADEs that use data that are available within EHRs used by PAC providers.

- Claims-Based

The claims-based quality measure, Healthcare-Associated Infections in Skilled Nursing Facility (SNF) received several comments of support, a few suggesting subcategorization to distinguish SNF-acquired infections and non-SNF-acquired infections such as infections acquired in the hospital or community.

- Standardized Patient Assessment Data Elements (SPADEs)

One commenter offered support for the SPADE categories, stating that each of these SPADE categories represent elements that will provide a fuller picture of the patients in the SNF setting and could be used for creating and risk adjusting quality measures.

Several commenters supported SPADEs related to cognitive complexity such as executive function and memory, dementia, and caregiver status. One commenter noted that regularly assessing cognitive function and mental status presents opportunities for better care and quality of life, and that regular assessment of caregivers will also result in better care for the beneficiary and better quality of life for both individuals. Another commenter suggested that CMS should further consider the prevalence and clinical and economic burden of agitation in Alzheimer's disease when evaluating future SPADEs for dementia, suggesting that treatment of symptoms of agitation in patients with Alzheimer's disease reduces caregiver burden and the cost of care for the patient symptoms of agitation in patients with Alzheimer's disease. One commenter encouraged CMS to continue to place emphasis on the importance of innovative payment approaches to ensuring the financial stability of organizations delivering care related to

Alzheimer's and dementia.

One commenter suggested that it is critical to consider the patient's needs and experience when measuring the quality of such care and supported the development and testing of patient experience measures to ensure reliability as well as validity of the measures. This commenter suggested development of a standardized tool as part of the SNF QRP to truly measure patient and/or caregiver experiences in the SNF setting, initially through a voluntary data collection phase.

One commenter supported SPADEs focused on bowel and bladder continence including appliance use and episodes of incontinence. Another commenter requested that CMS evaluate existing data MDS elements before adding additional data elements in to SPADEs in the areas of Dementia and Bladder and Bowel Continence.

For the collection of SPADE related to education, sex and gender identity, and sexual orientation, one commenter agreed that gender identity and sexual orientation are important and relevant to understanding patient care delivery needs and outcomes, and believes more information is needed to understand what data points would be collected. Another commenter proposed that CMS consider adding some measure of trauma history citing that a history of trauma can result in increased care needs and that in light of SNFs providing trauma-informed care, more SNFs will be assessing and addressing trauma and this should be captured in the measures.

One commenter endorsed adding Veteran status as a SPADE, as it may encourage more patient-centered care practices and system-wide focus on older Veterans' post-acute healthcare needs and may also encourage more research/analysis of Veteran status as a health determinant in PAC settings, particularly for investigators outside of VA for whom this information may be more difficult to access.

Finally, there were suggestions for SPADE development for other specific clinical areas such as behavioral and bariatric care.

f. 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 patient⁷⁵ 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 impaired ability to hear, see, or swallow, and (6) other categories deemed necessary and appropriate by the Secretary.

⁷⁵ 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 final rule and going forward, we will use the term “standardized patient assessment data” to refer to the collect of SPADEs from SNF residents.

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 have proposed to adopt many of the same SPADEs that we previously proposed to adopt, along with other SPADEs.

We proposed that SNFs would be required to report these SPADEs beginning with the FY 2022 SNF QRP. If finalized, 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 proposed 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 also proposed that SNFs that submit the Hearing, Vision, Race, and Ethnicity SPADEs with respect to admission 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 SPADEs. In selecting the 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 PAC providers (26 LTCHs, 60 SNFs, 22 IRFs, and 35 HHAs) from November 2017 to August 2018 to evaluate the feasibility, reliability, and validity of candidate data elements across PAC settings. The 3,121 patients and residents with an admission assessment included 507 in LTCHs, 1,167 in SNFs, 794 in IRFs, and 653 in HHAs. 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.

Comment: One commenter expressed support for the addition of SPADEs to the SNF-Resident Assessment Instrument (RAI), noting that many of them are already collected and reported on today. A second commenter noted support for the use of existing MDS items as SPADEs, noting that it will not increase provider burden. Another commenter recognized that

data standardization will help facilitate appropriate payment reforms and appropriate quality measures.

Response: We thank the commenters for their support for the proposed SPADEs. We wish to clarify that we proposed the addition of the SPADEs to the MDS for SNFs, which is one component of the RAI. We agree with the commenters that many of the SPADEs are already collected and reported currently through the MDS, and that data standardization will help facilitate appropriate payment reforms and quality measures.

Comment: One commenter noted appreciation for CMS' transparency and responsiveness to stakeholders and noted that the SPADEs are much improved from earlier draft versions and reflect many of the concerns and recommendations CMS had previously offered. The commenter stated that the SPADEs appear to reflect a reasonable compromise between the need to collect meaningful standardized resident assessment data across the continuum of care to improve care, and the need to minimize provider administrative burden.

Response: We appreciate the commenter's recognition of our stakeholder engagement activities.

Comment: One commenter noted support for the goals of the IMPACT Act, but expressed concern about the scope and timing of proposed changes, including the SPADEs. The same commenter went on to urge CMS to share with the public a data use strategy and analysis plan for the SPADEs so that providers better understand how CMS will assess the potential usability of the SPADEs to support changes to payment and quality programs.

Response: We thank the commenter for their support of the goals of the IMPACT Act and appreciate their concern about the proposed changes. 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 and prepare for additional changes.

We have provided regular updates to stakeholders and gathered feedback through Special Open Door Forums and other events as described in our proposal. CMS will continue to communicate and collaborate with stakeholders by soliciting input on how the SPADEs will be used in the SNF QRP through future rulemaking.

We are in the process of creating research identifiable files of data collected in the National Beta Test. We anticipate that these files will be available through a data use agreement sometime in 2019. We also note that additional volumes of the National Beta Test report will be available in late 2019. This report contains supplemental analyses of the SPADEs that may be of interest to stakeholders.

Comment: Some commenters stated support but noted reservations. One commenter described the SPADEs as an appropriate start, but noted that the SPADEs cannot stand alone, and must be built upon in order to be useful for risk adjustment and quality measurement. Similarly, another commenter urged CMS to continue working with clinicians and researchers to ensure that the SPADEs are collecting valid, reliable, and useful data, and to continue to refine and explore new data elements for standardization. Yet another commenter urged CMS to be cautious in its implementation of some of the SPADEs, specifically those associated with social determinants of health (SDOH).

Response: We agree with the commenter's statement that the SPADEs are an appropriate start for standardization, but we disagree that they cannot stand alone. While we intend to evaluate SPADE data as they are submitted and explore additional opportunities for standardization, we also believe that the SPADEs as proposed represent an important core set of information about clinical status and patient characteristics and they will be useful for quality measurement. We would welcome continued input, recommendations, and feedback from stakeholders – including clinicians and researchers – about refinement and new development of

SPADEs. Input can be shared with CMS through our PAC Quality Initiatives email address: PACQualityInitiative@cms.hhs.gov. We acknowledge the commenter's request that we be cautious implementing some SPADEs, particularly those associated with SDOH. We believe that our SPADE development process has been transparent and engaged stakeholders, as described in our proposals. However, we will monitor the implementation of the SPADEs in order to identify any issues that might arise.

Comment: Two commenters recommended that CMS seek greater alignment in its various data collection activities across settings. One commenter recommended alignment of SPADEs with the U.S. Core Data set for Interoperability (USCDI) once there is final rulemaking for ONC's Interoperability, Information Blocking and ONC Health IT Certification Program regulation. Although the USCDI only have current applicability in an acute care setting, the commenter pointed out that alignment, where possible (that is Cognitive Measures, Treatment Continuity, SDOH, Pain, Hearing, Speech, and Vision), would be advantageous to the quality and continuity of a patient's care. A second commenter also recommended alignment of SPADEs with the USCDI, but also mentioned the Requirements for Participation for Long Term Care Facilities (RoPs) and the Hospital Discharge Planning proposed rule as alternative guidelines with which to align the SPADEs. For data elements that are unlikely to change between settings, this commenter also urged CMS to require settings that are already collecting these data elements to send them to the next setting (that is, from acute care to PAC settings).

Response: We appreciate the commenters' recommendation for the potential for greater alignment to reduce burden and improve continuity of information as patients move between health care provider types. We are proposing SPADEs to satisfy the requirements of the IMPACT Act, which focuses on the four PAC provider types. At this time, alignment of patient assessment requirements with acute care and long-term care facilities is out of scope for these

proposals. We will take the commenters' recommendations into consideration with future data element development work.

Comment: A commenter expressed concerns about the level of evidence to support the SPADEs shared by CMS from the National Beta Test. The commenter described several concerns about the scope and implementation of the National Beta Test, including the representativeness of SNFs included in the sample, the share of total SNF patients included in the National Beta Test, the reported exclusion of patients with communication and cognitive impairments, and the exclusion of non-English speaking patients, and described how these concerns compromise their confidence in the findings of the National Beta Test. The commenter also remarked on the lack of information about clinical characteristics that has been shared with stakeholders, limiting their ability to draw conclusions about the data, and requested that CMS release the data from the National Beta Test to be analyzed by third parties.

Response: In a supplementary document to the proposed rule (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 described key findings from the National Beta Test related to the proposed SPADEs. We also referred readers to an initial volume of the National Beta Test report that details the methodology of the field test ("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>). Additional volumes of the National Beta Test report will be available in late 2019. In addition, we are committed to making data available for researchers

and the public to analyze, and to doing so in a way that protects the privacy of patients and providers who participated in the National Beta Test. We are in the process of creating research identifiable files that we anticipate will be available through a data use agreement sometime in 2019.

To address the commenter's specific concerns, we note that the National Beta Test was designed to generate valid and robust national SPADE performance estimates for each of the four PAC provider types, which required acceptable geographic diversity, sufficient sample size, and reasonable coverage of the range of clinical characteristics. To meet these requirements, the National Beta Test was carefully designed so that data could be collected from a wide range of environments, allowing for thorough evaluation of candidate SPADE performance in all PAC settings. The approach included a stratified random sample, to maximize generalizability, and subsequent analyses included extensive checks on the sampling design.

The National Beta Test did not exclude non-communicative patients/residents; rather, it had two distinct samples, one of which focused on patients/residents who were able to communicate, and one of which focused on patient/residents who were not able to communicate. The assessment of non-communicative patients/residents differed primarily in that observational assessments were substituted for some interview assessments. Non-English speaking patients were excluded from the National Beta Test due to feasibility constraints during the field test. Including limited English proficiency patients/residents in the sample would have required the Beta test facilities to engage or involve translators during the test assessments. We anticipated that this would have added undue complexity to what facilities/agencies were being requested to do, and would have undermined the ability of facility/agency staff to complete the requested number of assessments during the study period. Moreover, there is strong existing evidence for the feasibility of all patient/resident interview SPADEs included in this proposed rule (BIMS

section III.E.1.g.(1) in this final rule), Pain Interference (section III.E.1.g.(4) in this final rule), PHQ (section III.E.1.g.(2) in this final rule) when administered in other languages, either through standard PAC workflow (for example, as tested and currently collected in the MDS 3.0) and/or through rigorous translation and testing (for example, PHQ). For all these reasons, we determined that the performance of translated versions of these patient/resident interview SPADEs did not need to be further evaluated. In addition, because their exclusion did not threaten our ability to achieve acceptable geographic diversity, sufficient sample size, and reasonable coverage of the range of PAC patient/resident clinical characteristics, the exclusion of limited English proficiency patients/residents was not considered a limitation to interpretation of the National Beta Test results.

Comment: Some commenters expressed concerns for the scope of the standardized patient assessment data proposals. These commenters were concerned that the proposed standardized patient assessment data reporting requirements will impose significant burden on providers, given the volume of new standardized patient assessment data elements that were proposed to be simultaneously added to the MDS within a short timeframe.

Response: We acknowledge the additional burden that the SPADEs will impose on SNF providers and residents. Our development and selection process for the SPADEs we are adopting in this final rule prioritized data elements that are essential to comprehensive patient care. In selecting the SPADEs that we are adopting, we took into consideration clinical relevance, ability to capture medical complexity, data element performance, and expert and stakeholder input. We maintain that there will be significant benefit associated with each of the SPADEs to providers and patients, in that they are clinically useful (for example, for care planning), they support patient-centered care, and they will promote interoperability and data exchange between providers. During the SPADE development process, we were cognizant of the changes that

providers will need to implement these additions to the MDS. We note that CMS has modified many current MDS data elements to reduce the impact of SPADEs on overall burden. This effort resulted in the total addition of only 59.5 items across the PPS admission and PPS discharge assessments. In addition, changes to the SNF QRP were coordinated across CMS' quality, payment, and policy teams so that collection of SPADES will begin after the October 1, 2019 implementation of the Patient Driven Payment Model. The PDPM streamlines the PPS assessments schedule eliminating the need for the 14-day, 30-day, 60-day and 90-day assessments. When burden is evaluated in these broader terms we believe providers will find the burden of the SPADES to be negligible.

Comment: Two commenters expressed concern that this additional burden was not justified because, in their view, there was limited or no evidence for the SPADEs to improve patient care.

Response: The IMPACT Act requires that we foster interoperable data exchange between PAC providers, including SNFs, by establishing a core set of data elements. We contend that supporting care transitions through improved data exchange will improve patient care.

Comment: One commenter stated that time burden (as in, "time-to-complete") estimates are underestimated. This commenter stated that because testing conditions focused on cognitively intact, English-speaking patients with no speech or language deficits, the estimates of impact to providers' time and resources is inadequate.

Response: We disagree with the commenter that the National Beta Test time-to-complete estimates are underestimates. We wish to clarify that the National Beta Test did exclude patients/residents who were not able to communicate in English but did not categorically exclude patients with cognitive impairment or patients with speech or language deficits. Therefore, we believe that time-to-complete estimates from the National Beta Test capture the full range of

SNF residents who are able to communicate, including those with speech and language deficits.

Comment: To reduce administrative burden, some commenters' recommended changes to when and how SPADEs would be collected. One commenter was concerned that asking patients or their care partners to repeat questions throughout the admission could create a perception of poor communication and ineffectiveness that could result in an undesirable patient experience. This commenter urged CMS to reduce the number of additional standardized patient assessment data elements to ensure questions and categories do not create an undue administrative and patient burden. Other recommendations included collecting data only at admission when answers are unlikely to change between admission and discharge, adopting a staged implementation or only a subset of the proposed data elements, and that CMS explore options for obtaining these data via claims or voluntary reporting only.

Response: We appreciate the commenters' recommendations. We acknowledge that several SPADEs being finalized in this rule require the patient to be asked questions directly. We believe that direct patient assessment and patient-reported outcomes on these topics have benefits for providers and patients. These data elements support patient-centered care by soliciting the patient's perspective, and better information on a patient's status should improve the care the patient receives.

To support data exchange between settings, and to support quality measurement, section 1899B(b)(1)(A) of the Act requires that the SPADEs be collected with respect to both admission and discharge. In the FY 2020 SNF PPS proposed rule (84 FR 17644), we proposed that SNFs that submit four SPADEs with respect to admission will be deemed to have submitted those SPADEs with respect to both admission and discharge because we asserted that it is unlikely that the assessment of those SPADEs at admission would differ from the assessment of the same SPADEs at discharge. We note that a patient's ability to hear or ability to see are more likely to

change between admission and discharge than, for example, a patient's self-report of his or her race, ethnicity, preferred language, or need for interpreter services, (although it is possible that any of these data elements may change). The Hearing and Vision SPADEs are also different from the other SPADEs (that is, Race, Ethnicity, Preferred Language, and Interpreter Services) because evaluation of sensory status is a fundamental part of the ongoing nursing assessment conducted for SNF patients. Therefore, significant changes that occur in a patient's hearing or vision impairment during the SNF stay would be captured as part of the clinical record, even if they are not assessed by a SPADE. After consideration of public comments discussed in sections III.E.1.g.(5) and (6) of this final rule, we will deem SNFs that submit the Hearing, Vision, Race, Ethnicity, Preferred Language, and Interpreter Services SPADEs with respect to admission to have submitted with respect to both admission and discharge.

Regarding the number of SPADEs proposed, we note that these items span many substantive clinical areas and patient characteristics, and are comprised of a mix of patient interview and non-interview assessments. We contend that we have been highly selective when identifying SPADEs, and that our selections reflect a balanced approach to assessor and patient burden versus need for assessment data to support care planning, foster interoperability, and inform future quality measures. We will take into consideration the recommendation to obtain patient data from claims data in future work.

Comment: A commenter encouraged CMS to create and make transparent a data use strategy and analysis plan for the SPADEs so PAC providers, including SNFs, better understand how the agency will further assess the adequacy and usability of the SPADEs. This commenter noted appreciation for CMS' efforts to provide opportunities for stakeholder communication and input, but also urged CMS to develop additional lines of communication with stakeholders, such as a multi-disciplinary stakeholder workgroup representing all PAC settings to advise on

strategic and operational implications of implementation and a data analytics advisory group to assist CMS in establishing a framework for SPADE analysis and ongoing assessment. Another commenter believed that the SPADEs would provide a more accurate reflection on the resident's SNF resource use and could inform refinements to case-mix methodology. This commenter stated that CMS should include the potential impact of the SPADEs on case-mix payment methodology in the final rule.

Response: We appreciate the commenter's recommendation. It is our intention, as delineated by the IMPACT Act, to use the SPADE data to inform care planning, the common standards and definitions to facilitate interoperability, and to allow for comparing assessment data for standardized measures. In order to maintain open lines of communication with our stakeholders, we have used the public comment periods, TEPs, Subject Matter Expert working groups, stakeholder meetings, data forums, MLNs, open door forums, help desks, in-person trainings, webinars with communication with the public, "We Want to Hear From You" sessions, and have had stakeholders serve as consultants on our measure work. If there are any other opportunities for communication and comment, we will publish those opportunities. We will continue to communicate with stakeholders about how the SPADEs will be used in quality programs, as those plans are established, by soliciting input during the development process and establishing use of the SPADEs in quality programs through future rulemaking.

Comment: One commenter recommended that CMS focus on providing funding and administrative support to allow improvements and standardization to the electronic medical record to allow effective interoperability across all post-acute sites.

Response: We appreciate the commenter's recommendation. At this time, funding for electronic medical record adoption and support is not authorized for PAC providers.

Final decisions on the SPADEs are given below, following more detailed comments on

each SPADE proposal.

g. Standardized Patient Assessment Data by Category

VII. (1) 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.⁷⁶ 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,⁷⁷ and because these assessments provide opportunity for improving quality of care.

Symptoms of dementia may improve with pharmacotherapy, occupational therapy, or physical activity,^{78, 79, 80} and promising treatments for severe traumatic brain injury are currently being tested.⁸¹ For older patients and residents diagnosed with depression, treatment options to reduce symptoms and improve quality of life include antidepressant medication and psychotherapy,^{82, 83, 84, 85} and targeted services, such as therapeutic recreation, exercise, and

⁷⁶ 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>.

⁷⁷ 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.

⁷⁸ Casey D.A., Antimisiaris D., O'Brien J. (2010). Drugs for Alzheimer's Disease: Are They Effective? *Pharmacology & Therapeutics*, 35, 208–211.

⁷⁹ Graff M.J., Vernooij-Dassen M.J., Thijssen M., Dekker J., Hoefnagels W.H., Rikkert M.G.O. (2006). Community Based Occupational Therapy for Patients with Dementia and their Care Givers: Randomised Controlled Trial. *BMJ*, 333(7580): 1196.

⁸⁰ 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.

⁸¹ 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.

⁸² 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.

⁸³ Arean P.A., Cook B.L. (2002). Psychotherapy and combined psychotherapy/pharmacotherapy for late life depression. *Biological Psychiatry*, 52(3), 293-303.

⁸⁴ 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.

restorative nursing, to increase opportunities for psychosocial interaction.⁸⁶

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 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

⁸⁵ Wagenaar D, Colenda CC, Kreft M, Sawade J, Gardiner J, Poverejan E. (2003). Treating depression in nursing homes: practice guidelines in the real world. *J Am Osteopath Assoc.* 103(10), 465-469.

⁸⁶ 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.

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 invited comments on our proposals to collect as standardized patient assessment data the following data with respect to cognitive function and mental status.

Commenters submitted the following comments related to the proposed rule's discussion of the cognitive function and mental status data elements.

Comment: A few commenters were supportive of the proposal to adopt the BIMS, CAM, and PHQ-2 to 9 as SPADEs on the topic of cognitive function and mental status. One commenter agreed that standardizing cognitive assessments will allow providers to identify changes in status, support clinical decision-making, and improve care continuity and interventions.

Response: We thank the commenters for their support. We selected the Cognitive Function and Mental Status data elements for proposal as standardized data in part because of the attributes that the commenters noted.

Comment: A few commenters noted limitations of these SPADEs to fully assess all areas of cognition and mental status, particularly mild to moderate cognitive impairment, and performance deficits that may be related to cognitive impairment. A few commenters urged CMS to continue exploring assessment tools on the topic of cognition and to include a more comprehensive assessment of cognitive function for use in PAC settings, noting that highly vulnerable patients with a mild cognitive impairment cannot be readily identified through the

current SPADEs.

Response: We acknowledge the limitations of the SPADEs to fully assess all areas of cognition and mental status. We have strived to balance the scope and level of detail of the data elements against the potential burden placed on patients and providers. In our past work, we evaluated the potential of several different cognition assessment for use as standardized data elements in PAC settings. We ultimately decided on the data elements in our proposal as a starting point, and we welcome continued input, recommendations, and feedback from stakeholders about additional data elements for standardization, which can be shared with CMS through our PAC Quality Initiatives email address: PACQualityInitiative@cms.hhs.gov.

Comment: Regarding future use of these data elements, one commenter recommended that CMS monitor the use of the cognition and mental status SPADEs as risk adjustors and make appropriate adjustments to methodology as needed.

Response: We intend to monitor data submitted via the proposed SPADEs and will consider the use of SPADEs as risk adjustors in the future. We will also continue to review recommendation and feedback from stakeholders regarding candidate data for standardization that would provide meaningful data for PAC providers and patients.

Final decisions on the SPADEs are given below, following more detailed comments on each SPADE proposal.

- Brief Interview for Mental Status (BIMS)

In the FY 2020 SNF PPS proposed rule (84 FR 17645 through 17646), we proposed 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.⁸⁷ 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.⁸⁸

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 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 “Final 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

⁸⁷ 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.

⁸⁸ RTI International. Proposed Measure Specifications for Measures Proposed in the FY 2017 IRF QRP NPRM. Research Triangle Park, NC. 2016.

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 “Final

Specifications for SNF 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 (SODFs) 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 patient assessment data elements. However, taking together the importance of assessing for cognitive status, stakeholder input, and strong test results, we proposed 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.

Commenters submitted the following comments related to the proposed rule's discussion of the BIMS data elements.

Comment: Several commenters support the use of the BIMS to assess cognitive function and mental status.

Response: We thank the commenters for their support of the BIMS data element.

Comment: One commenter supported the collection of BIMS at both admission and discharge and believes it will result in more complete data and better care.

Response: We thank the commenter for their support of collecting the BIMS data element at admission and discharge.

Comment: Several commenters stated that the BIMS fails to detect mild cognitive impairment or functional cognition, differentiate cognitive impairment from a language impairment, link impairment to functional limitation, or identify issues with problem solving and executive function. One commenter recommended use of the Development of Outpatient

Therapy Payment Alternatives (DOTPA) items for PAC as well as a screener targeting functional cognition.

Response: We recognize that the BIMS assesses components of cognition and does not, alone, provide a comprehensive assessment of potential cognitive impairment. However, we would also like to clarify that any SPADE or set of data elements that may be proposed in the future would be intended as a minimum assessment and would not limit the ability of providers to conduct more comprehensive assessment of cognition to identify the complexities or potential impacts of cognitive impairment that the commenter describes.

We evaluated the suitability of the DOTPA, as well as other screening tools that targeted functional cognition, by engaging our TEP, through “alpha” feasibility testing, and through soliciting input from stakeholders. At the second meeting of TEP in March 2017, members questioned the use of data elements that rely on assessor observation and judgment, such as DOTPA CARE tool items, and favored other assessments of cognition that required patient interview or patient actions. The TEP also discussed performance-based assessment of functional cognition. These are assessments that require patients to respond by completing a simulated task, such as ordering from a menu, or reading medication instructions and simulating the taking of medications, as required by the Performance Assessment of Self-Care Skills (PASS) items.

In Alpha 2 feasibility testing, which was conducted between April and July 2017, we included a subset of items from the DOTPA as well as the PASS. Findings of that test identified several limitations of the DOTPA items for use as SPADEs, such as relatively long to administer (5 to 7 minutes), especially in the LTCH setting. Assessors also indicated that these items had low relevance for SNF and LTCH patients. In addition, interrater reliability was highly variable among the DOTPA items, both overall and across settings, with some items showing very low agreement (as low as 0.34) and others showing excellent agreement (as high as 0.81). Similarly,

findings of the Alpha 2 feasibility test identified several limitations of the PASS for use as SPADEs. The PASS was relatively time-intensive to administer (also 5 to 7 minutes), many patients in HHAs and IRFs needed assistance completing the PASS tasks, and missing data were prevalent. Unlike the DOTPA items, interrater reliability was consistently high overall for PASS (ranging from 0.78 to 0.92), but the high reliability was not deemed to outweigh fundamental feasibility concerns related to administration challenges. A summary report for the Alpha 2 feasibility testing titled “Development and Maintenance of Standardized Cross Setting Patient Assessment Data for Post-Acute Care: Summary Report of Findings from Alpha 2 Pilot Testing” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Alpha-2-SPADE-Pilot-Summary-Document.pdf>.

Feedback was obtained on the DOTPA and other assessments of functional cognition through a call for input that was open from April 26, 2017 to June 26, 2017. While we received support for the DOTPA, PASS, and other assessments of functional cognition, commenters also raised concerns about the reliability of the DOTPA, given that it is based on staff evaluation, and the feasibility of the PASS, given that the simulated medication task requires props, such as a medication bottle with printed label and pill box, which may not be accessible in all settings. A summary report for the April 26 to June 26, 2017 public comment period titled “Public Comment Summary Report 2” is available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Public-Comment-Summary-Report_Standardized-Patient-Assessment-Data-Element-Work_PC2_Jan-2018.pdf.

Based on the input from our TEP, results of alpha feasibility testing, and input from stakeholders, we decided to propose the BIMS for standardization at this time due to the body of research literature supporting its feasibility and validity, its relative brevity, and its existing use

in the MDS and IRF-PAI.

Comment: One commenter stated that the BIMS is a screening tool for cognition, and not necessarily an assessment item for confirming a diagnosis.

Response: As stated previously, the BIMS was developed to be a brief, objective screening tool, with a focus on learning and memory. It is designed to be a relatively quick and easy to score assessment that could identify cognitively impaired patients as well as those who may be at risk for cognitive decline and require further assessment. We recognize that the BIMS assesses components of cognition and does not, alone, provide a comprehensive assessment of potential cognitive impairment. However, we would also like to clarify that any SPADE or set of data elements that may be proposed in the future would be intended as a minimum assessment and would not limit the ability of providers to conduct more comprehensive assessment of cognition to identify the complexities or potential impacts of cognitive impairment that the commenter describes.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the BIMS as standardized patient assessment data beginning with the FY 2022 SNF QRP as proposed.

- Confusion Assessment Method (CAM)

In the FY 2020 SNF PPS proposed rule (84 FR 17646 through 17647), we proposed 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.⁸⁹ 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 proposed 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 “Final 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, 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

⁸⁹ 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.

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 “Final 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 proposed 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.

Commenters submitted the following comments related to the proposed rule’s discussion of the CAM data elements.

Comment: Several commenters support the use of the CAM to assess cognitive function and mental status.

Response: We thank the commenters for their support of the CAM data element.

Comment: One commenter believed the CAM would be difficult to administer and raised concerns about the training that staff would receive in order to ensure that administration is consistent and valid.

Response: We appreciate the commenter's recommendation to provide clear training for administering the CAM. We note that the CAM is already collected on the MDS. We will take this recommendation into consideration in our review of the current training information for the MDS.

Comment: One commenter stated that the CAM is a screening tool for cognition, and not necessarily an assessment item for confirming a diagnosis.

Response: We agree with the commenter that the CAM assessment alone, is not sufficient for confirming a diagnosis of delirium. We also recognize that the CAM assesses components of cognition and does not, alone, provide a comprehensive assessment of potential cognitive impairment. However, we would also like to clarify that any SPADE or set of data elements is intended as a minimum assessment and would not limit the ability of providers to conduct more comprehensive assessment of cognition to identify the complexities or potential impacts of cognitive impairment, such as delirium.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the CAM as standardized patient assessment data beginning with the FY 2022 SNF QRP as proposed.

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

In the FY 2020 SNF PPS proposed rule (84 FR 17647 through 17648), we proposed 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 a 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 a screening tool for identifying depression, to assess depression severity, and to monitor patient mood over time.^{90,91} 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 assessment for residents who fail to report the cardinal symptoms of depression. The design of

⁹⁰ 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.

⁹¹ 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.

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 proposed 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 “Final 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,⁹² 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 contractor from November 2017 to August 2018. Results of this test found the PHQ-2 to 9 to be

⁹² 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.

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 “Final 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 proposed 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.

Commenters submitted the following comments related to the proposed rule’s discussion of the PHQ-2 to 9 data elements.

Comment: Several commenters support the use of the PHQ-2 to 9 to assess cognitive function and mental status.

Response: We thank the commenters for their support of the PHQ-2 to 9.

Comment: One commenter stated that the PHQ-2 to 9 is a screening tool for depression, and not necessarily an assessment item for confirming a diagnosis.

Response: We agree with the commenter that the PHQ-2 to 9 alone is not sufficient for confirming a diagnosis of depression. Rather, the PHQ-2 to 9 is a screening tool that identifies residents who should receive further evaluation for depression. We would also like to clarify that any SPADE or set of data elements is intended as a minimum assessment and would not limit the ability of providers to conduct a more comprehensive assessment of depression to identify the complexities or potential impacts of depression.

Comment: One commenter noted that experts in geriatric psychiatry have identified care transitions as a prime period for intervening in suicide risk among older adults. This commenter

was concerned that there would be no universal screening for suicide risk in patients discharged from SNFs unless the patient meets the required threshold on the PHQ-2 assessment and suggested that CMS consider adding the suicide ideation item from the PHQ-9 to the PHQ-2 at points of transition (for example discharge and transition to the community or between settings) as a step toward universal screening of suicide risk.

Response: We appreciate the commenter's concern for a universal screening for suicide risk. The PHQ-2 screens for the cardinal symptoms of depression, but does not ask about being bothered "by thoughts that you would be better off dead, or hurting yourself in some way."⁹³ We will take the commenter's recommendation into consideration in future item development work. We note that despite not being adopted as a SPADE, individual providers have the ability to include this particular question or any screening or assessment tools that they believe would benefit their ability to provide high-quality care to their residents.

Comment: Lastly, one commenter expressed confusion about how depression relates to cognitive function.

Response: Section 1899B(b)(1)(B)(ii) of the Act specifies that the category of "cognitive function, such as ability to express ideas and to understand, and mental status, such as depression and dementia." This category includes both cognitive function and mental status. The PHQ-2 to 9 data elements do not pertain to cognitive function, but do pertain to mental status. After careful consideration of the public comments we received, we are finalizing our proposal to adopt the PHQ-2 to 9 data elements as standardized patient assessment data beginning with the FY 2022 SNF QRP as proposed.

⁹³ The Patient Health Questionnaire-9 (PHQ-9) states: "Over the last 2 weeks, have you been bothered by any of the following problems?" The ninth response option state: "Thoughts that you would be better off dead, or of hurting yourself in some way."

IX. (3) Special Services, Treatments, and Interventions Data

Special services, treatments, and interventions performed in PAC can have a major effect on an individual's health status, self-image, and quality of life. The assessment of these special services, treatments, and interventions in PAC is important to ensure the continuing appropriateness of care for the patients and residents receiving them, and to support care transitions from one PAC provider to another, an acute care hospital, or discharge. 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 invited comments on our proposals to collect as standardized patient assessment data the following data with respect to special services, treatments, and interventions.

Commenters submitted the following comments related to the proposed rule’s discussion of the special services, treatments, and interventions data elements.

Comment: Some commenters were supportive of collecting these data elements, one noting that collection will help to better inform CMS and SNF providers on the severity and needs of patients in this setting.

Response: We thank the commenters for their support of these items. We selected the Special Services, Treatments, and Interventions data elements for proposal as standardized data in part because of the attributes noted.

Comment: One commenter expressed concern about the relevance of the Special Services, Treatments, and Interventions data elements to patients in SNFs. This and other commenters also noted concern around burden of completion of these data elements, in particular, the documentation burden taking away from patient care in the SNF settings.

Response: We acknowledge the commenters’ concern for burden on completion of these data elements. We note that many of the SPADEs in this category are already collected on the MDS and the additional burden introduced by the sub-elements is minimal. To the extent that assessment and reporting may detract from time spent in direct patient care, we assert that SNFs

already have processes in place to provide special services, treatments, and interventions for patients upon admission, during their stay, and at the time of discharge. We are asking that this available information be recorded on the Part A Discharge assessment.

Comment: One commenter was concerned about the reliability of the Special Services, Treatments, and Interventions data elements, noting that the results of the National Beta Test indicated that these data elements had a low interrater reliability kappa statistic, relative to other data elements in the test.

Response: In the category of Special Services, Treatments, and Interventions, for SPADEs where kappas could be calculated, 1 data element and 2 sub-elements demonstrated overall reliabilities in the moderate range (0.41 – 0.60) and only 1 sub-element demonstrated an overall reliability in the slight/poor range (0.00 – 0.20). These overall reliabilities were as follows: 0.60 for the Therapeutic Diet data element, 0.55 for the “Continuous” sub-element of Oxygen Therapy, 0.46 for the “Other” sub-element of IV Medications, and 0.13 for the “Anticoagulant” sub-element of IV Medications. However, the overall reliabilities for all other Special Services, Treatments, and Interventions data elements and sub-elements where kappas could be calculated were substantial/good or excellent/almost perfect. When looking at percent agreement – an alternative measure of interrater agreement – values of overall percent agreement for all Special Services, Treatments, and Interventions SPADEs and sub-elements ranged from 80 to 100 percent.

Comment: One commenter expressed concern that the Special Services, Treatments, and Interventions data elements assess the presence or absence of something rather than the clinical rationale or patient outcomes. This commenter stressed the importance of bringing this assessment to the “next level” in order to determine impact of these treatments on patients’ outcomes.

Response: We agree with the commenter's concern that recording the presence or absence of certain treatments is only a first step in characterizing the complexity that is often the cause of a patient's receipt of special services, treatments, and interventions. We would like to clarify that all the SPADEs we proposed are intended as a minimum assessment and do not limit the ability of providers to conduct a more comprehensive evaluation of a patient's situation to identify the potential impacts on outcomes that the commenter describes.

Final decisions on the SPADEs are given below, following more detailed comments on each SPADE proposal.

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

In the FY 2020 SNF PPS proposed rule (84 FR 17649 through 17650), we proposed 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 proposed 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 "Final 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, some 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 “Final 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 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 chemotherapy, stakeholder input, and strong test results, we proposed 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.

Commenters submitted the following comments related to the proposed rule's discussion of the Chemotherapy (IV, Oral, Other) data element.

Comment: One commenter was supportive of collecting this data element.

Response: We thank the commenter for the support of the Chemotherapy data element.

Comment: One commenter agreed that it is important to know if a patient is receiving chemotherapy for cancer and the method of administration, but also expressed concern about the lack of an association with a patient outcome. This commenter noted that implications of chemotherapy for patients needing speech-language pathology services include chemotherapy-related cognitive impairment, dysphagia, and speech and voice related deficits.

Response: We appreciate the commenter's concern. We agree with the commenter that chemotherapy can create related treatment needs for patients, such as the examples noted by the commenter. We believe that it is not feasible for SPADEs to capture all of a patient's needs related to any given treatment, and we maintain that the Special Services, Treatments, and Interventions SPADEs provide a common foundation of clinical assessment, which can be built on by the individual provider or a patient's care team.

Comment: One commenter noted concern around burden of completion of the

Chemotherapy data element, in particular the additional administrative burden because this data element adds sub-elements to an existing MDS item. However, the commenter also stated their belief that the Chemotherapy data element would provide a more accurate reflection of residents' resource needs that could inform case-mix payment methodology.

Response: We appreciate the commenter's concern for administrative burden. We agree that assessment of Chemotherapy received by patients in the SNF setting would provide important information for care planning and resource use in SNFs.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the Chemotherapy (IV, Oral, Other) data element as standardized patient assessment data beginning with the FY 2022 SNF QRP as proposed.

(b) Cancer Treatment: Radiation

In the FY 2020 SNF PPS proposed rule (84 FR 17650 through 17651), we proposed 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 “Final 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, some 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 “Final 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 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 radiation, stakeholder input, and strong test results, we proposed 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.

Commenters submitted the following comments related to the proposed rule's discussion of the Radiation data element.

Comment: One commenter was supportive of collecting this data element.

Response: We thank the commenter for the support of the Radiation data element.

Comment: One commenter expressed concern that the Radiation data element assesses whether a patient is receiving radiation for cancer treatment, but does not identify the rationale for and outcomes association with radiation. The commenter noted that implications of radiation for patients needing speech-language pathology services include reduced head and neck range of motion due to radiation or severe fibrosis, scar bands, and reconstructive surgery complications and that these can impact both communication and swallowing abilities.

Response: We appreciate the commenter's concern. We agree with the commenter that radiation can create related treatment needs for patients, such as the examples noted by the commenter. We believe that it is not feasible for SPADEs to capture all of a patient's needs related to any given treatment, and we maintain that the Special Services, Treatments, and Interventions SPADEs provide a common foundation of clinical assessment, which can be built on by the individual provider or a patient's care team.

After careful consideration of the public comments we received, we are finalizing our

proposal to adopt the Radiation data element as standardized patient assessment data beginning with the FY 2022 SNF QRP as proposed.

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

In the FY 2020 SNF PPS proposed rule (84 FR 17651 through 17652), we proposed 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 “Final 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 “Final 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 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 oxygen therapy, stakeholder input, and strong test results, we proposed 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.

Commenters submitted the following comments related to the proposed rule’s discussion of the Oxygen Therapy (Continuous, Intermittent, High-concentration Oxygen Delivery System) data element.

Comment: One commenter was supportive of collecting this data element.

Response: We thank the commenter for the support of the Oxygen Therapy data element.

Comment: One commenter noted concern around burden of completing the Oxygen Therapy data element, in particular the additional administrative burden because this data element adds sub-elements to an existing MDS item. However, the commenter also stated their belief that the Oxygen Therapy data element would provide a more accurate reflection of residents' resource needs that could inform case-mix payment methodology.

Response: We appreciate the commenter's concern for burden on clinical staff. The primary data element, Oxygen Therapy, is already included in the MDS. Our clinical advisors and stakeholders have stated that the type of oxygen support received by a patient -- that is, Continuous, Intermittent, High-concentration Oxygen Delivery System -- can be reasonably expected to be included in the medical record with the indication for oxygen therapy overall. We contend that the addition of sub-elements to the existing MDS data element will not require the assessor to undertake an entirely new search within the medical record for this information. Rather, the additional information required by the sub-elements will be documented within or adjacent to information on the primary data element. , Therefore, the additional burden of data collection related to the sub-elements is minimal, requiring only that the assessor document in the MDS additional information that should be readily available in a patient's medical record with the documentation of the primary data element. We agree that assessment of Oxygen Therapy received by patients in the SNF setting would provide important information for care planning and resource use in SNFs.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the Oxygen Therapy (Intermittent, Continuous, High-Concentration Oxygen Delivery System) data element as standardized patient assessment data beginning with the FY

2022 SNF QRP as proposed.

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

In the FY 2020 SNF PPS proposed rule (84 FR 17652 through 17653), we proposed 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 proposed 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 “Final 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, some 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 "Final 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](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 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 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 proposed 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.

Commenters submitted the following comments related to the proposed rule's discussion of the Suctioning (Scheduled, As needed) data element.

Comment: One commenter was supportive of collecting this data element.

Response: We thank the commenter for the support of the Suctioning data element.

Comment: One commenter requested that this data element also assess the frequency of suctioning, as it can impact resource utilization and potential medication changes in the plan of care.

Response: We appreciate that the response options for this data element may not fully capture impacts to resource utilization and care plans. The Suctioning data element includes sub-elements to identify if suctioning is performed on a "Scheduled" or "As Needed" basis, but it does not directly assess the frequency of suctioning by, for example, asking an assessor to specify how often suctioning is scheduled. This data element differentiates between patients who only occasionally need suctioning, and patients for whom assessment of suctioning needs is a frequent and routine part of the care (that is, where suctioning is performed on a schedule according to physician instructions). In our work to identify standardized data elements, we strived to balance the scope and level of detail of the data elements against the potential burden placed on patients and providers, and we believe that modifying the Suctioning data element to assess frequency of suction would collect an overly-detailed and potentially burdensome level of clinical information about a patient that is not necessary to support quality measures, care planning, or care transitions. Therefore, we will not be modifying the Suctioning data element to assess the frequency of suctioning. However, we would like to clarify that any standardized

patient assessment data element is intended as a minimum assessment and does not limit the ability of providers to conduct a more comprehensive evaluation of a patient's situation to identify the potential impacts on outcomes that the commenter describes.

Comment: One commenter noted concern around burden of completion of the Suctioning data element, in particular the additional administrative burden because this data element adds sub-elements to an existing MDS item. However, the commenter also stated their belief that the Suctioning data element would provide a more accurate reflection of residents' resource needs that could inform case-mix payment methodology.

Response: We appreciate the commenter's concern for burden on clinical staff. The primary data element, Suctioning, is already included in the MDS. Our clinical advisors and stakeholders have stated that the type of suctioning support received by a patient, that is, Scheduled or As Needed, can be reasonably expected to be included in the medical record with the indication for suctioning overall. We contend that the addition of sub-elements to the existing MDS data element will not require the assessor to undertake an entirely new search within the medical record for this information. Rather, the additional information required by the sub-elements will be documented within or adjacent to information on the primary data element. Therefore, the additional burden of data collection related to the sub-elements is minimal, requiring only that the assessor document in the MDS additional information that should be readily available in a patient's medical record with the documentation of the primary data element. We agree that assessment of Suctioning received by patients in the SNF setting would provide important information for care planning and resource use in SNFs.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the Suctioning (Scheduled, As needed) data element as standardized patient assessment data beginning with the FY 2022 SNF QRP as proposed.

(e) Respiratory Treatment: Tracheostomy Care

In the FY 2020 SNF PPS proposed rule (84 FR 17653 through 17654), we proposed 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

“Final 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 “Final 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 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 tracheostomy care, stakeholder input, and

strong test results, we proposed 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.

Commenters submitted the following comments related to the proposed rule's discussion of the Tracheostomy Care data element.

Comment: One commenter was supportive of collecting this data element.

Response: We thank the commenter for the support of the Tracheostomy Care data element.

Comment: One commenter noted the importance of determining if a patient had a tracheostomy as it helps with risk adjustment and identifying increased resource utilization, but recommended that the SPADE be expanded to ask about the size of the tracheostomy and whether the tracheostomy has a cuff or is fenestrated.

Response: Risk adjustment determinations is an issue that we continue to evaluate in all of our QRP programs. We will note this issue for further analysis in our future work to determine how the SPADEs will be used. With regard to the commenter's request to expand the Tracheostomy Care SPADE to include more detail about the type of tracheostomy, we do not believe that this level of clinical detail is needed to fulfill the purposes of the SPADEs, which are to support care coordination, care planning, and future quality measures. We believe the broad indication that a patient is receiving Tracheostomy Care will be sufficient for the purposes of standardization and quality measurement, and that additional detail would generate unnecessary burden.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the Tracheostomy Care data element as standardized patient assessment data

beginning with the FY 2022 SNF QRP as proposed.

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

In the FY 2020 SNF PPS proposed rule (84 FR 17654 through 17655), we proposed 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 proposed 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 “Final 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, some 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 “Final 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 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 non-invasive mechanical ventilation, stakeholder input, and strong test results, we proposed 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.

Commenters submitted the following comments related to the proposed rule’s discussion of the Non-invasive Mechanical Ventilator (BiPAP, CPAP) data element.

Comment: One commenter was supportive of collecting this data element.

Response: We thank the commenter for the support of the Non-Invasive Mechanical Ventilator data element.

Comment: One commenter noted concern around burden of completion of the Non-Invasive Mechanical Ventilator data element, in particular the additional administrative burden because this data element adds sub-elements to an existing MDS item. However, the commenter also stated their belief that the Non-Invasive Mechanical Ventilator data element would provide

a more accurate reflection of residents' resource needs that could inform case-mix payment methodology.

Response: We appreciate the commenter's concern on additional administrative burden. The primary data element, Non-Invasive Mechanical Ventilator, is already included in the MDS. Our clinical advisors and stakeholders have stated that the type of ventilator received by a patient -- that is, CPAP or BiPAP -- can be reasonably expected to be included in the medical record with the indication for ventilator overall. We contend that the addition of sub-elements to the existing MDS data element will not require the assessor to undertake an entirely new search within the medical record for this information. Rather, the additional information required by the sub-elements will be documented within or adjacent to information on the primary data element. Therefore, the additional burden of data collection related to the sub-elements is minimal, requiring only that the assessor document in the MDS additional information that should be readily available in a patient's medical record with the documentation of the primary data element. We agree that assessment of non-mechanical ventilator services received by patients in the SNF setting would provide important information for care planning and resource use in SNFs.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the Non-invasive Mechanical Ventilator (BiPAP, CPAP) data element as standardized patient assessment data beginning with the FY 2022 SNF QRP as proposed.

(g) Respiratory Treatment: Invasive Mechanical Ventilator

In the FY 2020 SNF PPS proposed rule (84 FR 17655 through 17656), we proposed 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.⁹⁴

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 proposed to rename this data 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 "Final 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>.

⁹⁴ 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.

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 “Final 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 proposed 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.

Commenters submitted the following comments related to the proposed rule’s discussion of the Invasive Mechanical Ventilator data element.

Comment: One commenter was supportive of collecting this data element.

Response: We thank the commenter for the support of the Invasive Mechanical Ventilator data element.

Comment: One commenter was disappointed to see that this data element only assesses whether or not a patient is on a mechanical ventilator. The commenter urged CMS to consider collecting data to track functional outcomes related to progress towards independence in communication and swallowing.

Response: We have attempted to balance the scope and level of detail of the data elements against the potential burden placed on patients and providers. We believe that assessing the use of an invasive mechanical ventilator will be a useful point of information to inform care planning and further assessment, such as related to functional outcomes, as the commenter suggests, but we do not believe it is necessary to track functional outcomes related to progress towards independence in communication and swallowing as part of the SPADEs.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the Invasive Mechanical Ventilator data element as standardized patient assessment data beginning with the FY 2022 SNF QRP as proposed.

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

In the FY 2020 SNF PPS proposed rule (84 FR 17656 through 17657), we proposed 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 proposed 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 proposed 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 “Final 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, some 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 “Final 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 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 IV medications, stakeholder input, and strong test results, we proposed 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.

Commenters submitted the following comment related to the proposed rule's discussion of the IV Medications (Antibiotics, Anticoagulants, Vasoactive Medications, Other) data element.

Comment: One commenter noted concern around burden of completion of the IV Medication data element, in particular the additional administrative burden because this data element adds sub-elements to an existing MDS item. However, the commenter also stated their belief that IV Medication data element would provide a more accurate reflection of residents' resource needs that could inform case-mix payment methodology.

Response: We appreciate the commenter's concern for administrative burden. The primary data element, IV Medications, is already included in the MDS. Our clinical advisors and stakeholders have stated that the type of IV Medications received by a patient can be reasonably expected to be included in the medical record with the indication for IV medications overall. We contend that the addition of sub-elements to the existing MDS data element will not require the assessor to undertake an entirely new search within the medical record for this information. Rather, the additional information required by the sub-elements will be documented within or adjacent to information on the primary data element. Therefore, the additional burden of data collection related to the sub-elements is minimal, requiring only that the assessor document in the MDS additional information that should be readily available in a patient's medical record with the documentation of the primary data element. We agree that assessment of IV

medications received by patients in the SNF setting would provide important information for care planning and resource use in SNFs.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the IV Medications (Antibiotics, Anticoagulants, Vasoactive Medications, Other) data element as standardized patient assessment data beginning with the FY 2022 SNF QRP as proposed.

(i) Transfusions

In the FY 2020 SNF PPS proposed rule (84 FR 17657 through 17658), we proposed 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 "Final 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, some 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 “Final 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 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 transfusions, stakeholder input, and strong test results, we proposed 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.

Commenters submitted the following comments related to the proposed rule’s discussion of the Transfusions data element.

Comment: One commenter applauded CMS for including the Transfusion data element noting that it will provide information on care planning, clinical decision making, patient safety, care transitions, and resource use in SNFs and will contribute to higher quality and coordinated care for patients who rely on these life-saving treatments.

Response: We thank the commenter for the support. We selected the Transfusions data element for proposal as standardized data in part because of the attributes that the commenters noted.

Comment: One commenter was concerned that SNFs will not have the resources needed to provide patients with access to blood transfusions and requested that CMS consider whether payments to SNFs are adequate to cover the cost of this resource intensive, specialized service.

Response: At this time, this item will not be used for any payment purposes, and thus we are not able to comment on cost of this service. We wish to clarify that the Transfusion SPADE collects information on the complexity of the patient and resources the patient requires. This SPADE is not intended to measure the ability of a SNF to provide in-house transfusions, only to capture the services a given resident may be receiving. We are not evaluating the costs that SNFs incur when providing blood transfusions. Further, for patients who require services related to blood transfusions, information collected by this data element is a part of common clinical workflow, and thus, we believe that burden on resource intensity would not be affected by the standardization of this data element.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the Transfusions data element as standardized patient assessment data beginning with the FY 2022 SNF QRP as proposed.

(j) Dialysis (Hemodialysis, Peritoneal dialysis)

In the FY 2020 SNF PPS proposed rule (84 FR 17658 through 17659), we proposed 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 proposed 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, we proposed 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 “Final 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 proposed 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, some 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 “Final 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 proposed 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.

Commenters submitted the following comments related to the proposed rule’s discussion of the Dialysis (Hemodialysis, Peritoneal dialysis) data element. A discussion of these comments, along with our responses, appears below.

Comment: One commenter noted concern around burden of completion of the Dialysis data element, in particular the additional administrative burden because this data element adds sub-elements to an existing MDS item. However, the commenter also stated their belief that the Dialysis data element would provide a more accurate reflection of residents’ resource needs that could inform case-mix payment methodology.

Response: We appreciate the commenter’s concern for additional administrative burden. The primary data element, Dialysis, is already included in the MDS. Our clinical advisors and stakeholders have stated that the type of dialysis received by a patient -- that is, Hemodialysis or Peritoneal Dialysis -- can be reasonably expected to be included in the medical record with the indication for dialysis overall. We contend that the addition of sub-elements to the existing MDS data element will not require the assessor to undertake an entirely new search within the medical record for this information. Rather, the additional information required by the sub-elements will

be documented within or adjacent to information on the primary data element. Therefore, the additional burden of data collection related to the sub-elements is minimal, requiring only that the assessor document in the MDS additional information that should be readily available in a patient's medical record with the documentation of the primary data element. We agree that assessment of dialysis services received by patients in the SNF setting would provide important information for care planning and resource use in SNFs.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the Dialysis (Hemodialysis, Peritoneal dialysis) data element as standardized patient assessment data beginning with the FY 2022 SNF QRP as proposed.

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

In the FY 2020 SNF PPS proposed rule (84 FR 17659 through 17660), we proposed 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 “Final 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, some 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 “Final 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 proposed 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.

Commenters submitted the following comments related to the proposed rule’s discussion of the IV Access (Peripheral IV, Midline, Central line) data element.

Comment: One commenter noted concern around burden of completion of the IV Access data element, in particular the additional administrative burden because this data element adds sub-elements to an existing MDS item. However, the commenter also stated their belief that IV Access data element would provide a more accurate reflection of residents’ resource needs that could inform case-mix payment methodology.

Response: We appreciate the commenter's concern for additional administrative burden. The primary data element, IV Access, is already included in the MDS. Our clinical advisors and stakeholders have stated that the type of IV access received by a patient can be reasonably expected to be either plainly apparent or included in the medical record at the same place as the indication for IV access overall. We contend that the addition of sub-elements to the existing MDS data element will not require the assessor to undertake an entirely new search within the medical record for this information. Rather, the additional information required by the sub-elements will be documented within or adjacent to information on the primary data element. Therefore, the additional burden of data collection related to the sub-elements is minimal, requiring only that the assessor document in the MDS additional information that should be readily available in a patient's medical record with the documentation of the primary data element. We agree that assessment of IV access for patients in the SNF setting would provide important information for care planning and resource use in SNFs.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the IV Access (Peripheral IV, Midline, Central line) data element as standardized patient assessment data beginning with the FY 2022 SNF QRP as proposed.

(I) Nutritional Approach: Parenteral/IV Feeding

In the FY 2020 SNF PPS proposed rule (84 FR 17660 through 17661), we proposed 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 "Final 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, some 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 “Final 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-](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)

[Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html](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 parenteral/IV feeding, stakeholder input, and strong test results, we proposed 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.

A commenter submitted the following comment related to the proposed rule’s discussion of the Parenteral/IV Feeding data element.

Comment: One commenter was supportive of collecting this data element but noted that it should not be a substitute for capturing information related to swallowing which reflects additional patient complexity and resource use.

Response: We thank the commenter for their support and appreciate the concerns raised.

We agree that the Parenteral/IV Feeding SPADE should not be used as a substitute for an assessment of a patient's swallowing function. The proposed SPADEs are not intended to replace comprehensive clinical evaluation and in no way preclude providers from conducting further patient evaluation or assessments in their settings as they believe are necessary and useful. We agree that information related to swallowing can capture patient complexity, but we also note that Parenteral/IV Feeding data element captures a different construct. That is, the Parenteral/IV Feeding data element captures a patient's need to receive calories and nutrients intravenously, while an assessment of swallowing would capture a patient's functional ability to safely consume food orally for digestion in their gastrointestinal tract.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the Parenteral/IV Feeding data element as standardized patient assessment data beginning with the FY 2022 SNF QRP as proposed.

(m) Nutritional Approach: Feeding Tube

In the FY 2020 SNF PPS proposed rule (84 FR 17661 through 17662), we proposed 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.⁹⁵ 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. For more information on the Feeding Tube data element, we refer readers to the document titled “Final 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 proposed, 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

⁹⁵ 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.

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, some 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 “Final 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 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 feeding tubes, stakeholder input, and strong test results, we proposed 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.

A commenter submitted the following comment related to the proposed rule’s discussion of the Feeding Tube data element.

Comment: One commenter noted that in addition to identifying if the patient is on a feeding tube or not, it would be important to assess the patient’s progression towards oral feeding within this data element, as this impacts the tube feeding regimen.

Response: We agree that the progression to oral feeding is important for care planning and transfer, but we do not believe that standardizing the collection of this information would be useful for risk adjustment or the development of quality measures, which were considerations in the selection of the SPADEs. At this time, we are finalizing a singular Feeding Tube SPADE, which assesses the nutritional approach only and does not capture the patient's prognosis with regard to oral feeding. We wish to clarify that the proposed SPADEs are not intended to replace comprehensive clinical evaluation and in no way preclude providers from conducting further patient evaluation or assessments in their settings as they believe are necessary and useful. We will take this recommendation into consideration in future work on standardized data elements.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the Feeding Tube data element as standardized patient assessment data beginning with the FY 2022 SNF QRP as proposed.

(n) Nutritional Approach: Mechanically Altered Diet

In the FY 2020 SNF PPS proposed rule (84 FR 17662 through 17663), we proposed 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.⁹⁶

In PAC settings, there are a variety of reasons that patients and residents may have impairments related to oral feedings, including clinical or cognitive status. The provision of a mechanically altered diet may be resource intensive, and can signal difficulties associated with swallowing/eating safety, including dysphagia. In other cases, it signifies the type of altered food source, such as ground or puree that will enable the safe and thorough ingestion of nutritional substances and ensure safe and adequate delivery of nourishment to the patient. Often, patients 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 “Final Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,” available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Elements>,

⁹⁶ 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.

[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, some 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 “Final 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 proposed 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.

Commenters submitted the following comments related to the proposed rule’s discussion of the Mechanically Altered Diet data element.

Comment: One commenter was supportive of collecting this data element.

Response: We thank the commenter for their support of the Mechanically Altered Diet data element.

Comment: One commenter was concerned that this data element does not capture clinical complexity and does not provide any insight into resource allocation because it only measures whether the patient needs a mechanically altered diet and not, for example, the extent of help a patient needs in consuming his or her meal.

Response: We believe that assessing patients' needs for mechanically altered diets captures one piece of information about clinical complexity and resource allocation. That is, patients with this special nutritional requirement may require additional nutritional planning services, special meals, and staff to ensure that meals are prepared and served in the way the patient needs. Additional factors that would affect resource allocation, such as those noted by the commenter, are not captured by this data element. We have decided not to alter the SPADE as proposed in order to balance the scope and level of detail of the data elements against the potential burden placed on providers who must complete the assessment. We will take this suggestion into consideration in future refinement of the clinical SPADEs.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the Mechanically Altered Diet data element as standardized patient assessment data beginning with the FY 2022 SNF QRP as proposed.

(o) Nutritional Approach: Therapeutic Diet

In the FY 2020 SNF PPS proposed rule (84 FR 17663), we proposed 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 “Final 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. Some commenters stated that the coding instructions should be clear and more broadly applicable to patients and residents in all PAC settings. Other 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 “Final 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 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 therapeutic diet, stakeholder input, and strong test results, we proposed 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.

A commenter submitted the following comment related to the proposed rule's discussion of the Therapeutic Diet data element.

Comment: One commenter was supportive of collecting this data element.

Response: We thank the commenter for their support of the Therapeutic Diet data element.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the Therapeutic Diet data element as standardized patient assessment data beginning with the FY 2022 SNF QRP as proposed.

(p) High-Risk Drug Classes: Use and Indication

In the FY 2020 SNF PPS proposed rule (84 FR 17663 through 17665), we proposed 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.⁹⁷ 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.⁹⁸

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,⁹⁹ while the rate of ADEs in the long-term care setting is approximately 9.80 ADEs per 100 resident-months.¹⁰⁰ In the hospital setting, the incidence has been estimated at 15 ADEs per 100 admissions.¹⁰¹ 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.^{102,103,104} 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 65.¹⁰⁵

⁹⁷ 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.

⁹⁸ 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.

⁹⁹ 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.

¹⁰⁰ 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.

¹⁰¹ 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].

¹⁰² Barnsteiner JH. Medication reconciliation: transfer of medication information across settings-keeping it free from error. *J Infus Nurs*. 2005;28(2 Suppl):31-36.

¹⁰³ Rozich J, Roger, R. Medication safety: one organization's approach to the challenge. *Journal of Clinical Outcomes Management*. 2001(8):27-34.

¹⁰⁴ 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

¹⁰⁵ 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.

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.¹⁰⁶ We proposed one High-Risk Drug Class data element with six sub-elements. The response options that correspond to the six medication classes 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;^{107,108} fluid retention, heart failure, and lactic acidosis are associated with hypoglycemics;¹⁰⁹ misuse is associated with opioids;¹¹⁰ fractures and strokes are associated with antipsychotics;^{111,112} and various adverse events, such as central nervous systems effects and gastrointestinal intolerance, are associated with antimicrobials,¹¹³ 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.¹¹⁴ Finally, although a complete medication list should record several important

¹⁰⁶ Ibid.

¹⁰⁷ 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.

¹⁰⁸ 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.

¹⁰⁹ Hamnvik OP, McMahon GT. Balancing Risk and Benefit with Oral Hypoglycemic Drugs. *The Mount Sinai journal of medicine*, New York. 2009; 76:234–243.

¹¹⁰ Naples JG, Gellad WF, Hanlon JT. The Role of Opioid Analgesics in Geriatric Pain Management. *Clin Geriatr Med*. 2016;32(4):725-735.

¹¹¹ 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].

¹¹² 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.

¹¹³ Faulkner CM, Cox HL, Williamson JC. Unique aspects of antimicrobial use in older adults. *Clin Infect Dis*. 2005;40(7):997–1004.

¹¹⁴ 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.

attributes of each medication (for example, dosage, route, stop date), recording an indication for the drug is of crucial importance.¹¹⁵

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 required 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 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 proposed 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 "Final Specifications for SNF QRP Quality Measures and Standardized Patient Assessment

¹¹⁵ 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.

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.¹¹⁶ 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>.

¹¹⁶ 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.

[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 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 “Final 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 on-going 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 proposed 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.

Commenters submitted the following comments related to the proposed rule’s discussion of the High-Risk Drug Classes: Use and Indication data.

Comment: Several commenters supported the High-Risk Drug Class data element.

Response: We thank the commenters for their support of the High-Risk Drug Class data element.

Comment: One commenter requested detailed instructions and examples in the RAI Manual and a period established for ongoing feedback after data collection begins. Another commenter questioned whether “high-risk drugs” is the appropriate label for these medications and questioned whether the training and instruction manuals will cover all labeled indications within a drug class such as antipsychotics.

Response: We are committed to providing comprehensive training to providers for any new data elements, including standardized data elements, in order to foster common definitions, thereby ensuring the fidelity of the assessment. Resources available to SNFs will include the MDS RAI Manual, annual in-person trainings on the MDS, and CMS’ “helpdesk” web

resources.

We contend that the label of “high-risk drugs” is appropriate for this SPADE. We have selected drug classes that are commonly used by older adults and are related to adverse drug events which are clinically significant, preventable, and measurable. Anticoagulants, antibiotics, and diabetic agents have been implicated in an estimated 46.9 percent (95 percent CI, 44.2 percent - 49.7 percent) of emergency department visits for adverse drug events.¹¹⁷ Among older adults (aged ≥ 65 years), three drug classes (anticoagulants, diabetic agents, and opioid analgesics) have been implicated in an estimated 59.9 percent (95 percent CI, 56.8 percent - 62.9 percent) of emergency department visits for adverse drug events.¹¹⁸ Further, antipsychotic medications have been identified as a drug class for which there is a need for increased outreach and educational efforts to reduce use among older adults.

The commenter also inquired whether the training and instruction manuals will cover all labeled indications within a drug class such as antipsychotics. We wish to clarify that the assessor will be recording whether or not a patient is taking any medication within the named drug classes (for example, antipsychotics), then, if indications are known for all medications within the drug class. Training and instruction manuals, as well as the instructional text in the SPADE itself, will specify that medications be recorded according to their pharmacological classification, not by how they are used.

Comment: One commenter noted that an adverse drug event may be a causal factor for admission to a PAC setting rather than an adverse drug event occurring while in a PAC setting.

¹¹⁷ Shehab N, Lovegrove MC, Geller AI, Rose KO, Weidle NJ, Budnitz DS. US emergency department visits for outpatient adverse drug events, 2013-2014. JAMA 2016;316(2):2115-2125.

¹¹⁸ Shehab N, Lovegrove MC, Geller AI, Rose KO, Weidle NJ, Budnitz DS. US emergency department visits for outpatient adverse drug events, 2013-2014. JAMA 2016;316(2):2115-2125.

Further, the commenter urged CMS to avoid considering facilities with many patients taking a high-risk drug as negligent. Another cautioned that the quality of care of facilities should not be compared based on the mere presence of more high-risk drugs, which may be due to medical necessity.

Response: We appreciate the commenters' concern that the mere presence of medications in these drug classes should not be interpreted as a measure of quality; that is, we agree that having many patients at a facility taking high-risk drugs is not in and of itself an indicator of negligence or poor quality. We believe that medications in these classes can be safe, effective, and necessary for some patients/residents receiving care from PAC providers. We believe that each SNF serves a unique patient population with varying percentages of patients for whom high-risk medications are medically necessary, and therefore agree with the commenter that quality of care of PAC providers cannot be compared based on the presence of high-risk drugs alone.

Comment: One commenter encouraged CMS to collect more than the use of, and indication for, the drug. Another commenter suggested that the proposed antiplatelets item be combined with the existing anticoagulant MDS item and the proposed hypoglycemic medications item be added to the existing insulin injections MDS item.

Response: We appreciate the commenters' recommendations. We believe that gathering information on the use of and presence of an indication for these classes of medications is sufficient for a standardized data element, although we will take the recommendation to collect more information about medication under consideration in future work evaluating and refining the SPADEs. We decline the recommendation to combine antiplatelet and anticoagulants because of the different clinical considerations and associations related to each of these drug classes. We also believe that it would be inappropriate to combine the hypoglycemic drug class

with the insulin injections item, as the High-Risk Drugs: Use and Indication SPADE pertains to all medications, not only those taken by injection.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the High-Risk Drug Classes: Use and Indication data element as standardized patient assessment data beginning with the FY 2022 SNF QRP as proposed.

(4) 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.

In this section, 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.¹¹⁹ 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.^{120 121 122}

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 invited comment that apply specifically to the standardized patient assessment data for the category of medical conditions and co-morbidities. We did not receive any comments on

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 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>.

¹²¹ 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.

¹²² 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.

the category of medical conditions and co-morbidities.

Final decisions on the SPADEs are given below, following more detailed comments on each SPADE proposal.

(a) 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 sought comment on whether or not we should add these pain items in light of those concerns. Commenters were asked to address to what extent collection of the data below through patient queries might encourage providers to prescribe opioids.

In the FY 2020 SNF PPS proposed rule (84 FR 17666 through 17668), we proposed 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.¹²³ 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.¹²⁴ Quality pain

¹²³ 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/>.

¹²⁴ 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.

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.¹²⁵ 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.¹²⁶ 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 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 the FY 2020 SNF PPS proposed rule (84 FR 17663 to 17665) we proposed a SPADE that assess for the use of, as well as importantly the indication for the 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

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

¹²⁵ 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.

¹²⁶ National Pain Strategy: A Comprehensive Population-Health Level Strategy for Pain. https://iprcc.nih.gov/sites/default/files/HHSNational_Pain_Strategy_508C.pdf.

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,^{127 128 129} 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, stretching and strengthening exercises, chiropractic, electrical stimulation, radiotherapy, and ultrasound.^{130 131 132}

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

¹²⁷ 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.

¹²⁸ Fine, P. G. (2009). Chronic Pain Management in Older Adults: Special Considerations. *Journal of Pain and Symptom Management*, 38(2): S4-S14.

¹²⁹ 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.

¹³⁰ 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.

¹³¹ 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>.

¹³² 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.

interference would support providers in successfully tapering the dosage regimens in 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,¹³³ and consistent with HHS's 5-Point Strategy To Combat the Opioid Crisis¹³⁴ 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 OASIS. A similar data element on the effect on sleep is currently included in the MDS instrument. We proposed 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 "Final 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>.

¹³³ Society for Post-Acute and Long-Term Care Medicine (AMDA). (2018). Opioids in Nursing Homes: Position Statement. <https://paltc.org/opioids%20in%20nursing%20homes>.

¹³⁴ <https://www.hhs.gov/opioids/about-the-epidemic/hhs-response/index.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 "Final 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 proposed 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 (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.

Commenters submitted the following comments related to our proposal to adopt the Pain Interference data elements (Pain Effect on Sleep, Pain Interference with Therapy Activities, and Pain Interference with Day-to-Day Activities).

Comment: Several commenters expressed support for the Pain Interference SPADEs, noting that these SPADEs will provide a useful and more accurate assessment of a patient's ability to function, and that understanding the impact of pain on therapy and other activities, including sleep, can improve the quality of care, which in turn will support providers in their ability to provide effective pain management services.

Response: We thank the commenters for their support of the Pain Interference data elements.

Comment: One commenter noted that the proposed Pain Interference SPADEs document pain frequency but stated that it is important to identify both pain frequency and pain intensity. Another commenter noted that the Pain Interference questions do not address frequency of pain interference.

Response: We wish to clarify the Pain Interference SPADEs are interview data elements that ask the patient the frequency with which pain interferes with sleep, therapy, or non-therapy activities. These data elements therefore combine the concepts of frequency and intensity, with the measure of intensity being interference with the named activities. Self-reported measures of pain intensity are often criticized for being infeasible to standardize. In these data elements, interference with activities is an alternative to asking about intensity.

Comment: A commenter expressed concerns about the suitability of the Pain Interference SPADEs for use in patients with cognitive and communication deficits and urged CMS to consider the use of non-verbal means to allow patients to respond to SPADEs related to pain. Another commenter questioned how pain interference would be captured for residents who

refused or were unable to complete the pain interview.

Response: We appreciate the commenter's concern surrounding pain assessment with patients with cognitive and communication deficits. The Pain Interference SPADEs require that a patient be able to communicate, whether verbally, in writing, or using another method. Assessors may use non-verbal means to administer the questions (for example, providing the questions and response in writing for a patient with severe hearing impairment). Patients who are unable to communicate by any means, would not be required to complete the Pain Interference SPADEs. In addition, evidence suggests that pain presence can be reliably assessed in non-communicative patients through structural observational protocols. To that end, we tested observational pain presence elements in the National Beta Test, but have chosen not to propose those data elements as SPADEs at this time out of consideration of the scale of additions and changes that would be required of PAC providers. We will take the commenter's concern into consideration as the SPADEs are monitored and refined in the future.

Comment: A commenter expressed concerns about how CMS might use these data elements, noting particular concern that collection of these SPADEs may inappropriately translate into an assessment of quality, and that data collection on this topic could create incentives that directly or indirectly interfere with treatment decisions.

Response: We appreciate the commenter's concern related to wanting to understand how we will use the SPADEs. Any additional uses of these SPADEs for the assessment of quality will be adopted through the rulemaking process. We intend to communicate and collaborate with stakeholders about how the SPADEs will be used in the SNF QRP, as those plans are developed, by soliciting input through future rulemaking.

Comment: One commenter noted that there are currently seven MDS questions in the Resident Pain Assessment and that the current proposal adds three additional interview

questions, but it is unclear if the existing pain questions will be replaced. This commenter requested that CMS balance the need for additional documentation requirements with the impact on the clinician's ability to focus on patient care.

Response: We acknowledge the commenter's concern about the number of additional data elements being added to the MDS as part of the Pain Interview. The MDS currently contains two questions under the heading Pain Effect on Function (J0500) on the topics of pain interference with sleep and pain interference with day-to-day activities. The current items have Yes/No response options. The proposed SPADEs will make two changes to these items. First, we added a data element on pain interference with therapy activities. Second, we proposed response options that reflect the frequency of pain interference on a 5-point scale, ranging from "Rarely or not at all" to "Almost constantly." Other items on the MDS will remain unchanged. By adapting existing data elements from the MDS and integrating new SPADEs into existing skip patterns, we believe we have minimized additional documentation requirements while still ensuring that we have the appropriate data to foster interoperability, support care planning, and inform quality measurement.

Comment: One commenter appreciated CMS' request to provide feedback on the relation between pain assessment via the proposed Pain Interference SPADEs and the provider's willingness to prescribe opioids. This commenter believes CMS should monitor the correlation between the incidence of prescribing opioids and interview items and ensure expectations are aligned about what level of pain is acceptable and tolerable to the patient, through shared decision-making and education across the care delivery continuum, which includes the patients, their families, the patient care delivery teams, as well as regulators and surveyors.

Response: We intend to monitor the data submitted via the proposed SPADEs and will consider this use in the future.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the Pain Interference data elements (Pain Effect on Sleep, Pain Interference with Therapy Activities, and Pain Interference with Day-to-Day Activities) as standardized patient assessment data beginning with the FY 2022 SNF QRP as proposed.

(5) Impairment Data

Hearing and vision impairments are conditions that, if unaddressed, affect activities of daily living, communication, physical functioning, rehabilitation outcomes, and overall quality of life. Sensory limitations can lead to confusion in new settings, increase isolation, contribute to mood disorders, and impede accurate assessment of other medical conditions. Failure to appropriately assess, accommodate, and treat these conditions increases the likelihood that patients 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 and not discharge, and to use existing MDS items for hearing and vision, thereby not creating additional burden.

We invited comment on our proposals to collect as standardized patient assessment data the following data with respect to impairments. Commenters submitted the following comments related to the proposed rule's discussion of Impairments.

Comment: One commenter was concerned that screening for impairments would lead to an expectation that SNFs would need to take on the burden and cost of pursuing treatment for

these impairments on short-stay SNF patients. This commenter suggested a provision be added to the final rule to clarify that a SNF is not responsible for pursuing treatments and services beyond the scope of care and services normally provided by the SNF.

Response: We appreciate the commenter's concern. The adoption of SPADEs related to hearing and vision impairment are intended to collect data related to patient acuity and to ensure that clinically important information is assessed in a standardized way across settings, to support interoperability and care transitions. The adoption of the Hearing and Vision SPADEs does not affect the expectations that CMS has for SNF providers to provide a standard of care to residents that conforms to the CoPs. Under 42 CFR 483.21(b)(1), the facility must provide the treatment and services set out in the resident's care plan. The facility, however, may transfer or discharge a resident under 42 CFR 483.15(c)(1)(i)(A) if his or her needs cannot be met at that facility.

Final decisions on the SPADEs are given below, following more detailed comments on each SPADE proposal.

(a) Hearing

In the FY 2020 SNF PPS proposed rule (84 FR 17668 through 17669), we proposed 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.^{135,136} Treatment and

¹³⁵ 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.

accommodation of hearing impairment led to improved health outcomes, including but not limited to quality of life.¹³⁷ For example, hearing loss in elderly individuals has been associated with depression and cognitive impairment,^{138, 139, 140} higher rates of incident cognitive impairment and cognitive decline,¹⁴¹ and less time in occupational therapy.¹⁴² Accurate 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 “Final 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

¹³⁶ 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.

¹³⁷ 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.

¹³⁸ Sprinzl GM, Riechelmann H. Current trends in treating hearing loss in elderly people: a review of the technology and treatment options - a mini-review. *Gerontology.* 2010;56(3):351-358.

¹³⁹ 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.

¹⁴⁰ 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.

¹⁴¹ 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.

¹⁴² 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.

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, some 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 “Final 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 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, 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 proposed 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.

Commenters submitted the following comments related to the proposed rule's discussion of the Hearing data element.

Comment: Three commenters supported the collection of information on hearing impairment. One of these commenters also suggested that CMS consider how hearing impairment impacts a patient's ability to respond to the assessment tool in general.

Response: We thank the commenters for their support of the Hearing data element.

Comment: One commenter recommended adding "unable to assess" as a response option, which the commenter believed would be the appropriate choice if a patient has a diagnosis that may limit a hearing assessment.

Response: We appreciate the commenter's recommendation. The assessment of hearing is completed based on observing the patient during assessment, patient interactions with others, reviewing medical record documentation, and consulting with patient's family and other staff, in addition to interviewing the patient. Therefore, the assessment can be completed when the patient is unable to effectively answer questions related to an assessment of their hearing.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the Hearing data element as standardized patient assessment data beginning with the FY 2022 SNF QRP as proposed.

(b) Vision

In the FY 2020 SNF PPS proposed rule (84 FR 17669 through 17671), we proposed 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.^{143, 144, 145, 146, 147, 148, 149} 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 proposed 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 “Final Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,” available at

¹⁴³ 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.

¹⁴⁴ 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.

¹⁴⁵ Keepnews D, Capitman JA, Rosati RJ. Measuring patient-level clinical outcomes of home health care. *J Nurs Scholarsh.* 2004;36(1):79-85.

¹⁴⁶ 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.

¹⁴⁷ 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.

¹⁴⁸ Rovner BW, Ganguli M. Depression and disability associated with impaired vision: the MoVies Project. *J Am Geriatr Soc.* 1998;46(5):617-619.

¹⁴⁹ 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.

<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 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, some 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 “Final 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 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, 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 proposed 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.

Commenters submitted the following comments related to the proposed rule’s discussion of the Vision data element.

Comment: A few commenters supported the collection of information on vision impairment. One of these commenters additionally recommended that a doctor of optometry should play a lead role in conducting vision assessments, and that vision assessments done by other clinicians should also obtain the patient’s own assessment of his or her vision, such as used by the Centers for Disease Control and Prevention (CDC) Behavioral Risk Factors Surveillance System survey, which asks patients “Do you have serious difficulty seeing, even when wearing glasses?” This commenter expressed concerns about the proposed SPADE being subjective and risks of mis-categorizing patients.

Response: We thank the commenters for their support. We also appreciate the commenter's recommendation about how to assess for vision impairment. We do not require that a certain type of clinician complete assessments; the SPADEs have been developed so that any clinician who is trained in the administration of the assessment will be able to administer it correctly. The proposed item relies on the assessor's evaluation of the patient's vision, which has the advantage of reducing burden placed on the patient. We will take the recommendation to use patient-reported vision impairment assessment into consideration in the development of future assessments.

Comment: A commenter also urged CMS to require vision assessment at discharge, noting that vision impairment could be related to challenges in medication management and compliance with written follow-up instructions for care.

Response: We appreciate the commenter's feedback. We agree that adequate vision—or the accommodations and assistive technology needed to compensate for vision impairment—is important to patient safety in the community, in part for the reasons the commenter mentions. In the FY 2020 SNF PPS proposed rule (84 FR 17644), we proposed that SNFs that submit the Vision SPADE with respect to admission will be deemed to have submitted with respect to both admission and discharge, as there is a low likelihood that the assessment of this SPADEs at admission would differ from the assessment at discharge. Vision assessment, collected via the Vision SPADE with respect to admission, will provide information that will support the patient's care while in the SNF. We also contend that significant clinical changes to a patient's vision will be documented in the medical record as part of routine clinical practice, and would therefore be known to the provider at the time of discharge. Awareness of the patient's vision impairment would likely require accommodations with regard to written follow up instructions and medication management plan, but the information on visual impairment at discharge would be

available in the medical record even though it would not be collected as part of the Vision SPADE.

Out of consideration for the burden of data collection, and based on our understanding of visual impairments being monitored by providers throughout a patient's episode of care, SNFs that submit the Vision SPADE with respect to admission will be deemed to have submitted with respect to both admission and discharge. We note that during the discharge planning process, it is incumbent on SNF providers to make reasonable assurances that the patient's needs will be met in the next care setting, including in the home.

Comment: One commenter recommended adding "unable to assess" as a response option, which the commenter believed would be the appropriate choice if a patient has a diagnosis that may limit a vision assessment.

Response: We appreciate the commenter's recommendation. However, the assessment of vision is completed based on consulting with patient's family and other staff, observing the patient, including asking the patient to read text or examine pictures or numbers, in addition to interviewing the patient about their vision abilities. These other sources/methods can be used to complete the assessment of vision when the patient is unable to effectively answer questions related to an assessment of their vision.

Comment: One commenter noted that assessment through the vision data element is just an initial step towards a care coordination system that recognizes the impact that eye health has on overall health outcomes. This commenter noted that a critical next step would be to ensure that patients get to the physician who can address their eye health needs.

Response: We appreciate the commenter's recommendation and we agree that screening for vision impairment is an initial step towards ensuring patients receive the care they need. We expect SNF providers to provide a standard of care to residents that conforms to the CoPs, and

we defer to the clinical judgement of the resident's care team to determine when further assessment of vision or eye-related issues is warranted.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the Vision data element as standardized patient assessment data beginning with the FY 2022 SNF QRP as proposed.

(6) New Category: Social Determinants of Health

(a) 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 proposed 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. We proposed to collect and access data about social determinants of health (SDOH) in order 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 proposed 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 III.E.1.g.(6) of this final rule.

We also proposed 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 III.E.1.h.(4) of this final 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."¹⁵⁰ 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 proposed to collect and access under 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.

¹⁵⁰ 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.

CMS uses the term social determinants of health (SDOH) to denote social risk factors, which is consistent with the objectives of Healthy People 2020.¹⁵¹

ASPE issued its first Report to Congress, titled “Social Risk Factors and Performance Under Medicare’s Value-Based Purchasing Programs,” under section 2(d)(1)(A) of the IMPACT Act on December 21, 2016.¹⁵² 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 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-medicare-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

¹⁵¹ Social Determinants of Health. Healthy People 2020. <https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-of-health>. (February 2019).

¹⁵² 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.

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 sections (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, and 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 proposed 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 III.E.1.g.(6) of this final rule, under section 2(d)(2) of the IMPACT Act, would be independent of our proposal below (in section III.E.1.g.(6) of this final 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 proposed under section 2(d)(2) of the IMPACT Act, to collect the data on the following SDOH: (1) Race, as described in section III.E.1.g.(6)(b)(i) of this final rule; (2) Ethnicity, as described in section III.E.1.g.(6)(b)(i) of this final rule; (3) Preferred Language, as described in section III.E.1.g.(6)(b)(ii) of this final rule; (4) Interpreter Services as described in section III.E.1.g.(6)(b)(ii) of this final rule; (5) Health Literacy, as described in section III.E.1.g.(6)(b)(iii) of this final rule; (6) Transportation, as described in section III.E.1.g.(6)(b)(iv) of this final rule; and (5) Social Isolation, as described in section III.E.1.g.(6)(b)(v) of this final rule. These data elements are discussed in more detail below in section III.E.1.g.(6)(b) of this final rule. A detailed discussion of the comments we received, along with our responses, is included in each section.

(b) 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 proposed 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 also proposed 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 proposed 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 proposed 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 social determinants of health, we proposed 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.

We proposed 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>.

We solicited comment on these proposals

Comment: One commenter supported the incorporation of SDOH to promote access and assure high-quality care for all beneficiaries, but encouraged CMS to be mindful of meaningful collection and the potential for data overload as well as the ability to leverage existing data sources from across care settings. Since SDOH have impacts far beyond the post-acute care (PAC) setting, the commenter cautioned data collection that cannot be readily gathered, shared, or replicated beyond the PAC setting.

The commenter encouraged CMS to consider leveraging data points from primary care visits and pointed out that the ability to have a hospital’s or physician’s EHR also collect, capture, and exchange segments of this information is powerful. The commenter recommended

that CMS take a holistic view of SDOH across the care continuum so that all care settings may gather, collect or leverage this data efficiently and impactfully.

Response: We agree that collecting SDOH data elements can be useful in identifying and address health disparities and agree with the feedback that we should be mindful of meaningful collection of SDOH data collection efforts so that data elements that are selected are useful. The proposed SDOH SPADEs are aligned with SDOH identified in the 2016 National Academies of Sciences, Engineering, and Medicine (NASEM) report, which was commissioned by Office of the Assistant Secretary for Planning and Evaluation (ASPE). Regarding the commenter's suggestion that we consider how it can align existing and future SDOH data elements to minimize burden on providers, we agree that it is important to minimize duplication efforts and will take this under advisement for future consideration.

Comment: One commenter supported and applauded CMS' recognition of the impact of social determinants of health (SDOH), as well as its efforts to implement a data collection process for social risk factors. However, the commenter is concerned that CMS proposed to implement untested data elements and recommended CMS should first develop a thoughtful data analysis plan, as it has done in other provider settings that uses a proxy for SDOH to help inform next steps in data collection at the patient level.

Response: We want to note that each of the data elements proposed is currently in use and was developed with significant testing as part of our analysis plan before proposing. Additionally, as provided in the FY 2020 SNF PPS proposed rule (84 FR 17620), the proposed SPADE was developed after consideration of feedback we received from stakeholders and four TEPs convened by our contractors.

Comment: One commenter is pleased to see the proposal for a new category of SPADEs that would collect data on SDOH. In addition to potentially adding to the provider's knowledge

of the individual, when aggregated, this information will allow for greater understanding of the needs of vulnerable populations as well as permit the creation of tools to assess provider performance on quality metrics among different populations. One commenter recommended that CMS may also want to consider adding level of education to the data collected regarding social determinants of health.

Response: We will consider this feedback as we continue to improve and refine the SPADEs.

Comment: One commenter supported CMS' continuing emphasis on SDOH and recognized that well-executed SDOH approaches have wide-ranging effects on government payment systems, and are interconnected to the development of QRP reporting requirements. The commenter noted that any change to payment methodologies should account for these factors to maintain access to care in an equitable manner. Another commenter supports CMS' proposal to adopt the seven data elements as SPADEs under the proposed SDOH.

Response: We agree that SDOH impact patient outcomes and healthcare costs. We will share your feedback with those who provide oversight for the SNF prospective payment system.

Comment: Commenters were generally in favor of the concept of collecting SDOH data elements and provided that if implemented appropriately the data could be useful in identifying and addressing health care disparities, as well as refining the risk adjustment of outcome measures. However, some of the commenters suggested that CMS not finalize the proposed policy until it can address important issues around the potential future uses of these elements and the requirements around data collection for certain elements. The commenters provided that CMS did not state explicitly in the rule whether it anticipates the SDOH SPADEs will be used in adjusting measures and believe that the IMPACT Act's requirements make it likely the SPADEs will be considered for use in future adjustments. The commenters urged CMS to be circumspect

and transparent in its approaches to incorporating the data elements proposed in payment and quality adjustments, such as by collecting stakeholder feedback before implementing any adjustments.

Response: We thank the commenters for recognizing that collecting SDOH data elements can be useful in identifying and addressing health disparities. As provided in the FY 2020 SNF PPS proposed rule (84 FR 17672), accessing standardized data relating to the SDOH data elements on a national level is necessary to permit us to conduct periodic analyses, to assess appropriate adjustments to quality measures, resource use and other measures, and to assess and implement appropriate adjustments to Medicare payments based on those measures. Additionally, 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. We will continue to work with stakeholders to promote transparency and support providers who serve vulnerable populations, promote high quality care, and refine and further implement SDOH SPADE to meet the IMPACT Act requirements. We appreciate the comment on collecting stakeholder feedback before implementing any adjustments to measures based on the SDOH SPADE. Collection of this data will help us in identifying potential disparities, conducting analyses, and assessing whether any adjustments are needed. Any future policy development based on this data would be done transparently, and involve solicitation of stakeholder feedback through the notice and comment rulemaking process as appropriate.

Comment: One commenter supported the proposal to collect information on the seven proposed SDOH SPADE data elements. However, the commenter suggested that it is important to include metrics to determine if a resident is low-income in the SNF QRP SPADEs. The commenter referenced the ASPE report to Congress in 2016 that noted Medicare beneficiaries with social risk factors have worse outcomes on many quality measures; therefore, the

commenter urged CMS to incorporate risk adjustment for sociodemographic and socioeconomic status into the appropriate SNF QRP and SNF VBP performance measures. The commenter also recommended that CMS closely monitor the effects of its quality improvement initiatives on low-income communities to ensure that resources are not being driven away from these communities to more affluent communities solely on the basis of comparatively higher quality scores and consider new initiatives that provide incentives specifically targeted at reducing identified disparities.

Response: We appreciate the commenter's support. We understand the commenters concern that CMS ensure that the new SDOH data elements not negatively impact the resources of low-income communities and would note that at this time we did not propose using SDOH SPADEs for risk adjustment as part of this rulemaking. We will consider the commenter's feedback in future policy making, including in regard to risk adjustment, and as we monitor the effects of our quality improvement initiatives.

Comment: Several commenters recommended that CMS include disability status as a SDOH that contributes to overall patient access to care, health status, outcomes, and many other determinants of health since it is already included in some Medicare risk adjustment. The commenters stated that ASPE's report to Congress entitled "Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs" reported that disability is an independent predictor of poor mental and physical health outcomes, and that individuals with disabilities may receive lower-quality preventive care.

Response: We appreciate the comments and suggestions provided by the commenters, and we agree that it is important to understand the needs of patients with disabilities. While disability is not being currently assessed through the SPADE, it is comprehensively assessed as part of existing protocols around care plans and health goals. However, as we continue to

evaluate SDOH SPADEs, we will keep commenters' feedback in mind and may consider these suggestions in future rulemaking.

Comment: One commenter supported the use of the seven proposed SDOH data elements and suggested that CMS explore assessing if a patient has a family or caregiver and whether they are competent. They suggested this should be assessed since the health and capability of the family caregiver for someone with advanced illness can have a significant impact on their health and medical interventions.

Response: Thank you for the comment. We had to balance the importance of new SDOH data elements with the potential burden of adding more SDOH data elements to the assessment, beyond the seven that were selected. We will consider this feedback as we continue to improve and refine the SPADEs.

(i) Race and Ethnicity

The persistence of racial and ethnic disparities in health and health care is widely documented, including in PAC settings.^{153,154,155,156,157} 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,

¹⁵³ 2017 National Healthcare Quality and Disparities Report. Rockville, MD: Agency for Healthcare Research and Quality; September 2018. AHRQ Pub. No. 18-0033-EF.

¹⁵⁴ 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.

¹⁵⁵ 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.

¹⁵⁶ 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.

¹⁵⁷ 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.

and insurance.¹⁵⁸ 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.¹⁵⁹ Studies have also shown that African Americans are significantly more likely than white Americans to die prematurely from heart disease and stroke.¹⁶⁰ 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.¹⁶¹

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.¹⁶² 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

¹⁵⁸ National Healthcare Quality and Disparities Reports. (December 2018). Agency for Healthcare Research and Quality, Rockville, MD. <http://www.ahrq.gov/research/findings/nhqdr/index.html>.

¹⁵⁹ National Center for Health Statistics. Health, United States, 2017: With special feature on mortality. Hyattsville, Maryland. 2018.

¹⁶⁰ HHS. Heart disease and African Americans. 2016b. (October 24, 2016). <http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=19>.

¹⁶¹ 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/>.

¹⁶² “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>.

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/omh/browse.aspx?lvl=3&lvlid=54>.

We proposed 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 proposed two separate data elements: one for Race and one for Ethnicity, that would conform with the 2011 HHS Data Standards and 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 proposed 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 of Hispanic, Latino/a, or Spanish origin?” We proposed 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 are including the addition of “of” to the Ethnicity data element to read, “Are you of Hispanic, Latino/a, 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.^{163,164,165,166} 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

¹⁶³ 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.

¹⁶⁴ 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.

¹⁶⁵ IOM (Institute of Medicine). 2009. *Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement.* Washington, DC: The National Academies Press.

¹⁶⁶ “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.

health outcomes for Medicare beneficiaries begins with identifying and analyzing how SDOH, such as race and ethnicity, align with disparities in these areas.¹⁶⁷ Standardizing self-reported data collection for race and ethnicity allows for the equal comparison of data across multiple healthcare entities.¹⁶⁸ 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 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 proposed to adopt the Race and Ethnicity data elements described above as SPADEs with respect to the proposed Social Determinants of Health category.

¹⁶⁷ 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/>.

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

Specifically, we proposed to replace the current Race/Ethnicity data element with the proposed Race and Ethnicity data elements on the MDS. We also proposed 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.

We solicited comment on these proposals.

Commenters submitted the following comments related to the proposed rule's discussion of the Race and Ethnicity SPADEs. A discussion of these comments, along with our responses, appears below.

Comment: Some commenters noted that the response options for race do not align with those used in other government data, such as the U.S. Census or the Office of Management and Budget (OMB). The commenters also stated these responses are not consistent with the recommendations made in the 2009 Institute of Medicine (IOM) report. The commenters pointed out that IOM report recommended using broader OMB race categories and granular ethnicities chosen from a national standard set that can be "rolled up" into the broader categories. The commenters stated that it is unclear how CMS chose the 14 response options under the race data element and the five options under the ethnicity element and worried that these response options would add to the confusion that already may exist for patients about what terms like "race" and "ethnicity" mean for the purposes of health care data collection. The commenters also noted that CMS should confer directly with experts in the issue to ensure patient assessments are collecting the right data in the right way before these SDOH SPADEs are finalized. One commenter also suggested that in lieu of data collection on Race/Ethnicity, collection of cultural information such

as End of Life decisions, cultural holidays, celebrations or ceremonies, and other cultural norms is much more valuable for patient care outcomes and care delivery.

Response: The proposed Race and Ethnicity categories align with and are rolled up into the 1997 OMB minimum data standards and conforming with the 2011 HHS Data Standards as described in the implementation guidance titled “U.S. Department of Health and Human Services Implementation Guidance on Data Collection Standards for Race, Ethnicity, Sex, Primary Language, and Disability Status” at <https://aspe.hhs.gov/basic-report/hhs-implementation-guidance-data-collection-standards-race-ethnicity-sex-primary-language-and-disability-status>. As stated in the proposed rule, the 14 race categories and the 5 ethnicity categories conform with the 2011 HHS Data Standards for person-level data collection, which were developed in fulfillment of section 4302 of the Affordable Care Act that required the Secretary of HHS to establish data collection standards for race, ethnicity, sex, primary language, and disability status. Through the HHS Data Council, which is the principal, senior internal Departmental forum and advisory body to the Secretary on health and human services data policy and coordinates HHS data collection and analysis activities, the Section 4302 Standards Workgroup was formed. The Workgroup included representatives from HHS, the OMB, and the Census Bureau. The Workgroup examined current federal data collection standards, adequacy of prior testing, and quality of the data produced in prior surveys; consulted with statistical agencies and programs; reviewed OMB data collection standards and the Institute of Medicine (IOM) Report Race, Ethnicity, and Language Data Collection: Standardization for Health Care Quality Improvement; sought input from national experts; and built on its members' experience with collecting and analyzing demographic data. As a result of this Workgroup, a set of data collection standards were

developed, and then published for public comment. This set of data collection standards is referred to as the 2011 HHS Data Standards.¹⁶⁹ The categories of race and ethnicity under the 2011 HHS Data Standards allow for more detailed information to be collected and the additional categories under the 2011 HHS Data Standards can be aggregated into the OMB minimum standards set of categories.

As noted in the FY 2020 SNF PPS proposed rule (84 FR 17672 through 17675), CMS conferred with experts by conducting a listening session regarding the proposed SDOH data elements regarding 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 Data Standards to better reflect state and local diversity.

Collecting Race/Ethnicity is important for evaluating the impact that SDOHs have on health outcomes. Because of this, CMS will collect Race/Ethnicity instead of replacing these data element with the collection of cultural information such as End of Life decisions, cultural holidays, celebrations or ceremonies, and other cultural norms.

Comment: A commenter supported the opportunities to better account for SDOH in the diagnosis and treatment of patients but was concerned by the specificity of several of the seven proposed element for data collection for example, collection of race by Japanese, Chinese, Korean, etc. The commenter's concern was with the added burden in collecting the level of specificity outlined, and they requested that CMS provide more detailed guidance in the final

¹⁶⁹ HHS Data Standards. Available at <https://aspe.hhs.gov/basic-report/hhs-implementation-guidance-data-collection-standards-race-ethnicity-sex-primary-language-and-disability-status>

rule regarding how this information should be collected and shared in compliance with HIPAA. Further, the commenter requested that the agency outlines its expectations for how this newly collected information will be used by Medicare for payment and public reporting.

Response: For the Race and Ethnicity SPADE data element, this data should be completed based on the response of the patient, which is considered the gold standard of assessing race and ethnicity. It is important ask the patient to select the category or categories that most closely correspond to their race and ethnicity. Respondents should be offered the option of selecting one or more race and ethnicity categories. Observer identification or medical record documentation may not be used.

Finally, as provided in the FY 2020 SNF PPS proposed rule (84 FR 17671 through 17672), 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 and other measures, and to assess and implement appropriate adjustments to Medicare payments based on those measures. Any potential future use of the data for payment and public reporting purposes would be done through rulemaking.

SDOH Data elements should be treated the same as other information currently collected on the assessment tool. As to any specific HIPAA question, we appreciate the commenter's commitment to compliance with the HIPAA requirements, but note that the Office for Civil Rights (OCR) is tasked with implementing and enforcing HIPAA, not CMS. Commenters should consult appropriate counsel in instances in which they are unsure of their HIPAA status, or the permissibility of a disclosure under the HIPAA Privacy Rule. In doing so, commenters may wish to consult 45 CFR 164.103 (definition of "required by law") and 164.512(a) (allowing "required by law" disclosures).

After careful consideration of the public comments we received, we are finalizing our

proposal to adopt the Race data element as SPADE as proposed, and the Ethnicity data element as SPADE with the addition of one technical change discussed above, beginning with the FY 2022 SNF QRP.

(ii) 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).¹⁷⁰ Individuals with LEP have been shown to receive worse care and have poorer health outcomes, including higher readmission rates.^{171,172,173} Communication with individuals with LEP is an important 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

¹⁷⁰ U.S. Census Bureau, 2013-2017 American Community Survey 5-Year Estimates.

¹⁷¹ 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.

¹⁷² 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.

¹⁷³ 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.

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.¹⁷⁴

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-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

¹⁷⁴ IOM (Institute of Medicine). 2009. Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement. Washington, DC: The National Academies Press.

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.¹⁷⁵ 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 proposed 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

¹⁷⁵ 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>.

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 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 proposed 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.

We solicited comment on these proposals.

Commenters submitted the following comments related to the proposed rule’s discussion of Preferred Language and Interpreter Services SPADEs. A discussion of these comments, along

with our responses, appears below.

Comment: Some commenters noted that, if finalized, SNFs only would need to submit data on the race and ethnicity SPADEs with respect to admission and would not need to collect and report again at discharge, as it is unlikely that patient status for these elements will change. The commenters believe that a patient's preferred language and need for an interpreter also are unlikely to change between admission and discharge; thus, the commenter urged CMS to deem SNFs that submit data with respect to admission for these SDOH SPADEs to have submitted with respect to both admission and discharge.

Response: We thank the commenters for the comment. With regard to the submission of the Preferred Language and the Interpreter Services SPADE, we agree with the commenters that it is unlikely that the assessment of Preferred Language and Interpreter Services at admission would differ from assessment at discharge. As discussed in previous response for Vision and Hearing, we believe that the submission of preferred language and the need for an interpreter is similar to the submission of Race, Ethnicity, Hearing, and Vision SPADEs.

In response to commenters' feedback, we are finalizing that SNFs that submit the Preferred Language and Interpreter Services SPADES with respect to admission will be deemed to have submitted with respect to both admission and discharge.

Based on the comments received, and for the reasons discussed, we are finalizing that the Preferred Language and Interpreter Services SPADEs be collected with the modification that we will deem SNFs that submit these two SPADEs with respect to admission to have submitted with respect to discharge as well.

(iii) 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.”¹⁷⁶ 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.¹⁷⁷

Health literacy is prioritized by Healthy People 2020 as an SDOH.¹⁷⁸ 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.¹⁷⁹ 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.

¹⁷⁶ 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.

¹⁷⁷ 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.

¹⁷⁸ Social Determinants of Health. Healthy People 2020. <https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-of-health>. (February 2019).

¹⁷⁹ 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.

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 primary care practices participating in the Vermont Diabetes Information System.^{180,181} 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.¹⁸² Furthermore, the S-TOFHLA instrument is proprietary and subject to purchase for individual entities or users.¹⁸³ 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 proposed 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

¹⁸⁰ 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.

¹⁸¹ 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.

¹⁸² 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>.

¹⁸³ Nurss, J.R., Parker, R.M., Williams, M.V., & Baker, D.W. David W. (2001). TOFHLA. Peppercon Books & Press. Available from: http://www.pepperconbooks.com/catalog/information.php?info_id=5.

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 at an appropriate literacy level based on individualized assessment of health literacy.¹⁸⁴ 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.¹⁸⁵ 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 proposed to adopt the SILS question, described above for

¹⁸⁴ 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.

¹⁸⁵ 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.

the Health Literacy data element, as SPADE under the Social Determinants of Health Category. We proposed to add the Health Literacy data element to the MDS.

We solicited comment on these proposals.

Commenters submitted the following comments related to the proposed rule's discussion of the Health Literacy data element. A discussion of these comments, along with our responses, appears below.

Comment: Some commenters noted that, if finalized, SNFs should only need to submit data on the race and ethnicity SPADEs with respect to admission and would not need to collect and report again at discharge, as it is unlikely that patient status for these elements will change. The commenters believe that a patient's health literacy is unlikely to change between admission and discharge; thus, the commenter suggested that CMS require collection of all SDOH SPADEs, including Health Literacy, with respect to admission only.

Response: We thank the commenters for their comments. We disagree with the commenters that it is unlikely patient status for health literacy will change from admission to discharge. Unlike the Vision, Hearing, Race, Ethnicity, Preferred Language, and Interpreter Services SPADEs, we believe that the response to this data element is likely to change from admission to discharge for some patients. For example, some patients may develop health issues, such as cognitive decline, during their stay that could impact their response to health literacy thus changing their status at discharged. Although not directly evaluated for health literacy, clinical conditions that impact a patient's health literacy status would be captured in the clinical record, even if they are not assessed by a SPADE. Therefore, we proposed to collect this SPADEs with respect to both admission and discharge.

Comment: One commenter did not support the proposal to add health literacy data element because the question focuses on whether an individual may (or may not) have a literacy

deficit, but fails to identify the many reasons why a literacy deficit may exist, which the commenter notes would be more valuable to patient care delivery and patient care outcomes. The commenter also requested more clarification on the connection between the frequencies in which an individual needs assistance with reading in lieu of the reasons why an individual has a literacy deficit.

Response: As provided in the proposed rule (84 FR 17675 through 17676), low health literacy can interfere with communication between the provider and patient and the ability for patients or their caregivers to understand and follow treatment plans, including medication management. Assessing for health literacy across PAC settings would facilitate better care coordination and discharge planning. While we agree that exploring the reasons for low health literacy are important, we proposed the Health Literacy SPADE while balancing the need to avoid excessive burden on patients and health care providers, and we believe that a Health Literacy SPADE that identifies reasons why a literacy deficit exists creates additional burden on both the patients and the providers. The SILS Health Literacy data element we proposed performed well when tested, and it minimizes concerns related to burden by requiring one, instead of multiple, questions on health literacy.^{186 187}

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the Health Literacy data element as standardized patient assessment data beginning with the FY 2022 SNF QRP as proposed.

¹⁸⁶ 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.

¹⁸⁷ 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.

(iv) 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.¹⁸⁸ Access to transportation for ongoing health care and medication access needs, particularly for those with chronic diseases, is essential to successful chronic disease 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 proposed 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.¹⁸⁹

¹⁸⁸ 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.

¹⁸⁹ 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. www.aha.org/transportation.

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.¹⁹⁰ 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 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.¹⁹¹ 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 proposed to adopt the Transportation data element from PRAPARE. More information about development of the PRAPARE tool is available on the website at

¹⁹⁰ 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.

¹⁹¹ Northwestern University. (2017). PROMIS Item Bank v. 1.0 – Emotional Distress – Anger - Short Form 1.

<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 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 proposed 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.

We solicited comment on these proposals.

Commenters submitted the following comments related to the proposed rule’s discussion of the Transportation data element. A discussion of these comments, along with our responses, appears below.

Comment: One commenter supported the proposal to add the Transportation data element

to the MDS because they agreed that this information is valuable to discharge planning and understanding the outcomes of post discharge from an inpatient stay. The commenter provided that transportation has been a long-standing barrier to health care and quality of life for the elderly and that an increase in financial or community resources would improve a patient's capacity to comply with their discharge plan of care or their ability to stay engaged in social activities.

Response: We thank the commenter.

Comment: One commenter requested that CMS consider the limited resources in the community to assist patients in meeting their transportation needs and requested that CMS consider using this data to facilitate the increase in access to transportation services for the elderly patients living in the community.

Response: Thank you for the comment and we will consider this feedback as we continue to improve and refine the SPADES.

Comment: The commenters believe that a patient's access to transportation is unlikely to change between admission and discharge; thus, the commenter urged CMS to require collection of all SDOH SPADEs, including Transportation, with respect to admission only.

Response: We disagree with the commenters that stated that access to transportation will always be the same from admission to discharge. Unlike the Vision, Hearing, Race, Ethnicity, Preferred Language, and Interpreter Services SPADEs, as previously discussed, we believe that the response to this data element is likely to change from admission to discharge for some patients. For example, a patient could lose a family member or caregiver between admission and discharge, which could impact his or her access to transportation and impact how the patient responds to the access to transportation SPADE data element. Therefore, we believe that the response to this SDOH data element is likely to change from admission to discharge for some

patients and we proposed to collect this SPADE data element with respect to both admission and discharge. As outlined in the FY 2020 SNF QRP proposed rule, multiple studies have demonstrated that access to transportation has an impact on the health of patients (84 FR 17676 through 17677). Therefore, it is important for providers to be able to identify a patient's needs when the patient is admitted and when the patient is discharged in order to better inform the patient's care decisions made during and after the stay, including understanding the patient's unique risk factors and treatment preferences. Because of this, we are keeping our proposal to require SNFs to submit the Transportation data element at both admission and discharge.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the Transportation data element as standardized patient assessment data beginning with the FY 2022 SNF QRP as proposed.

(v) 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.^{192,193} Social isolation tends to increase with age, is a risk factor for physical and mental illness, and a predictor of mortality.^{194,195,196} Post-acute care providers are well-suited to design and implement programs 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

¹⁹² 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.

¹⁹³ 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>

¹⁹⁴ 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.

¹⁹⁵ 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.

¹⁹⁶ Leigh-Hunt, N., Baggeley, 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.

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 proposed 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.¹⁹⁷ 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 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,

¹⁹⁷ Northwestern University. (2017). PROMIS Item Bank v. 1.0 – Emotional Distress – Anger - Short Form 1.

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 proposed to adopt the Social Isolation data element described above as SPADE with respect to the proposed Social Determinants of Health category. We proposed to add the Social Isolation data element to the MDS.

We solicited comment on these proposals.

Commenters submitted the following comments related to the proposed rule’s discussion the Social Isolation data element. A discussion of these comments, along with our responses, appears below.

Comment: One commenter did not support the proposal to add the social isolation data element. The commenter provided that the MDS currently collects data on mood using the Resident Mood Interview and that the current data items in the Resident Mood Interview are sufficient to adequately assess the resident’s mood without adding additional documentation requirements. The commenter also believed that the existing interview is the beginning of a larger conversation that often occurs between the resident and the interviewer. Additional insight is also needed to understand the purpose of collecting this information in addition to the existing mood questions. The commenter requested that CMS consider that there are life events that may occur in which it may be appropriate for an individual to feel lonely or isolated.

Response: As provided in the MDS, the intent of Resident Mood Interview items is to “address mood distress, a serious condition that is underdiagnosed and undertreated in the nursing home and is associated with significant morbidity. It is particularly important to identify signs and symptoms of mood distress among nursing home residents because these signs and symptoms can be treatable”. However, the intent of the social isolation data element is not to assess how the individual feels, but whether the individual feels connected to those around them and can affect their mood. To collect and analyze information about social isolation in SNFs and across PAC settings would facilitate the identification of patients who are socially isolated and who may benefit from engagement efforts. We appreciate the suggestion from the commenter that CMS should consider that there are life events that may occur in which it may be appropriate for an individual to feel lonely or isolated and will take the suggestion under consideration.

Comment: One commenter supported the addition of SDOH to the SPADEs, recognizing how these elements impact care use, cost and outcomes for Medicare beneficiaries. The commenter believed that an accurate understanding of the impact of SDOH is imperative and suggest adding clarifiers to the SDOH measures for transportation and social isolation. Adding a qualifying statement such as “in your normal home environment” to each of the two data elements would help patients to consider their normal daily living experiences rather than their acute experiences of the hospital and post-acute care stays when answering these questions.

Response: We thank the commenter and we will consider this feedback as we continue to improve and refine the SPADES.

Comment: A commenter supported the addition of SDOH to the SPADEs and noted that gathering these data will inform their understanding of resident and patient complexity and risk factors that may affect utilization of care, care outcomes and associated costs, and facilitate better alignment of payments with the added challenges posed by SDOHs. However, the

commenter recommended adding a qualifier to the proposed SDOH measure for Social Isolation to ensure the patient's response reflects his/her home environment.

Response: As we continue to evaluate SDOH SPADEs, we will keep this in mind and will evaluate the addition of this qualifier.

Comment: The commenters believe that a patient's response to social isolation is unlikely to change between admission and discharge; thus, the commenter urged CMS to require collection of all SDOH SPADEs, including Social Isolation, with respect to admission only.

Response: We disagree with the commenters that stated that the response to the Social Isolation data element will be the same from admission to discharge. Unlike the Vision, Hearing, Race, Ethnicity, Preferred Language, and Interpreter Services SPADEs as discussed previously, we believe that the response to this data element is likely to change from admission to discharge for some patients. For example, a patient could lose a family member or caregiver between admission and discharge, which could impact their response to the Social Isolation data element. Therefore, we proposed to collect this SPADE data element with respect to both admission and discharge. As outlined in the FY 2020 SNF PPS proposed rule, multiple studies have demonstrated that social isolation has an impact on the health of patients (84 FR 17677 through 17678). Therefore, we believe it is important for providers to be able to identify a patient's needs when the patient is admitted and when the patient is discharged in order to better inform the patient's care decisions made during and after the stay, including understanding the patient's unique risk factors and treatment preferences. Because of this, we are requiring that the Social Isolation data element be assessed at both admission and discharge.

Based on the comments received, and for the reasons discussed, we are finalizing our proposals for Social Isolation as proposed.

After consideration of the public comments, we are finalizing our proposals to collect

SDOH data for the purposes under section 2(d)(2)(B) of the IMPACT Act and section 1899B(b)(1)(B)(vi) of the Act as follows. We are finalizing our proposals for Race, Ethnicity, Health Literacy, Transportation, and Social Isolation as proposed. In response to stakeholder comments, we are revising our proposed policies and finalizing that SNFs that submit the Preferred Language and Interpreter Services data elements SPADEs with respect to admission will be deemed to have submitted with respect to both admission and discharge.

h. Form, Manner, and Timing of Data Submission under the SNF QRP

(1) Background

We refer readers to the regulatory text at § 413.360(b) for information regarding the current policies for reporting SNF QRP data.

(2) 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 proposed to designate that system as the data submission system for the SNF QRP once it becomes available. In the proposed rule, we anticipated the migration would occur no later than October 1, 2021. CMS can no longer commit to this date based on the current development timeline therefore, this migration will occur when technically feasible.

We proposed to revise our regulatory text at § 413.360(a) by replacing “Certification and Survey Provider Enhanced Reports (CASPER)” with “CMS designated data submission”. We proposed 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” effective October 1, 2019. We are correcting our proposal to revise § 413.360(d)(4) to remove the term “system” from “CMS designated data submission system”. In addition we proposed 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 invited public comments on this proposal.

Commenters submitted the following comments related to the proposed rule’s discussion of the Form, Manner, and Timing of Data Submission under QRP. A discussion of these comments, along with our responses, appears below.

Comment: Several commenters noted support for the revisions to the regulatory text to reflect the migration to the new iQIES system for MDS data submission. One commenter further supported the proposal to notify the public of any future changes to the CMS designated system using subregulatory mechanisms. Another commenter suggested that CMS increase the number of unique users per provider number that may have access to the system, as the number of reports available and the number of staff members utilizing these reports has increased.

Response: We thank the commenters for their support, and would like to take this opportunity to inform SNFs that users will no longer require a virtual private network (VPN) or CMSNet to access iQIES so providers will no longer have limited unique user ID’s per provider.

After considering the comments, we are finalizing the regulatory text with the technical revision described above.

(3) Schedule for Reporting the Transfer of Health Information Quality Measures Beginning With the FY 2022 SNF QRP

As discussed in section III.E.1.d. of this final rule, we proposed 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 proposed 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 invited public comment on this proposal and did not receive any comments.

We are finalizing the schedule for our proposal that SNFs report the data on 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 using the MDS as proposed. SNFs will be required to collect data on both measures for residents beginning with October 1, 2020 discharges for the FY 2022 SNF QRP.

(4) Schedule for Reporting Standardized Patient Assessment Data Elements

As discussed in section III.E.1.f. of this final rule, we proposed to adopt SPADEs beginning with the FY 2022 SNF QRP. We proposed 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 would be considered to have submitted data with respect to both admissions and 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 invited public comment on this proposal. For a discussion of the comments and responses we received regarding this proposal we refer the reader to section III.E.1.f.

After consideration of the comments received, we are finalizing our proposal that SNFs must submit SPADEs for all patients discharged on or after October 1, 2020, with respect to both admission and discharge, using the MDS. SNFs that submit data with respect to admission for the Hearing, Vision, Race, Ethnicity, Preferred Language, and Interpreter Services SPADEs will be deemed to have submitted data with respect to both admissions and discharges.

(5) Data Reporting on All Residents for the SNF Quality Reporting Program Beginning with the FY 2022 SNF QRP

We 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,¹⁹⁸ the TEPs held by our measure development contractor,¹⁹⁹ as well as through comments we received 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

¹⁹⁸ 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>.

¹⁹⁹ 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.

Strategy for Post-Acute Care and Long-Term Care Performance Measurement.²⁰⁰ 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 proposed that for purposes of meeting the requirements of the SNF QRP, SNFs would be required to collect and submit MDS data on all SNF residents regardless of their payer. We believe that this will ensure that Medicare residents are receiving the same quality of SNF care as other residents.

While we appreciate that collecting quality data on all residents regardless of payer may

²⁰⁰ 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.

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.

We proposed that, if finalized, this policy would be effective beginning with the FY 2022 program year.

We invited public comment on this proposal.

Commenters submitted the following comments on the proposed Data Reporting on Residents for the SNF Quality Reporting Program Beginning with the FY 2022 SNF QRP. Below is a summary of the comments as well as our responses.

Comment: Several commenters expressed support for the collection of data on all SNF residents regardless of payer. One commenter stated that ensuring that the quality of care is not conditional based on payer source is essential to the overall wellbeing of all SNF residents. Another commenter stated that collecting data on all patients regardless of payer is consistent with other quality programs. This commenter noted that collecting data from all payers gives consumers a more complete picture of quality of care within a SNF. Similarly, another commenter stated that requiring SNFs to report data on all patients regardless of payer would more accurately represent quality of care within a SNF.

Response: We thank the commenters for their support.

Comment: One commenter requested that CMS delay implementation until after FY 2022 SNF QRP to allow for added transition time for adoption of the SPADEs. One commenter

requested that CMS make this requirement voluntary in the short-term. Several commenters expressed concern for the collection of data on all SNF residents regardless of payer and requested clarification on the details of this proposal including which residents the required data collection pertained to, the intended use of the data from payers other than Medicare, and how this proposal would affect penalties for non-compliance in the SNF QRP. One commenter questioned how this proposal would change the types and number of assessments applicable to this requirement, and how CMS would define which residents would be used to determine compliance with this requirement. This commenter requested that CMS consider staffing constraints and the technical complexity/coding rules required for accurate completion of SNF QRP items and suggested that CMS provide quarterly feedback via QIES that would display the SNF QRP all-payer MDS data submission to allow providers an opportunity to ensure they are meeting the data submission requirements or establish performance improvement processes. Another commenter has long been concerned about the attention to quality measurement for fee-for-service SNF patients compared to the paucity of information on corresponding quality measures regarding Medicare Advantage patients in a SNF, and suggested Medicare Advantage patients be included in quality measures displayed on Nursing Home Compare.

Response: We appreciate the feedback we have received for the all payer proposal and agree with the comments that providing clear policy and implementation guidelines would be most appropriate for the intended purposes of this proposal. We understand that more information is needed to better understand which residents the required data collection pertains to, the intended use of the data, and how this proposal would affect penalties for non-compliance in the SNF QRP. We acknowledge the feedback provided by some commenters with respect to administrative challenges such as staffing, the assessments that would be required for collection, the technicalities of coding, and the desire for detailed policy and training. We understand the

concerns raised by commenters that more details for this proposal are needed in order to better understand which residents the implementation of all payer would affect. We recognize the commenters' concerns about this proposal's implementation timeline and the implementation activities of for the SPADEs. We would like to note that the implementation of the SPADEs and the timeline proposed for this all payer proposal do not overlap, and therefore we do not believe the implementation of the SPADEs would have an effect on this proposal. Further, while we appreciate the suggestion that CMS make this requirement voluntary in the short-term, we believe that making this proposal a voluntary requirement would not further the intent to conduct a meaningful comparison of quality data. However, after consideration of the public comments we received on these issues, we have decided that at this time to not finalize the all payer proposal. Although we believe that the reporting of all-payer data under the SNF QRP would add value to the program and provide a more accurate representation of the quality provided by SNFs, we believe we need to better quantify the new reporting burden on SNFs there is from this proposal for stakeholders to comment on. We agree that it would be useful to assess further how to best implement the collection of data for all payers for the SNF QRP. As part of this effort, we intend to further evaluate which assessments are appropriate for reporting and define the population of residents. We plan to propose to expand the reporting of MDS data used for the SNF QRP to include data on all residents, regardless of their payer, in future rulemaking.

Comment: Some of the commenters expressed that this proposal would present additional burden challenges for providers and suggested that CMS conduct an analysis on the burden associated with collecting data on all patients regardless of payer. One commenter believed this proposal will add substantially to the reporting burden associated with the SNF QRP, since facilities will be expected to respond to additional questions on virtually all MDS assessments performed for a much larger number of residents to meet QRP requirements. One

commenter suggested that collection of data on all payers would expand the use of the assessment tool from the current Fee-for-Service (FFS) population to patients covered by other payers and noted for CMS that significant variation currently exists in SNFs for the percentage of patients having the MDS 3.0 completed for the SNF QRP. This commenter identified that the percentage may be high in some SNFs with a large portion of FFS patients. In other SNFs, the greater portion of patients may be covered by Medicare Advantage and SNFs may be completing other assessments for other payers, particularly as it relates to payment systems that continue to utilize older versions of the Resource Utilization Group (RUG) system. One commenter stated they could only support this proposal if the burden associated with the reporting requirements is sufficiently funded.

Response: We are sensitive to the issue of burden associated with data collection and acknowledge the commenters' concerns about the additional burden required to collect quality data on all residents. We intend to identify and report the burden in future rulemaking when we propose a new all-payer policy that addresses the concerns raised by comments. Once these residents are identified, CMS would only require data elements designated for the SNF QRP to be reported. To be clear, many payment items are collected on the PPS admission and PPS discharge assessments which would not be required to satisfy the proposal to collect data on all SNF residents regardless of payer. While we have acknowledged 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 for OBRA and other purposes 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. As stated prior, we are not finalizing the all payer proposal, and we intend to identify and report the burden in future rulemaking when we propose a new all-payer policy that addresses the concerns raised by

comments.

We appreciate feedback we received from commenters on our proposal to collect data on all SNF residents regardless of the resident's payer. We believe that the collection of quality data to include all residents would help to ensure that Medicare residents receive the same quality of care as other residents who are treated by SNFs. We appreciate the thoughtful questions and comments we received specific to this proposal. Therefore, after careful consideration of the public comments we received, we have decided not to finalize the proposal to expand the reporting of SNF quality data to include all patients, regardless of payer, at this time. We plan to use the input received in this cycle of rulemaking to revise our policy and propose it in future rulemaking whereby SNFs would be required to collect and submit MDS data on all SNF residents regardless of their payer.

i. 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 the proposed rule, we proposed 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 proposed 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 proposed 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 invited public comment on our proposal.

Commenters submitted the following comments related to the proposed rule's discussion of the Policies Regarding Public Display of Measure Data for the SNF QRP. A discussion of these comments, along with our responses, appears below.

Comment: Several commenters supported the proposal 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 in CY 2020 or as soon as technically feasible, including the exception for SNFs with fewer than 20 eligible cases.

Response: We appreciate the commenters support.

After consideration of the public comments, we are finalizing our proposal 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.

2. Skilled Nursing Facility Value-Based Purchasing Program (SNF VBP)

a. 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 continue to 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.

We received the following general comment on the SNF VBP Program.

Comment: A commenter suggested that CMS consider recognizing special patient populations, such as patients living with HIV/AIDS, for purposes of the SNF VBP Program. The commenter suggested that we incorporate states' recognition of special patient populations into the SNF VBP Program in some way to ensure that SNFs that treat these populations do not experience unintended consequences.

Response: We appreciate the commenter's concern about special populations. We would like to clarify that the readmission measure used for this program is risk-adjusted to account for a SNF resident's clinical characteristics, including HIV/AIDs, to ensure a fair comparison across SNFs with different case-mixes. However, our monitoring and evaluation activities for this program are intended, in part, to ensure that the program does not cause unintended consequences, and we will take this issue into consideration as we conduct those activities.

b. Measures

(1) 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.

We received the following general comments on the SNF VBP Program measures.

Comment: A commenter recommended that CMS incorporate risk adjustment for socioeconomic status (SES) in the SNFRM to guard against unduly penalizing facilities that predominantly serve very low-income residents. The commenter acknowledged that the SNF VBP statute requires a MedPAC study of SES effects on beneficiaries but stated that the report that MedPAC will prepare for Congress will not be sufficient to address the issue in the Program. The commenter specifically suggested that CMS adjust the SNFRM for dual eligibility status as a proxy for SES until better data are available.

Response: The SNFRM was included in the initial phase of the National Quality Forum (NQF) SES trial period, in which this and other measures were assessed by NQF to determine if risk adjustment for SES is appropriate for these measures. As part of this process, we tested dual eligibility as a potential risk-adjuster for the SNFRM and found that it was associated with lower odds of readmission. We intend to continue to monitor the effects of the SNF VBP Program on SNFs that serve different types of populations and we will consider the MedPAC report, which is due from MedPAC to Congress by June 30, 2021, as well as ongoing stakeholder feedback, as we consider whether to incorporate SES-based adjustments in the Program.

Comment: A commenter stated that the SNFPPR measure's calculations should not be based on the Statewide Planning and Research Cooperative System (SPARCS) because that system is inaccessible to nursing home providers. Commenter suggested that CMS explore a mechanism that would have performance information readily accessible to nursing home providers.

Response: We would like to clarify that the SNF VBP Program assesses SNF performance on a hospital readmission measure that is calculated using Medicare fee-for-service claims data submitted to CMS by acute care hospitals and SNFs. We do not use SPARCS data. We appreciate the commenter's concern that SNFs may not have access to all-payer state data; however, we use a different data source (Medicare claims) and furnish quarterly confidential feedback reports to SNFs that contain detailed data derived from Medicare claims data so that all SNFs have access to the underlying data.

Comment: A commenter requested that CMS work with Congress to include additional measures beyond measures of hospital readmissions in the SNF VBP Program. The commenter suggested that additional measures could draw from sources like Nursing Home Compare and from the SNF QRP. The commenter specifically suggested measures of turnover as a percentage of nursing staff, total CNA hours per patient day, and total licensed nursing hours per patient day.

Response: We thank the commenter for these suggestions and will take them into account if Congress should expand the Program's authority to allow us to adopt other measures.

Comment: A commenter requested that CMS align the measure specifications for the potentially preventable hospital readmissions measures used in our value-based purchasing and quality reporting programs.

Response: As we noted in the FY 2020 SNF PPS proposed rule (84 FR 17680), the

SNFPPR utilizes a 30-day post-hospital discharge readmission window, while the SNF QRP's potentially preventable readmission measure utilizes a 30-day post-SNF discharge readmission window, which is consistent with the discharge readmission window specified in other measures that we have developed with respect to domains described in section 1899B of the Act. Those other measures include 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 we explained in the proposed rule, with reference to the FY 2017 SNF PPS final rule (81 FR 51992), our rationale for having adopted two different measures of potentially preventable hospital readmissions for use in the SNF VBP Program and SNF QRP was that the readmission window associated with each measure assesses different aspects of care. We continue to believe that this distinction is useful, and we are finalizing our policy to rename the SNFPPR to minimize confusion between these measures.

(2) 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.

We received several comments on the proposed measure renaming and on the Program's plans to transition to the SNFPPR. The comments and our responses are discussed below.

Comment: Several commenters supported CMS' proposal to rename the SNFPPR. A commenter noted too many similarly named measures can be confusing. Another commenter stated that the new name will provide a more accurate description of the measure. Other commenters requested that CMS clarify what acronym they would prefer that stakeholders use to refer to the renamed measure and requested that CMS announce its plans to implement the measure as soon as possible.

Response: As we did in the FY 2020 SNF PPS proposed rule (84 FR 17680), we intend to refer to the renamed measure as the SNFPPR measure, and we intend to assess when to transition the Program to the SNFPPR measure once we have submitted the measure to NQF for endorsement review.

Comment: A commenter applauded CMS' decision to submit the SNFPPR for NQF endorsement and suggested that CMS delay the measure's implementation until after endorsement has been received.

Response: We thank the commenter for its support. As stated above, we intend to assess when to transition the Program to the SNFPPR measure once we have submitted the measure to NQF for endorsement review.

Comment: A commenter encouraged CMS to provide plans for the SNFPPR's implementation in the SNF VBP Program as soon as possible. The commenter suggested that monitoring performance across multiple program years prior to transitioning to the SNFPPR will help SNFs track how their assessments change and how their quality planning affects their performance.

Response: We intend to provide as much information as possible to SNFs about their performance under the Program when we propose to transition the measure.

Comment: Commenter urged CMS to transition the SNF VBP Program to the SNFPPR, stating that SNFs have incentives to treat low-acuity patients and avoid high-acuity patients since the Program uses a measure of all-cause hospital readmissions.

Response: As we stated in the FY 2020 SNF PPS proposed rule (84 FR 17680), we intend to submit the measure for NQF endorsement review as soon as that is feasible, and we intend to assess when to transition the Program to the SNFPPR measure once we have submitted it for review. Regarding the commenter's concern that the SNFRM could create an incentive for SNFs to avoid high-acuity patients, as we stated in the FY 2016 SNF PPS final rule (80 FR 46413), the SNFRM, which was endorsed by the NQF, has been risk-adjusted for case-mix to account for differences in patient populations. The goal of risk adjustment is to account for these differences so that providers who treat sicker or more vulnerable patient populations are not unnecessarily penalized for factors that are outside of their control. However, we continually evaluate and monitor the Program for unintended consequences.

Comment: A commenter encouraged CMS to seek NQF endorsement of the SNFPPR.

Two commenters requested that CMS provide a timeline for the measure's incorporation into the program as a replacement for the SNFRM.

Response: As we stated in the FY 2020 SNF PPS proposed rule (84 FR 17680), we intend to submit the measure for NQF endorsement review as soon as that is feasible, and intend to assess when to transition the Program to the SNFPPR measure once we have submitted it for review.

After consideration of the comments that we received, we are finalizing our proposal to rename the Skilled Nursing Facility Potentially Preventable Readmissions after Hospital Discharge measure as proposed.

c. FY 2022 Performance Period and Baseline Period

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.

d. Performance Standards

(1) 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).

(2) FY 2022 Performance Standards

As we discussed in the proposed rule and in this final 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 estimated in the proposed rule that the performance standards would have the numerical values noted in Table 14. We stated that these values represented estimates based on the most recently-available data, and that we would update the numerical values in the FY 2020 SNF PPS final rule. For reference, we are displaying those values again in Table 14.

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

We received the following comment on the estimated performance standards.

Comment: A commenter supported CMS’ finalized methodology for performance standards calculation, but suggested that CMS consider adopting an “optimal” or “appropriate” rate of readmission that would not move with the national average. The commenter explained its concern that the financial incentives to reduce readmissions rates under the Program could create perverse incentives for providers to keep patients in SNFs when they should more appropriately be sent back to the hospital.

Response: We would like to clarify that the SNF VBP Program’s achievement threshold is defined as the 25th percentile of SNFs’ performance during the baseline period, not the mean of SNFs’ performance during the baseline period. However, as we discussed in the FY 2017 SNF PPS final rule (81 FR 51996), we adopted the Program’s performance standards definitions because we believe them to represent achievable performance levels. We also note that our data analysis has found no evidence that the Program’s performance standards will create perverse incentives for participating SNFs. We will continue monitoring SNFs’ performance on the SNFRM for any unintended consequences of the Program as we assess when to transition the Program to the SNFPPR.

Table 15 contains the final numerical values for the FY 2022 SNF VBP Program based on the FY 2018 baseline period.

TABLE 15: Final FY 2022 SNF VBP Program Performance Standards*

Measure ID	Measure Description	Achievement Threshold	Benchmark
SNFRM	SNF 30-Day All-Cause Readmission Measure (NQF #2510)	0.79025	0.82917

e. 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 did not propose any updates to SNF VBP scoring policies in the proposed rule.

f. 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 did not propose any updates to SNF VBP payment policies in the 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 estimated 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.

We received several comments on SNF VBP incentive payments policy. The comments and our responses are discussed below.

Comment: Commenters expressed concern about the payback percentage that we finalized for the SNF VBP Program, stating instead that the full amount taken from SNFs' Medicare payments should be remitted to SNFs, similar to how the withheld funds are redistributed in the Hospital VBP Program.

Response: As we have explained in prior rulemaking (see, for example, the FY 2019 SNF PPS final rule, 82 FR 36620), section 1888(h)(5)(C)(ii)(III) of the Act provides that the total amount of value-based incentive payments for all SNFs in a fiscal year must be greater than or equal to 50 percent, but not greater than 70 percent of the total amount of the reductions to SNFs' Medicare payments for that fiscal year, as estimated by the Secretary. We do not have the authority to set the payback percentage higher than 70 percent as the commenter suggests.

Comment: Commenters urged CMS to revisit the payback percentage policy and remit 70 percent of the amount withheld from SNFs' Medicare payments instead of the finalized 60 percent. Commenters also recommended that CMS use the remaining 30 percent of funds for quality improvement initiatives in SNFs.

Response: We responded to numerous comments recommending that we adopt a 70 percent payback percentage in the FY 2018 SNF PPS final rule (82 FR 36620 through 36621) and we do not believe, at this time, that it is appropriate to change the payback percentage since the SNF VBP Program is only entering its second year of incentive payments. We believe that additional time is necessary for CMS to assess the Program's impacts on the quality of care provided to Medicare beneficiaries. We will continue monitoring the SNF VBP Program's effects on SNFs' Medicare payments and quality improvement practices and will consider revisiting our finalized payback percentage policy in the future. Additionally, we note that the funds that are not paid back to SNFs as incentive payments represent savings to the Medicare program, and those funds cannot be allocated separately for quality improvement initiatives in SNFs.

g. Public Reporting on the Nursing Home Compare Website

(1) 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.

(2) 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. 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 stated that we did 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 stated our concerns 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 proposed 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 estimated 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 stated our belief 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

stated that we believed that this policy will provide stakeholders with meaningful information about SNFs' performance under the Program.

We welcomed public comment on this proposal.

Comment: Several commenters supported CMS' proposed public reporting policies. Some commenters suggested that CMS explain on the Nursing Home Compare website why scores are suppressed so that consumers can accurately interpret the data presented.

Response: We agree with the commenters. We intend to provide as much information as possible so that the Nursing Home Compare website's users clearly understand the performance information presented about the Program.

After consideration of the public comments that we have received, we are finalizing our changes to the public reporting of SNF Performance Scores, Achievement and Improvement Scores, and Ranking as proposed.

h. 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 FY 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 stated our concerns 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 stated our belief 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 were to approve a correction request, we would 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 stated that we did 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 stated our belief 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 stated our belief that we could mitigate this uncertainty by adopting a 30-day deadline for Phase One correction requests, and noted that this proposal would align the Phase One review and correction process with the Phase Two process. Under current Program 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 proposed

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 noted 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 proposed this 30-day deadline in lieu of the current March 31 deadline for Phase One corrections. We noted 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 stated that we now believe that a 30-day timeframe is sufficient for SNFs to determine if there were errors in the measure calculation by CMS or its contractor.

We stated our belief 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 also stated our belief 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 indicated that very few SNFs would be adversely impacted by the earlier deadline. We also sought to provide SNFs with earlier final annual payment percentage information for their financial planning purposes.

We welcomed public comments on this proposal.

Comment: A commenter agreed that the current Phase One Review and Corrections deadline may not be ideal, but expressed concern about the proposed 30-day deadline. The commenter suggested that 30 days may not provide enough time for SNFs to complete Phase One corrections, especially if they must collaborate with hospitals, and recommended that CMS adopt a 60-day deadline instead. Another commenter suggested a 90-day deadline, stating that smaller SNFs often do not have the manpower available to review feedback reports promptly.

Response: As we stated in the proposed rule, our proposal would not forestall SNFs from submitting correction requests prior to their receipt of the June report if they believe that an error has occurred, after reviewing data from quarterly reports delivered prior to the June report. Our intention with this proposal is, as we stated, to ensure that any corrections submitted under Phase One do not result in changes to quality measure data months after the incentive payment calculations are completed, which would necessitate changes to the exchange function, and as a result, changes to other SNFs' value-based incentive payment percentages for a fiscal year. Additionally, we note that we previously received public comments supportive of a 30-day deadline for Review and Corrections to which we provided responses in the FY 2017 SNF PPS final rule (81 FR 52008). We believe that SNFs have, by now, accumulated extensive experience with the SNF VBP Program's report system, as well as the finalized Review and Corrections processes. Further, the 30-day review and correction deadline would align the SNF VBP Program with other similar CMS programs.

We will continue to conduct outreach and education to ensure that SNFs are fully aware of the Program's operational deadlines, and we will strive to be as clear as possible about the timeline for corrections once we provide each report to SNFs.

After consideration of the public comments that we have received, we are finalizing our proposed update to the Phase One Review and Corrections deadline as proposed.

IV. 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 30-day notice in the **Federal Register** and solicit public comment before a "collection of information" requirement is submitted to the Office of Management and Budget (OMB) for review and approval. 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.

In our April 25, 2019 proposed rule (84 FR 17620), we solicited public comment on each of the section 3506(c)(2)(A)-required issues for the following information collection requirements. As indicated in section IV.B.1. of this final rule, we received public comments and provide a summary of the comments and our responses in that section. Based on internal

review, we have revised the number of items we are adding across the PPS 5-day and PPS discharge assessments to 59.5 items, as compared to the proposed 60.5 items in the FY 2020 SNF PPS proposed rule.

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' (BLS) May 2018 National Occupational Employment and Wage Estimates for all salary estimates (as compared to the FY 2020 SNF PPS proposed rule which used BLS' May 2017 estimates of \$41.18/hr for a health information technician and \$70.72/hr for a registered nurse) (http://www.bls.gov/oes/current/oes_nat.htm). In this regard, Table 16 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 16: 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	21.16	21.16	42.32
Registered Nurse	29-1141	36.30	36.30	72.60

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. Information Collection Requirements (ICRs)

1. ICRs Regarding the SNF Quality Reporting Program (QRP)

The following changes will be submitted to OMB for approval under control number

0938-1140 (CMS-10387). While the changes do not impose any new or revised burden, they revise our SNF QRP requirements by adding 59.5 items across the PPS 5-day and PPS discharge assessments. Costs have been adjusted to account for more recent wage data. An analysis of the impact for adding the 59.5 items can be found in section V. of this final rule. 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 PDPM for the purpose of reimbursement and for the SNF QRP for the purpose of monitoring the quality of care in SNFs.

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 the aforementioned control number. For the readers' convenience, the active burden estimates are summarized in Table 17. 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 established section 1899B of 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 MDS required to achieve standardization of patient assessment data are exempt from PRA requirements. Standardization has been met upon our adoption of the

proposed data elements and standardized patient assessment data in this final rule. For FY 2020 and thereafter, 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 (83 FR 39283) we continue to 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 III.E.1.d. and III.E.1.g. of this rule, we are adding 59.5 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, with updated cost estimates based on more recent BLS wage figures, as a courtesy to interested parties.

When calculating the burden for each assessment, we estimate it will take 40 minutes (0.6667 hours) at \$72.60/hr for an RN to collect the information necessary for preparing the assessment, 10 minutes (0.1667 hours) at \$57.46/hr (the average hourly wage for RN (\$72.60/hr) and health information technician (\$42.32/hr)) for staff to code the responses, and 1 minute (0.0167 hours) at \$42.32/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 \$58.69 $[(\$72.60/\text{hr} \times 0.6667 \text{ hr}) + (\$57.46/\text{hr} \times 0.1667 \text{ hr}) + (\$42.32/\text{hr} \times 0.0167 \text{ hr})]$ 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 will be completed across all facilities is 4,905,042 assessments $(2,406,401 + 2,406,401 + 92,240)$, respectively). In aggregate, we estimate an annual burden for all assessments across all facilities of 4,169,286 hours $(4,905,042 \text{ assessments} \times 0.85 \text{ hours/assessment})$ at a cost of \$287,876,914 $(4,905,042 \text{ assessments} \times \$58.69/\text{assessment})$.

Given that adding 59.5 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 revising or adjusting any of our active burden estimates, except for adjusting our cost

estimates as indicated above. In this regard, we will be submitting a revised information collection request to OMB to account for the added items and adjusted costs.

Further, in section III.E.1.h.(2) of this final rule, there are no burden implications associated with updating the data submission system to the iQIES for the SNF QRP once it becomes available. 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.

We received the following comments on our collections of information estimates.

Comment: One commenter stated that adding items across the PPS 5-day and discharge assessments would result in increased burden, especially due to the time required to complete resident interview items.

Response: We acknowledge that adding items for the SNF QRP across the PPS 5-day and discharge assessments increases burden for providers. However, we continue to believe that these items are accounted for in our active burden estimates, given that we use the PPS OMRA as the proxy for all assessments. 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 59.5 added items are accounted for since the PPS OMRA is used as a proxy for the shorter PPS discharge assessment. Therefore, we intend to move forward with the addition of these 59.5 items.

Comment: Another commenter requested that CMS consider staging additional SNF QRP requirements in a way that would allow SNFs more time to adapt the to the PDPM payment methodology.

Response: We note that the PDPM takes effect in the October 1, 2019, while SNFs are not required to begin data collection for the SNF QRP requirements finalized in this final rule until October 1, 2020, thereby by allowing a year to adjust to the PDPM before the finalized SNF

QRP requirements take effect. Therefore, we intend to move forward with the addition of these 59.5 items.

2. ICRs Regarding the SNF VBP Program

We are not removing, adding, or revising any of our SNF VBP measure-related requirements or burden. Consequently, the rule contains no SNF-VBP related collections of information that are subject to OMB approval under the authority of the PRA.

C. Summary of Requirements and Annual Burden Estimates

TABLE 17: Summary of 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
Changes under CMS-1718-F	0	0	0	0	0	varies	+7,455,663
TOTAL	15,471	317.04	4,905,042	0.85	4,169,286	varies	287,876,914

V. Economic Analyses

A. Regulatory Impact Analysis

1. Statement of Need

This final rule updates the FY 2020 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 final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA, September 19, 1980, Pub. L. 96-354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA, March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), 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 final 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 \$851 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 (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 18. In updating the SNF PPS rates for FY 2020, we made a number of standard annual revisions and clarifications mentioned elsewhere in this final rule (for example, the update to the wage and market basket indexes used for adjusting the federal rates).

The annual update set forth in this final rule applies to SNF PPS payments in FY 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 18. 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 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 18 (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 18 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 2.4 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 2.4 percent, assuming facilities do not change their care delivery and billing practices in response.

As illustrated in Table 18, the combined effects of all of the changes vary by specific types of providers and by location. For example, due to changes in this final rule, providers in the urban Pacific region will experience a 1.6 percent increase in FY 2020 total payments.

TABLE 18: 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%	2.4%
Urban	10,951	-0.7%	0.0%	1.7%
Rural	4,127	3.7%	0.2%	6.2%
Hospital-based urban	380	9.9%	0.1%	12.4%
Freestanding urban	10,571	-1.0%	0.0%	1.4%
Hospital-based rural	245	20.4%	0.3%	23.1%
Freestanding rural	3,882	3.1%	0.2%	5.6%
Urban by region				
New England	775	2.0%	-0.4%	4.0%
Middle Atlantic	1,470	-3.1%	-0.1%	-0.8%
South Atlantic	1,868	-0.7%	-0.2%	1.5%
East North Central	2,118	0.1%	0.0%	2.4%
East South Central	536	0.7%	-0.2%	2.9%
West North Central	921	3.8%	0.6%	6.8%
West South Central	1,323	-1.3%	0.2%	1.3%
Mountain	527	0.1%	0.2%	2.7%
Pacific	1,407	-0.9%	0.1%	1.6%
Outlying	6	58.5%	-0.4%	60.5%
Rural by region				
New England	126	5.4%	-1.5%	6.3%
Middle Atlantic	194	2.3%	0.0%	4.8%
South Atlantic	462	4.2%	0.4%	7.0%
East North Central	908	3.4%	-0.1%	5.7%
East South Central	452	2.4%	0.3%	5.1%
West North Central	1,020	10.2%	0.4%	13.1%
West South Central	666	-0.5%	0.3%	2.2%
Mountain	207	6.0%	1.2%	9.6%
Pacific	92	1.4%	0.3%	4.1%
Ownership				
For profit	10,729	-0.6%	0.0%	1.8%
Non-profit	3,469	1.5%	0.0%	3.9%
Government	880	4.5%	0.1%	7.0%

Note: The Total column includes the 2.4 percent market basket increase factor. Additionally, we found no SNFs in rural outlying areas.

5. Impacts for the Skilled Nursing Facility (SNF) Quality Reporting Program (QRP)

As discussed in this final rule, we are adopting two new quality measures beginning with the FY 2022 SNF QRP (see section III.E.1.d. of this final rule). For these two quality measures, we are adding 4 data elements on discharge which would require an additional 1.2 minutes of

nursing staff time per discharge. We estimate these data elements for these quality measures would be completed by Registered Nurses (25 percent of the time or 0.30 minutes) at \$72.60/hr and by Licensed Practical Nurses (75 percent of the time or 0.90 minutes) at \$45.24/hr. With 2,406,401 discharges from 15,471 SNFs annually (see section IV.B. of this final rule), we estimate an annual burden of 48,128 additional hours (2,406,401 discharges x 1.2 min/60) at a cost of \$2,506,507 (2,406,401 x [(0.30/60 x \$72.60/hr) + (0.90/60 x \$45.24/hr)]). For each SNF we estimate an annual burden of 3.11 hours (48,128 hr/15,471 SNFs) at a cost of \$162.01 (\$2,506,507/15,471 SNFs).

We are finalizing requirements to collect 55.5 standardized patient assessment data elements consisting of 8 data elements on admission and 47.5 data elements on discharge beginning with the FY 2022 SNF QRP. We estimate that the data elements would take an additional 12.675 minutes of nursing staff time consisting of 1.725 minutes to report on each admission and 10.95 minutes to report on each discharge. We assume the added data elements would be performed by both Registered Nurses (25 percent of the time or 3.169 minutes) and Licensed Practical Nurses (75 percent of the time or 9.506 minutes). We estimate the reporting of these assessment items will impose an annual burden of 508,352 total hours (2,406,401 discharges x 12.675 min/60) at a cost of \$26,474,983 ((508,352 hr x 0.25 x \$72.60/hr) + (508,352 hr x 0.75 x \$45.24/hr)). For each SNF the annual burden is 32.86 hours (508,352 hr/15,471 SNFs) at a cost of \$1,711.27 (\$26,474,983/15,471 SNFs).

The overall annual cost of the finalized changes associated with the newly added 59.5 assessment items is estimated at \$1,873.28 per SNF annually (\$162.01 + \$1,711.27), or \$28,981,490 (\$2,506,507 + \$26,474,983) for all 15,471 SNFs annually.

6. Impacts for the SNF VBP Program

The impacts of the FY 2020 SNF VBP Program are based on historical data and appear in

Table 19. 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 19.

TABLE 19: 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 \$851 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 20 through 22, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final rule for FY 2020. Tables 18 and 20 provide our best estimate of the possible changes in Medicare payments under the SNF PPS as a result of the policies in this final rule, based on the data for 15,078 SNFs in our database. Table 21 provides our best estimate of the costs for SNFs to submit data under the SNF QRP as a result of the policies in this final rule. Tables 19 and 22 provide our best estimate of the possible changes in Medicare payments under the SNF VBP as a result of the policies in this final rule.

TABLE 20: 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	\$851 million*
From Whom To Whom?	Federal Government to SNF Medicare Providers

* The net increase of \$851 million in transfer payments is a result of the market basket increase of \$851 million.

TABLE 21: Accounting Statement: Estimated Cost to Update the SNF Quality Reporting Program

Category	Cost
Cost for SNFs to Submit Data for QRP	\$29 million*

*Costs associated with the submission of data for the QRP will occur in FY 2021 and likely continue in the future years.

TABLE 22: 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 final 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 \$851 million, or 2.4 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 1.7 percent increase and 6.2 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 60.5 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 final 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 \$851 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 2.4 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 final 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 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an MSA and has fewer than 100 beds. This final rule will affect small rural hospitals that (1) furnish SNF services under a swing-bed agreement or (2) have a hospital-based SNF. We anticipate that the impact on small rural hospitals 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 final 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 2.4 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 final 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 final rule will 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, entitled “Reducing Regulation and Controlling Regulatory Costs,” was issued on January 30, 2017 and requires that the costs associated with significant new regulations “shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.” This final rule is considered an EO 13771 regulatory action. We estimate the rule generates \$20.68 million in annualized costs in 2016 dollars, discounted at 7 percent relative to year 2016 over a perpetual time horizon. Details on the estimated costs of this rule can be found in the preceding and subsequent analyses.

F. Congressional Review Act

This final regulation is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 et seq.) and has been transmitted to the Congress and the Comptroller General for review.

G. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this final 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 is a fair estimate of the number of reviewers of this rule. In the FY 2020 SNF PPS proposed rule (84 FR 17689), we welcomed 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 the proposed rule, and therefore, for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We sought comments on this assumption in the FY 2020 SNF PPS proposed rule (84 FR 17689).

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 \$109.36 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 \$437.44 (4 hours x \$109.36). Therefore, we estimate that the total cost of reviewing this regulation is \$27,559 (\$437.44 x 63 reviewers).

In accordance with the provisions of Executive Order 12866, this final 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 amends 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—
 - a. By removing the phrase “the 5-day assessment” and adding in its place the phrase “the initial Medicare assessment”; and
 - b. By removing the phrase “must occur” and adding in its place the phrase “must be set for”.

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 Pub. L. 106-113, 113 Stat. 1501A- 332; sec. 3201 of Pub. L. 112-96, 126 Stat. 156; sec. 632 of Pub. L 112-240, 126 Stat. 2354; sec. 217 of Pub. L. 113-93, 129 Stat. 1040; and sec. 204 of Pub. L. 113-295, 128 Stat. 4010; and sec. 808 of Pub. L. 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 Medicare assessment with an assessment reference date that is set for 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-F

Dated: July 26, 2019.

Seema Verma,

Administrator,

Centers for Medicare & Medicaid Services.

Dated: July 26, 2019.

Alex M. Azar II,

Secretary,

Department of Health and Human Services.

[FR Doc. 2019-16485 Filed: 7/30/2019 4:15 pm; Publication Date: 8/7/2019]