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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 409, 414, and 484

[CMS-1711-P]

RIN 0938-AT68

Medicare and Medicaid Programs; CY 2020 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; Home Health Quality Reporting Requirements; and Home Infusion Therapy Requirements

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would update the home health prospective payment system (HH PPS) payment rates and wage index for CY 2020; implement the Patient-Driven Groupings Model (PDGM), a revised case-mix adjustment methodology, for home health services beginning on or after January 1, 2020. This proposed rule also implements a change in the unit of payment from 60-day episodes of care to 30-day periods of care, as required by section 51001 of the Bipartisan Budget Act of 2018, hereinafter referred to the "BBA of 2018", and proposes a 30-day payment amount for CY 2020. Additionally, this proposed rule proposes to: modify the payment regulations pertaining to the content of the home health plan of care; allow physical therapy assistants to furnish maintenance therapy; and change the split percentage payment approach under the HH PPS. This proposed rule would also solicit comments on the wage index used to adjust home health payments and suggestions for possible updates and improvements to the geographic adjustment of home health payments. In addition, it proposes public reporting of

certain performance data under the Home Health Value-Based Purchasing (HHVBP) Model. We are proposing to publicly report the Total Performance Score (TPS) and the TPS Percentile Ranking from the Performance Year 5 (CY 2020) Annual TPS and Payment Adjustment Report for each home health agency in the nine Model states that qualified for a payment adjustment for CY 2020. It also proposes changes with respect to the Home Health Quality Reporting Program to remove one measure, to adopt two new measures, modify an existing measure, adopt new standardized patient assessment data beginning with the CY 2022 HH QRP, codify the HH QRP policies in a new section, and to remove question 10 from all the HH Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys. Lastly, it would set forth routine updates to the home infusion therapy payment rates for CY 2020 and propose payment provisions for home infusion therapy services for CY 2021 and subsequent years.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on September 9, 2019.

ADDRESSES: In commenting, please refer to file code CMS-1711-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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

1. Electronically. You may submit electronic comments on this regulation to **http://www.regulations.gov**. Follow the "Submit a comment" instructions.

2. By regular mail. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-1711-P,

P.O. Box 8013,

Baltimore, MD 21244-8013.

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

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

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-1711-P,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

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

FOR FURTHER INFORMATION CONTACT: Kelly Vontran, (410) 786-0332, for Home Health Prospective Payment System (HH PPS) or home infusion payment.

For general information about the Home Health Prospective Payment System (HH PPS), send your inquiry via email to: HomehealthPolicy@cms.hhs.gov.

For general information about home infusion payment, send your inquiry via email to: HomeInfusionPolicy@cms.hhs.gov.

For information about the Home Health Value-Based Purchasing (HHVBP) Model, send your inquiry via email to: HHVBPquestions@cms.hhs.gov.

For information about the Home Health Quality Reporting Program (HH QRP), send your inquiry via email to HHQRPquestions @cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

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

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I. Executive Summary

A. Purpose

1. Home Health Prospective Payment System (HH PPS)

This proposed rule would update the payment rates for home health agencies (HHAs) for calendar year (CY) 2020, as required under section 1895(b) of the Social Security Act (the Act). This proposed rule would also update the case-mix weights under section 1895(b)(4)(A)(i) and (b)(4)(B) of the Act for 30-day periods of care beginning on or after January 1, 2020. This rule would also implement the PDGM, a revised case-mix adjustment methodology that was finalized in the CY 2019 HH PPS final rule (83 FR 56406), which would also implement the removal of therapy thresholds for payment as required by section 1895(b)(4)(B)(ii) of the Act, as amended by section 51001(a)(3) of the BBA of 2018, and changes the unit of home health payment from 60-day episodes of care to 30-day periods of care, as required by section 1895 (b)(2)(B) of the Act, as amended by 51001(a)(1) of the BBA of 2018. This proposed rule also proposes to allow therapist assistants to furnish maintenance therapy; proposes changes to the payment regulations

pertaining to the content of the home health plan of care; proposes technical regulations text changes clarifying the split-percentage payment approach for newly-enrolled HHAs in CY 2020 and proposes a change in the split percentage payment approach for existing HHAs in CY 2020 and subsequent years.

2. HHVBP

This rule proposes public reporting of the TPS and the TPS Percentile Ranking from the Performance Year 5 (CY 2020) Annual TPS and Payment Adjustment Report for each HHA that qualifies for a payment adjustment under the HHVBP Model for CY 2020.

3. HH QRP

This rule purposes changes to the Home Health Quality Reporting Program (HH QRP) requirements under the authority of section 1895(b)(3)(B)(v) of the Act

4. Home Infusion Therapy

This proposed rule would update the CY 2020 payment rates for the temporary transitional payment for home infusion therapy services as required by section 1834(u)(7) of the Act, as added by section 50401 of the BBA of 2018. This rule also proposes payment provisions for home infusion therapy services for CY 2021 and subsequent years in accordance with section 1834(u)(1) of the Act, as added by section 5012 of the 21st Century Cures Act (Pub. L. 114-255).

B. Summary of the Major Provisions

1. Home Health Prospective Payment System (HH PPS)

Section III.A. of this rule, sets forth planned implementation of the Patient-Driven Groupings Model (PDGM) as required by section 51001 of the BBA of 2018 (Pub. L. 115-123). The PDGM is an alternate case-mix adjustment methodology to adjust payments for home health periods of care beginning on and after January 1, 2020. The PDGM relies more heavily on

clinical characteristics and other patient information to place patients into meaningful payment categories and eliminates the use of therapy service thresholds, as required by section 1895(b)(4)(B) of the Act, as amended by section 51001(a)(3) of the BBA of 2018. Section III.B. of this rule also implements a change in the unit of payment from a 60-day episode of care to a 30-day period of care as required by section 1895(b)(2) of the Act, as amended by section 51001(a)(1) of the BBA of 2018.

Section III.C. of this proposed rule describes the CY 2020 case-mix weights for those 60-day episodes that span the implementation date of the PDGM and section III.D. of this proposed rule proposes the CY 2020 PDGM case-mix weights and LUPA thresholds for 30-day periods of care. In section III.E. of this proposed rule, we propose to update the home health wage index and to update the national, standardized 60-day episode of care and 30-day period of care payment amounts, the national per-visit payment amounts as well and the non-routine supplies (NRS) conversion factor for 60-day episodes of care that begin in 2019 and span the 2020 implementation date of the PDGM. The home health payment update percentage for CY 2020 will be 1.5 percent, as required by section 53110 of the BBA of 2018. We also solicit comments on concerns stakeholders may have regarding the wage index used to adjust home health payments and suggestions for possible updates and improvements to the geographic adjustment of home health payments. Section III.F. of this proposed rule proposes a change to the fixed-dollar loss ratio to 0.63 for CY 2020 under the PDGM in order to ensure that outlier payments as a percentage of total payments is closer to, but no more than, 2.5 percent, as required by section 1895(b)(5)(A) of the Act. Section III.G. of this proposed rule, proposes a technical regulations text correction at § 484.205 regarding split-percentage payments for newly-enrolled HHAs in CY 2020; proposes changes to reduce the split-percentage payment amounts for existing HHAs

in CY 2020; and proposes to eliminate split-percentage payments entirely beginning in CY 2021. In section III.H. of this proposed rule, we propose to allow physical therapist assistants to furnish maintenance therapy under the Medicare home health benefit, and section III.I. of this proposed proposes a change in the payment regulations at § 409.43 related to home health plan of care requirements for payment.

2. HHVBP

In section IV. of this proposed rule, we are proposing to publicly report performance data for Performance Year (PY) 5 of the HHVBP Model. Specifically, we are proposing to publicly report the TPS and the TPS Percentile Ranking from the PY 5 (CY 2020) Annual TPS and Payment Adjustment Report for each HHA in the nine Model states that qualified for a payment adjustment for CY 2020.

3. HH QRP

In section V. of this rule, we propose updates to the Home Health Quality Reporting Program (HH QRP) including: the removal of one quality measure, the adoption of two new quality measures, the modification of an existing measure, and the reporting of standardized patient assessment data described under section 1899B(b)(1)(B) of the Act. In section V.J. of this rule, we are proposing to codify HH QRP policies in a newly created section of the regulations. Finally, in section V.K. of the rule we propose removing question 10 from all HHCAHPS Surveys (both mail surveys and telephone surveys).

4. Home Infusion Therapy

In section VI.A. of this proposed rule, we discuss general background of home infusion therapy services and how that will relate to the implementation of the new home infusion benefit in CY 2021. Section VI.B. of this proposed rule updates the CY 2020 home infusion therapy

services temporary transitional payment rates, in accordance with section 1834(u)(7) of the Act. In section VI.C. of this proposed rule, we are proposing to add a new subpart P under the regulations at 42 CFR part 414 to incorporate conforming regulations text regarding conditions for payment for home infusion therapy services for CY 2021 and subsequent years. Proposed subpart P would include beneficiary qualifications and plan of care requirements in accordance with section 1861(iii) of the Act. In section VI.D. of this proposed rule, we propose payment provisions for the full implementation of the home infusion therapy benefit in CY 2021 upon expiration of the home infusion therapy services temporary transitional payments in CY 2020. The home infusion therapy services payment system is to be implemented starting in CY 2021, as mandated by section 5012 of the 21st Century Cures Act. The provisions in this section include proposed payment categories, amounts, and required and optional payment adjustments. In section VI.E. of this proposed rule, we propose to use the Geographic Adjustment Factor (GAF) to wage adjust the home infusion therapy payment as required by section 1834(u)(1)(B)(i) of the Act. In this section VI.F. of this proposed rule, we offer a discussion on several topics for home infusion therapy services for CY 2021 such as: optional payment adjustments, prior authorization, and high-cost outliers. Lastly, in section VI.H. of this proposed rule, we discuss billing procedures for CY 2021 home infusion therapy services.

C. Summary of Costs, Transfers, and Benefits

TABLE 1: SUMMARY OF COSTS, TRANSFERS, AND BENEFITS

Provision Description	Costs and Cost Savings	Transfers	Benefits
CY 2020 HH PPS Payment Rate Update		The overall economic impact of the HH PPS payment rate update is an estimated $250 million (1.3 percent) in increased payments to HHAs in CY 2020.	To ensure home health payments are consistent with statutory payment authority for CY 2020.

Provision Description	Costs and Cost Savings	Transfers	Benefits
CY 2020 HHVBP Model		The overall economic impact of the HHVBP Model for CYs 2018 through 2022 is an estimated $378 million in total savings to Medicare from a reduction in unnecessary hospitalizations and SNF usage as a result of greater quality improvements in the HH industry. As for payments to HHAs, there are no aggregate increases or decreases expected to be applied to the HHAs competing in the model.	
New HH QRP requirements	The total addition in costs beginning in CY 2021 for HHAs as a result of the new quality reporting requirements is estimated to be $169.9 million.		
CY 2020 Temporary Transitional Payments for Home Infusion Therapy Services		The overall economic impact of the temporary transitional payment for home infusion therapy services is an estimated to be either a $1 million increase or decrease in payments to home infusion therapy suppliers in CY 2020 depending upon any changes to Physician Fee Schedule payment amounts for such services.	To ensure temporary transitional payments for home infusion therapy are consistent with statutory authority for CY 2020.
CY 2021 Payments for Home Infusion Therapy Services		The overall economic impact of the payments for home infusion therapy services is an estimated $3 million in decreased payments to eligible home infusion therapy suppliers in CY 2021.	To ensure that payment for home infusion therapy services are consistent with statutory authority for CY 2021.

II. Overview of the Home Health Prospective Payment System

A. Statutory Background

The Balanced Budget Act of 1997 (BBA) (Pub. L. 105-33, enacted August 5, 1997), significantly changed the way Medicare pays for Medicare home health services. Section 4603 of the BBA mandated the development of the HH PPS. Until the implementation of the HH PPS on October 1, 2000, HHAs received payment under a retrospective reimbursement system. Section 4603(a) of the BBA mandated the development of a HH PPS for all Medicare-covered home health services provided under a plan of care (POC) that were paid on a reasonable cost basis by adding section 1895 of the Social Security Act (the Act), entitled "Prospective Payment For Home Health Services." Section 1895(b)(1) of the Act

requires the Secretary to establish a HH PPS for all costs of home health services paid under Medicare. Section 1895(b)(2) of the Act required that, in defining a prospective payment amount, the Secretary will consider an appropriate unit of service and the number, type, and duration of visits provided within that unit, potential changes in the mix of services provided within that unit and their cost, and a general system design that provides for continued access to quality services.

Section 1895(b)(3)(A) of the Act required the following: (1) the computation of a standard prospective payment amount that includes all costs for HH services covered and paid for on a reasonable cost basis, and that such amounts be initially based on the most recent audited cost report data available to the Secretary (as of the effective date of the 2000 final rule), and (2) the standardized prospective payment amount be adjusted to account for the effects of case-mix and wage levels among HHAs.

Section 1895(b)(3)(B) of the Act requires the standard prospective payment amounts be annually updated by the home health applicable percentage increase. Section 1895(b)(4) of the Act governs the payment computation. Sections 1895(b)(4)(A)(i) and (b)(4)(A)(ii) of the Act require the standard prospective payment amount to be adjusted for case-mix and geographic differences in wage levels. Section 1895(b)(4)(B) of the Act requires the establishment of an appropriate case-mix change adjustment factor for significant variation in costs among different units of services.

Similarly, section 1895(b)(4)(C) of the Act requires the establishment of area wage adjustment factors that reflect the relative level of wages, and wage-related costs applicable to home health services furnished in a geographic area compared to the applicable national average level. Under section 1895(b)(4)(C) of the Act, the wage-adjustment factors used by the Secretary may be the factors used under section 1886(d)(3)(E) of the Act. Section 1895(b)(5) of the Act gives the Secretary the option to make additions or adjustments to the payment amount otherwise paid in the case of outliers due to unusual variations in the type or amount of medically necessary care. Section 3131(b)(2) of the Affordable Care Act revised section 1895(b)(5) of the Act so that total outlier payments in a given year would not exceed 2.5 percent of total payments projected or estimated. The provision also made permanent a 10 percent agency-level outlier payment cap.

In accordance with the statute, as amended by the BBA, we published a final rule in the July 3, 2000 **Federal Register** (65 FR 41128) to implement the HH PPS legislation. The July 2000 final rule established requirements for the new HH PPS for home health services as required by section 4603 of the BBA, as subsequently amended by section 5101 of the Omnibus Consolidated and Emergency Supplemental Appropriations Act for Fiscal Year 1999 (OCESAA), (Pub. L. 105-277, enacted October 21, 1998); and by sections 302, 305, and 306 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, (BBRA) (Pub. L. 106-113, enacted November 29, 1999). The requirements include the implementation of a HH PPS for home health services, consolidated billing requirements, and a number of other related changes. The HH PPS described in that rule replaced the retrospective reasonable cost-based system that was used by Medicare for the payment of home health services under Part A and Part B. For a complete and full description of the HH PPS as required by the BBA, see the July 2000 HH PPS final rule (65 FR 41128 through 41214).

Section 5201(c) of the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109-171, enacted February 8, 2006) added new section 1895(b)(3)(B)(v) to the Act, requiring HHAs to submit data for purposes of measuring health care quality, and linking the quality data submission to the annual applicable payment percentage increase. This data submission requirement is applicable for CY 2007 and each subsequent year. If an HHA does not submit quality data, the home health market basket percentage increase is reduced by 2 percentage points. In the November 9, 2006 **Federal Register** (71 FR 65935), we published a final rule to implement the pay-for-reporting requirement of the DRA, which was codified at § 484.225(h) and (i) in accordance with the statute. The pay-for-reporting requirement was implemented on January 1, 2007.

The Affordable Care Act made additional changes to the HH PPS. One of the changes in section 3131 of the Affordable Care Act is the amendment to section 421(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173, enacted on December 8, 2003) as amended by section 5201(b) of the DRA. Section 421(a) of the MMA, as amended by section 3131 of the Affordable Care Act, requires that the Secretary increase, by 3 percent, the payment amount otherwise

made under section 1895 of the Act, for HH services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Act) with respect to episodes and visits ending on or after April 1, 2010, and before January 1, 2016.

Section 210 of the Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114-10) (MACRA) amended section 421(a) of the MMA to extend the 3 percent rural add-on payment for home health services provided in a rural area (as defined in section 1886(d)(2)(D) of the Act) through January 1, 2018. In addition, section 411(d) of MACRA amended section 1895(b)(3)(B) of the Act such that CY 2018 home health payments be updated by a 1 percent market basket increase. Section 50208(a)(1) of the BBA of 2018 again extended the 3 percent rural add-on through the end of 2018. In addition, this section of the BBA of 2018 made some important changes to the rural add-on for CYs 2019 through 2022, to be discussed later in this proposed rule.

B. Current System for Payment of Home Health Services

Generally, Medicare currently makes payment under the HH PPS on the basis of a national, standardized 60-day episode payment rate that is adjusted for the applicable case-mix and wage index. The national, standardized 60-day episode rate includes the six home health disciplines (skilled nursing, home health aide, physical therapy, speech-language pathology, occupational therapy, and medical social services). Payment for non-routine supplies (NRS) is not part of the national, standardized 60-day episode rate, but is computed by multiplying the relative weight for a particular NRS severity level by the NRS conversion factor. Payment for durable medical equipment covered under the HH benefit is made outside the HH PPS payment system. To adjust for case-mix, the HH PPS uses a 153-category case-mix classification system to assign patients to a home health resource group (HHRG). The clinical severity level, functional severity level, and service utilization are computed from responses to selected data elements in the Outcome and Assessment Information Set (OASIS) assessment instrument and are used to place the patient in a particular HHRG. Each HHRG has an associated case-mix weight which is used in calculating the payment for an episode. Therapy service use is measured by the number of therapy visits

provided during the episode and can be categorized into nine visit level categories (or thresholds): 0 to 5; 6; 7 to 9; 10; 11 to 13; 14 to 15; 16 to 17; 18 to 19; and 20 or more visits.

For episodes with four or fewer visits, Medicare pays national per-visit rates based on the discipline(s) providing the services. An episode consisting of four or fewer visits within a 60-day period receives what is referred to as a low-utilization payment adjustment (LUPA). Medicare also adjusts the national standardized 60-day episode payment rate for certain intervening events that are subject to a partial episode payment adjustment (PEP adjustment). For certain cases that exceed a specific cost threshold, an outlier adjustment may also be available.

C. New Home Health Prospective Payment System for CY 2020 and Subsequent Years

In the CY 2019 HH PPS final rule (83 FR 56446), we finalized a new patient case-mix adjustment methodology, the Patient-Driven Groupings Model (PDGM), to shift the focus from volume of services to a more patient-driven model that relies on patient characteristics. For home health periods of care beginning on or after January 1, 2020, the PDGM uses timing, admission source, principal and other diagnoses, and functional impairment to case-mix adjust payments. The PDGM results in 432 unique case-mix groups. Low-utilization payment adjustments (LUPAs) will vary; instead of the current four visit threshold, each of the 432 case-mix groups has its own threshold to determine if a 30-day period of care would receive a LUPA. Additionally, non-routine supplies (NRS) are included in the base payment rate for the PDGM instead of being separately adjusted as in the current HH PPS. Also in the CY 2019 HH PPS final rule, we finalized a change in the unit of home health payment from 60-day episodes of care to 30-day periods of care, and eliminated the use of therapy thresholds used to adjust payments in accordance with section 51001 of the BBA of 2018. Thirty-day periods of care will be adjusted for outliers and partial episodes as applicable. For LUPAs under the PDGM, we finalized that the LUPA threshold would vary for a 30-day period under the PDGM using 10^{th} percentile value of visits to create a payment group specific LUPA threshold with a minimum threshold of at least 2 visits for each payment group. Finally, for CYs 2020 through 2022, home health services provided to beneficiaries

residing in rural counties will be increased based on rural county classification (high utilization; low population density; or all others) in accordance with section 50208 of the BBA of 2018.

D. Analysis of FY 2017 HHA Cost Report Data for 60-day Episodes and 30-day Periods

In the CY 2019 HH PPS proposed rule (83 FR 32348), we provided a summary of analysis on fiscal year (FY) 2016 HHA cost report data and how such data, if used, would impact our estimate of the percentage difference between Medicare payments and HHA costs. We stated in the CY 2019 HH PPS final rule (83 FR 56414) that we will continue to monitor the impacts due to policy changes and will provide the industry with periodic updates on our analysis in rulemaking and/or announcements on the HHA Center webpage.

In this year's proposed rule, we examined FY 2017 HHA cost reports as this is the most recent and complete cost report data at the time of rulemaking. We examined the estimated 60-day episode costs using FY 2017 cost reports and CY 2017 home health claims and the estimated costs for 60-day episodes by discipline and the total estimated cost for a 60-day episode for 2017 is shown in Table 2.

TABLE 2: ESTIMATED COSTS FOR 60-DAY EPISODES IN CY 2017

Discipline	FY2017 Cost Per Visit [1]	Average # Total Visits [2]	60-Day Episode Costs [3]	NRS Cost Per Visit	60-Day Episode Costs with NRS
Skilled Nursing	$135.93	8.59	$1,167.64	$3.58	$1,198.39
Physical Therapy	$156.59	5.78	$905.09	$3.58	$925.78
Occupational Therapy	$153.13	1.7	$260.32	$3.58	$266.41
Speech Pathology	$169.89	0.35	$59.46	$3.58	$60.71
Medical Social Services	$223.96	0.14	$31.35	$3.58	$31.85
Home Health Aides	$61.83	1.63	$100.78	$3.58	$106.62
Total			**$2,524.64**		**$2,589.76**

[1] **Source:** Updated methodology described in the 2013 Rebasing Report using cost reports pulled in January 2019 and claims data from 2016 and 2017.
[2] **Source:** Home health episode data linked to OASIS assessments for episodes ending in CY 2017. PEP and LUPA episodes were excluded. Data derived from average of average total number of visits and average covered number of visits.
[3] **Source:** Calculated by multiplying Average Cost per Visit by Average Number of Total Visits.

To estimate the costs for CY 2020, we updated the estimated 60-day episode costs with NRS by the home health market basket update, minus the multifactor productivity adjustment for CYs 2018 and 2019. For CY 2020, the BBA of 2018 requires a market basket update of 1.5 percent. The estimated costs

for 60-day episodes by discipline and the total estimated cost for a 60-day episode for CY 2020 is shown in Table 3.

TABLE 3: ESTIMATED 60-DAY EPISODE COSTS IN CY 2020

Discipline	2017 60-day Episode Costs with NRS	2018 Market Basket Update minus MFP	2019 Market Basket Update minus MFP	2020 Market Basket Update (statutory)	2020 Estimated 60-Day Costs
Skilled Nursing	$1,198.39	1.01	1.022	1.015	$1,255.56
Physical Therapy	$925.78	1.01	1.022	1.015	$969.94
Occupational Therapy	$266.41	1.01	1.022	1.015	$279.12
Speech Pathology	$60.71	1.01	1.022	1.015	$63.61
Medical Social Services	$31.85	1.01	1.022	1.015	$33.37
Home Health Aides	$106.62	1.01	1.022	1.015	$111.71
Total	**$2,589.76**	1.01	1.022	1.015	**$2,713.30**

The CY 2019 60-day episode payment is $3,154.27. Updating this payment amount by the CY 2020 home health market basket of 1.5 percent results in an estimated CY 2020 60-day episode payment of $3,201.58, approximately 18 percent more than the estimated CY 2020 60-day episode cost of $2,713.30.

Next, we also looked at the estimated costs for 30-day periods of care in 2017 using FY 2017 cost reports and CY 2017 claims. Thirty-day periods were simulated from 60-day episodes and we excluded low-utilization payment adjusted episodes and partial-episode-payment adjusted episodes. The 30-day periods were linked to OASIS assessments and covered the 60-day episodes ending in CY 2017. The estimated costs for 30-day periods by discipline and the total estimated cost for a 30-day period for 2017 is shown in Table 4.

TABLE 4: ESTIMATED COSTS FOR 30-DAY PERIODS IN CY 2017

Discipline	2017 Average costs per visit (without NRS)	2017 Average number of visits	2017 30-day period costs (without NRS)	2017 Average NRS costs per visit	2017 Average Cost+NRS per visit	2017 30-day period costs with NRS
Skilled Nursing	$135.93	4.88	$663.34	$3.58	$139.51	$680.81
Physical Therapy	$156.59	3.45	$540.24	$3.58	$160.17	$552.59
Occupational Therapy	$153.13	1.03	$157.72	$3.58	$156.71	$161.41
Speech Pathology	$169.89	0.21	$35.68	$3.58	$173.47	$36.43
Medical Social Services	$223.96	0.08	$17.92	$3.58	$227.54	$18.20
Home Health Aides	$61.83	0.86	$53.17	$3.58	$65.41	$56.25

Discipline	2017 Average costs per visit (without NRS)	2017 Average number of visits	2017 30-day period costs (without NRS)	2017 Average NRS costs per visit	2017 Average Cost+NRS per visit	2017 30-day period costs with NRS
Total		10.50	**$1,468.07**			**$1,505.69**

Source: Medicare cost reports were pulled in January 2019. Medicare claims data from 2017 was pulled from the CCW in August 2018. The 30-day periods were simulated from 60-day episodes and excluded low-utilization payment adjusted episodes and partial-episode-payment adjusted episodes. The 30-day periods were linked to OASIS assessments and covered the 60-day episodes ending in CY 2017.

To estimate the costs for CY 2020, we updated the estimated 30-day period costs with NRS by the home health market basket update, minus the multifactor productivity adjustment for CYs 2018 and 2019. For CY 2020, the BBA of 2018 requires a market basket update of 1.5 percent. The estimated costs for 30-day periods by discipline and the total estimated cost for a 30-day period for CY 2020 is shown in Table 5.

TABLE 5: ESTIMATED COSTS FOR 30-DAY PERIODS IN CY 2020

Discipline	2017 30-day Period Costs with NRS	2018 Market Basket (statutory)	2019 Market Basket Update minus MFP	2020 Market Basket Update (statutory)	CY 2020 Estimated 30-Day Costs with NRS
Skilled Nursing	$680.81	1.01	1.022	1.015	$713.29
Physical Therapy	$552.59	1.01	1.022	1.015	$578.95
Occupational Therapy	$161.41	1.01	1.022	1.015	$169.11
Speech Pathology	$36.43	1.01	1.022	1.015	$38.17
Medical Social Services	$18.20	1.01	1.022	1.015	$19.07
Home Health Aides	$56.25	1.01	1.022	1.015	$58.93
Total	**$1,505.69**	1.01	1.022	1.015	**$1,577.52**

The estimated, budget-neutral 30-day payment for CY 2020 is, $1,754.37 as described in section III.E. of this proposed rule. Updating this amount by the CY 2020 home health market basket of 1.5 percent and the wage index budget neutrality factor results in an estimated CY 2020 30-day payment amount of $ $1,791.73, approximately 14 percent more than the estimated CY 2020 30-day period cost of $1,577.52. After implementation of the 30-day unit of payment and the PDGM in CY 2020, we will continue to analyze the costs by discipline as well as the overall cost for a 30-day period of care to determine the effects, if any, of these changes.

III. Proposed Provisions for Payment Under the Home Health Prospective Payment System (HH PPS)

A. Implementation of the Patient-Driven Groupings Model (PDGM) for CY 2020

1. Background and Legislative History

In the CY 2019 HH PPS final rule (83 FR 56406), we finalized provisions to implement changes mandated by the BBA of 2018 for CY 2020, which included a change in the unit of payment from a 60-day episode of care to a 30-day period of care, as required by section 51001(a)(1)(B), and the elimination of therapy thresholds used for adjusting home health payment, as required by section 51001(a)(3)(B). In order to eliminate the use of therapy thresholds in adjusting payment under the HH PPS, we finalized an alternative case mix-adjustment methodology, known as the Patient-Driven Groupings Model (PDGM), to be implemented for home health periods of care beginning on or after January 1, 2020.

In regard to the 30-day unit of payment, section 51001(a)(1) of the BBA of 2018 amended section 1895(b)(2) of the Act by adding a new subparagraph (B) to require the Secretary to apply a 30-day unit of service, effective January 1, 2020. Section 51001(a)(2)(A) of the BBA of 2018 added a new subclause (iv) under section 1895(b)(3)(A) of the Act, requiring the Secretary to calculate a standard prospective payment amount (or amounts) for 30-day units of service furnished that start and end during the 12-month period beginning January 1, 2020 in a budget neutral manner such that estimated aggregate expenditures under the HH PPS during CY 2020 are equal to the estimated aggregate expenditures that otherwise would have been made under the HH PPS during CY 2020 in the absence of the change to a 30-day unit of service. Section 1895(b)(3)(A)(iv) of the Act requires that the calculation of the standard prospective payment amount (or amounts) for CY 2020 be made before the application of the annual update to the standard prospective payment amount as required by section 1895(b)(3)(B) of the Act.

Section 1895(b)(3)(A)(iv) of the Act additionally requires that in calculating the standard prospective payment amount (or amounts), the Secretary must make assumptions about behavior changes that could occur as a result of the implementation of the 30-day unit of service under section 1895(b)(2)(B) of the Act and case-mix adjustment factors established under section 1895(b)(4)(B) of the

Act. Section 1895(b)(3)(A)(iv) of the Act further requires the Secretary to provide a description of the behavior assumptions made in notice and comment rulemaking. CMS described these behavior assumptions in the CY 2019 HH PPS proposed rule (83 FR 32389) and these assumptions are further described in section III.F. of this proposed rule.

Section 51001(a)(2)(B) of the BBA of 2018 also added a new subparagraph (D) to section 1895(b)(3) of the Act. Section 1895(b)(3)(D)(i) of the Act requires the Secretary to annually determine the impact of differences between assumed behavior changes as described in section 1895(b)(3)(A)(iv) of the Act, and actual behavior changes on estimated aggregate expenditures under the HH PPS with respect to years beginning with 2020 and ending with 2026. Section 1895(b)(3)(D)(ii) of the Act requires the Secretary, at a time and in a manner determined appropriate, through notice and comment rulemaking, to provide for one or more permanent increases or decreases to the standard prospective payment amount (or amounts) for applicable years, on a prospective basis, to offset for such increases or decreases in estimated aggregate expenditures, as determined under section 1895(b)(3)(D)(i) of the Act. Additionally, 1895(b)(3)(D)(iii) of the Act requires the Secretary, at a time and in a manner determined appropriate, through notice and comment rulemaking, to provide for one or more temporary increases or decreases, based on retrospective behavior, to the payment amount for a unit of home health services for applicable years, on a prospective basis, to offset for such increases or decreases in estimated aggregate expenditures, as determined under section 1895(b)(3)(D)(i) of the Act. Such a temporary increase or decrease shall apply only with respect to the year for which such temporary increase or decrease is made, and the Secretary shall not take into account such a temporary increase or decrease in computing the payment amount for a unit of home health services for a subsequent year. And finally, section 51001(a)(3) of the BBA of 2018 amends section 1895(b)(4)(B) of the Act by adding a new clause (ii) to require the Secretary to eliminate the use of therapy thresholds in the case-mix system for CY 2020 and subsequent years.

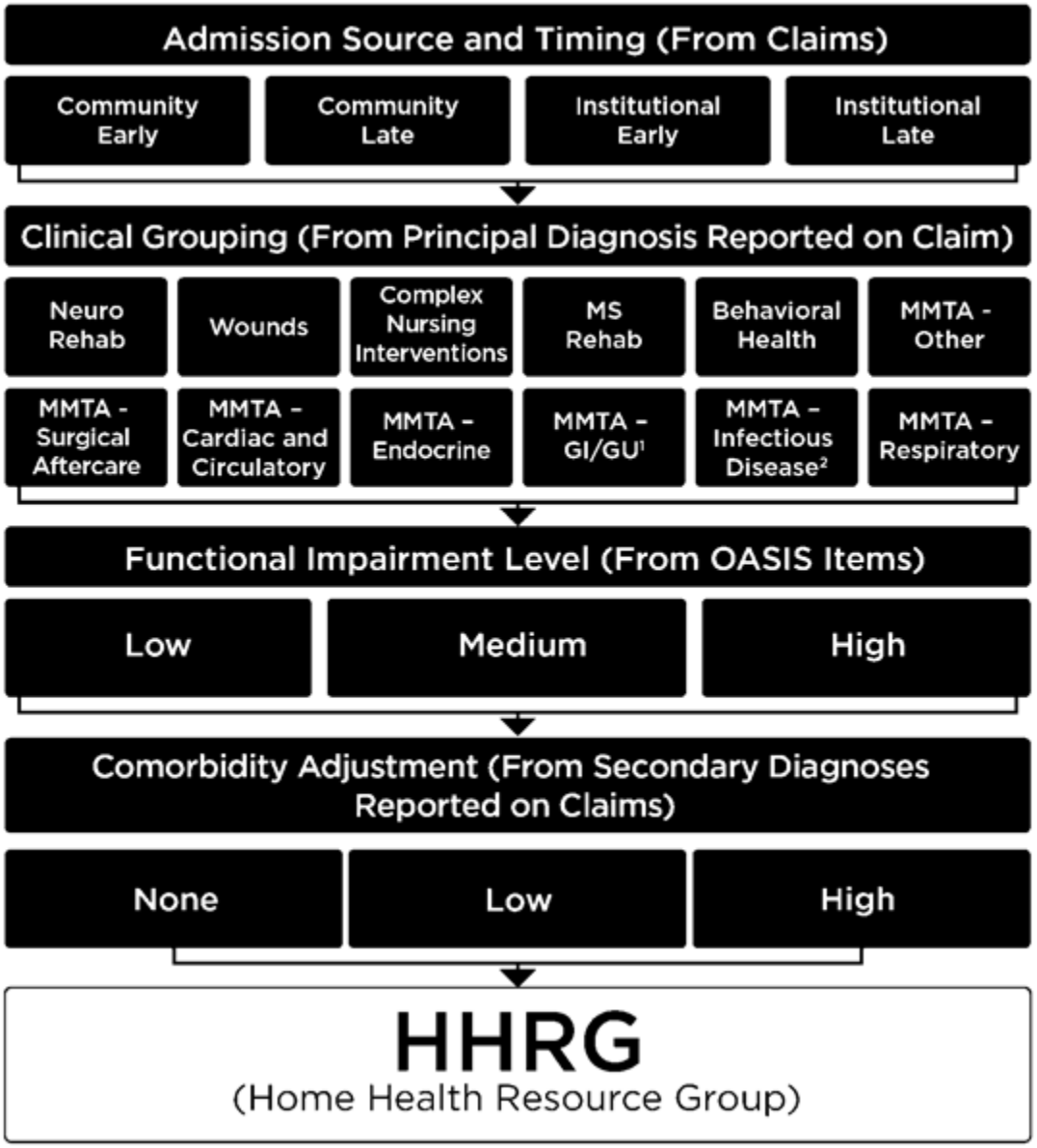
2. Overview and CY 2020 Implementation of the PDGM

To better align payment with patient care needs and better ensure that clinically complex and ill beneficiaries have adequate access to home health care, in the CY 2019 HH PPS final rule (83 FR 56406), we finalized case-mix methodology refinements through the PDGM for home health periods of care beginning on or after January 1, 2020. We believe that the PDGM case-mix methodology better aligns payment with patient care needs and is a patient-centered model that groups periods of care in a manner consistent with how clinicians differentiate between patients and the primary reason for needing home health care. This proposed rule would set forth the requirements for the implementation of the PDGM, as well as updates to the PDGM case-mix weights and payment rates, which would be effective on January 1, 2020. The PDGM and a change to a 30-day unit of payment were finalized in the CY 2019 HH PPS final rule (83 FR 56406) and, as such, there are no new policy proposals in this proposed rule on the structure of the PDGM or the change to a 30-day unit of payment. However, there are proposals related to the split-percentage payments upon implementation of the PDGM and the 30-day unit of payment in section III.G. of this proposed rule.

The PDGM uses 30-day periods of care rather than 60-day episodes of care as the unit of payment, as required by section 51001(a)(1)(B) of the BBA of 2018; eliminates the use of the number of therapy visits provided to determine payment, as required by section 51001(a)(3)(B) of the BBA of 2018; and relies more heavily on clinical characteristics and other patient information (for example, diagnosis, functional level, comorbid conditions, admission source) to place patients into clinically meaningful payment categories. A national, standardized 30-day period payment amount, as described in section III.F. of this proposed rule, would be adjusted by the case-mix weights as determined by the variables in the PDGM. Payment for non-routine supplies (NRS) is now included in the national, standardized 30-day payment amount. In total, there are 432 different payment groups in the PDGM. These 432 Home Health Resource Groups (HHRGs) represent the different payment groups based on five main case-mix variables under the PDGM, as shown in Diagram B1, and subsequently described in more detail throughout this section.

Under this new case-mix methodology, case-mix weights are generated for each of the different PDGM payment groups by regressing resource use for each of the five categories listed in this section of this proposed rule (timing, admission source, clinical grouping, functional impairment level, and comorbidity adjustment) using a fixed effects model. Annually recalibrating the PDGM case-mix weights ensures that the case-mix weights reflect the most recent utilization data at the time of annual rulemaking. The proposed CY 2020 PDGM case-mix weights are listed in section III.D. of this proposed rule.

FIGURE 1: CASE-MIX VARIABLES IN THE PDGM



a. Timing

Under the PDGM, 30-day periods of care will be classified as "early" or "late" depending on when they occur within a sequence of 30-day periods. Under the PDGM, the first 30-day period of care will be classified as early and all subsequent 30-day periods of care in the sequence (second or later) will be classified as late. A 30-day period will not be considered early unless there is a gap of more than 60 days between the end of one period of care and the start of another. Information regarding the timing of a 30-day period of care will come from Medicare home health claims data and not the OASIS assessment to determine if a 30-day period of care is "early" or "late". While the PDGM case-mix adjustment is applied to each 30-day period of care, other home health requirements will continue on a 60-day basis. Specifically, certifications and recertifications continue on a 60-day basis and the comprehensive assessment will still be completed within 5 days of the start of care date and completed no less frequently than during the last 5 days of every 60 days beginning with the start of care date, as currently required by § 484.55, "Condition of participation: Comprehensive assessment of patients."

b. Admission Source

Each 30-day period of care will also be classified into one of two admission source categories—community or institutional—depending on what healthcare setting was utilized in the 14 days prior to home health. Thirty-day periods of care for beneficiaries with any inpatient acute care hospitalizations, inpatient psychiatric facility (IPF) stays, skilled nursing facility (SNF) stays, inpatient rehabilitation facility (IRF) stays, or long-term care hospital (LTCH) stays within 14-days prior to a home health admission will be designated as institutional admissions.

The institutional admission source category will also include patients that had an acute care hospital stay during a previous 30-day period of care and within 14 days prior to the subsequent, contiguous 30-day period of care and for which the patient was not discharged from home health and readmitted (that is, the "admission date" and "from date" for the subsequent 30-

day period of care do not match), as we acknowledge that HHAs have discretion as to whether they discharge the patient due to a hospitalization and then readmit the patient after hospital discharge. However, we will not categorize post-acute care stays, meaning SNF, IRF, LTCH, or IPF stays, that occur during a previous 30-day period of care and within 14 days of a subsequent, contiguous 30-day period of care as institutional (that is, the "admission date" and "from date" for the subsequent 30-day period of care do not match), as we would expect the HHA to discharge the patient if the patient required post-acute care in a different setting, or inpatient psychiatric care, and then readmit the patient, if necessary, after discharge from such setting. All other 30-day periods of care would be designated as community admissions.

Information from the Medicare claims processing system will determine the appropriate admission source for final claim payment. The OASIS assessment will not be utilized in evaluating for admission source information. We believe that obtaining this information from the Medicare claims processing system, rather than as reported on the OASIS, is a more accurate way to determine admission source information as HHAs may be unaware of an acute or post-acute care stay prior to home health admission. While HHAs can report an occurrence code on submitted claims to indicate the admission source, obtaining this information from the Medicare claims processing system allows CMS the opportunity and flexibility to verify the source of the admission and correct any improper payments as deemed appropriate. When the Medicare claims processing system receives a Medicare home health claim, the systems will check for the presence of a Medicare acute or post-acute care claim for an institutional stay. If such an institutional claim is found, and the institutional claim occurred within 14 days of the home health admission, our systems will trigger an automatic adjustment to the corresponding HH claim to the appropriate institutional category. Similarly, when the Medicare claims processing system receives a Medicare acute or post-acute care claim for an institutional stay, the systems will check for the presence of a HH claim with a community admission source payment group. If such HH claim is found, and the institutional stay occurred within 14 days prior to the home health admission, our systems

will trigger an automatic adjustment of the HH claim to the appropriate institutional category. This process may occur any time within the 12-month timely filing period for the acute or post-acute claim.

However, situations in which the HHA has information about the acute or post-acute care stay, HHAs will be allowed to manually indicate on Medicare home health claims that an institutional admission source had occurred prior to the processing of an acute/post-acute Medicare claim, in order to receive higher payment associated with the institutional admission source. This will be done through the reporting of one of two admission source occurrence codes on home health claims--

- Occurrence Code 61: to indicate an acute care hospital discharge within 14 days prior to the "From Date" of any home health claim; or

- Occurrence Code 62: to indicate a SNF, IRF, LTCH, or IPF discharge with 14 days prior to the "Admission Date" of the first home health claim.

If the HHA does not include an occurrence code on the HH claim to indicate that that the home health patient had a previous acute or post-acute care stay, the period of care will be categorized as a community admission source. However, if later a Medicare acute or post-acute care claim for an institutional stay occurring within 14 days of the home health admission is submitted within the timely filing deadline and processed by the Medicare systems, the HH claim will be automatically adjusted as an institutional admission and the appropriate payment modifications will be made. For purposes of a Request for Anticipated Payment (RAP), only the final claim will be adjusted to reflect the admission source. More information regarding the admission source reporting requirements for RAP and claims submission can be found in Change Request 11081, "Home Health (HH) Patient-Drive Groupings Model (PDGM)-Split Implementation".[1] Accordingly, the Medicare Claims Processing Manual, chapter 10,[2] will be updated to reflect all of the claims processing changes associated with implementation of the PDGM.

c. Clinical Groupings

1 https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2019Downloads/R4244CP.pdf
2 https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c10.pdf

Each 30-day period of care will be grouped into one of 12 clinical groups which describe the primary reason for which patients are receiving home health services under the Medicare home health benefit. The clinical grouping is based on the principal diagnosis reported on home health claims. The 12 clinical groups are listed and described in Table 6.

TABLE 6: PDGM CLINICAL GROUPS

Clinical Groups	**The Primary Reason for the Home Health Encounter is to Provide:**
Musculoskeletal Rehabilitation	Therapy (physical, occupational or speech) for a musculoskeletal condition
Neuro/Stroke Rehabilitation	Therapy (physical, occupational or speech) for a neurological condition or stroke
Wounds – Post-Op Wound Aftercare and Skin/Non-Surgical Wound Care	Assessment, treatment & evaluation of a surgical wound(s); assessment, treatment & evaluation of non-surgical wounds, ulcers, burns, and other lesions
Behavioral Health Care	Assessment, treatment & evaluation of psychiatric and substance abuse conditions
Complex Nursing Interventions	Assessment, treatment & evaluation of complex medical & surgical conditions including IV, TPN, enteral nutrition, ventilator, and ostomies
Medication Management, Teaching and Assessment (MMTA)	
MMTA –Surgical Aftercare	Assessment, evaluation, teaching, and medication management for surgical aftercare
MMTA – Cardiac/Circulatory	Assessment, evaluation, teaching, and medication management for cardiac or other circulatory related conditions
MMTA – Endocrine	Assessment, evaluation, teaching, and medication management for endocrine related conditions
MMTA – GI/GU	Assessment, evaluation, teaching, and medication management for gastrointestinal or genitourinary related conditions
MMTA – Infectious Disease/Neoplasms/Blood-forming Diseases	Assessment, evaluation, teaching, and medication management for conditions related to infectious diseases, neoplasms, and blood-forming diseases
MMTA –Respiratory	Assessment, evaluation, teaching, and medication management for respiratory related conditions
MMTA – Other	Assessment, evaluation, teaching, and medication management for a variety of medical and surgical conditions not classified in one of the previously listed groups

It is possible for the principal diagnosis to change between the first and second 30-day period of care and the claim for the second 30-day period of care would reflect the new principal diagnosis. HHAs would not change the claim for the first 30-day period. However, a change in the principal diagnosis does not necessarily mean that an "other follow-up" OASIS assessment (RFA 05) would need to be completed just to make the diagnoses match. However, if a patient experienced a significant change in condition before the start of a subsequent, contiguous 30-day period of care, for example due to a fall, in accordance with § 484.55(d)(1)(ii) the HHA is required to update the comprehensive assessment. The Home Health Agency Interpretive Guidelines for § 484.55(d), state that a marked improvement or worsening of a patient's condition, which changes, and was not anticipated in, the patient's plan of care would be

considered a "major decline or improvement in the patient's health status" that would warrant update and revision of the comprehensive assessment.[3] Additionally, in accordance with § 484.60, the total plan of care must be reviewed and revised by the physician who is responsible for the home health plan of care and the HHA as frequently as the patient's condition or needs require, but no less frequently than once every 60 days, beginning with the start of care date.

In the event of a significant change of condition warranting an updated comprehensive assessment, an "other follow-up assessment" (RFA 05) would be submitted before the start of a subsequent, contiguous 30-day period, which may reflect a change in the functional impairment level and the second 30-day claim would be grouped into its appropriate case-mix group accordingly. An "other follow-up assessment" is a comprehensive assessment conducted due to a major decline or improvement in patient's health status occurring at a time other than during the last 5 days of the episode. This assessment is done to re-evaluate the patient's condition, allowing revision to the patient's care plan as appropriate. The "Outcome and Assessment Information Set OASIS-D Guidance Manual," effective January 1, 2019, provides more detailed guidance for the completion of an "other follow-up" assessment.[4] In this respect, two 30-day periods can have two different case-mix groups to reflect any changes in patient condition. HHAs must be sure to update the assessment completion date on the second 30-day claim if a follow-up assessment changes the case-mix group to ensure the claim can be matched to the follow-up assessment. HHAs can submit an adjustment to the original claim submitted if an assessment was completed before the start of the second 30-day period, but was received after the claim was submitted and if the assessment items would change the payment grouping.

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[3] State Operations Manual (SOM), Appendix B. https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/QSO18-25-HHA.pdf

[4] Outcome and Assessment Information Set OASIS-D Guidance Manual Effective January 1, 2019 available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/OASIS-D-Guidance-Manual-final.pdf

HHAs would determine whether or not to complete a follow-up OASIS assessment for a second 30-day period of care depending on the individual's clinical circumstances. For example, if the only change from the first 30-day period and the second 30-day period is a change to the principal diagnosis and there is no change in the patient's function, the HHA may determine it is not necessary to complete a follow-up assessment. Therefore, the expectation is that HHAs would determine whether an "other follow-up" assessment is required based on the individual's overall condition, the effects of the change on the overall home health plan of care, and in accordance with the home health CoPs, interpretive guidelines, and the OASIS D Guidance Manual instructions, as previously noted.

For case-mix adjustment purposes, the principal diagnosis reported on the home health claim will determine the clinical group for each 30-day period of care. Currently, billing instructions state that the principal diagnosis on the OASIS must also be the principal diagnosis on the final claim; however, we will update our billing instructions to clarify that there will be no need for the HHA to complete an "other follow-up" assessment (an RFA 05) just to make the diagnoses match. Therefore, for claim "From" dates on or after January 1, 2020, the ICD-10-CM code and principal diagnosis used for payment grouping will be from the claim rather than the OASIS. As a result, the claim and OASIS diagnosis codes will no longer be expected to match in all cases. Additional claims processing guidance, including the role of the OASIS item set will be included in the Medicare Claims Processing Manual, chapter 10.[5]

While these clinical groups represent the primary reason for home health services during a 30-day period of care, this does not mean that they represent the only reason for home health services. While there are clinical groups where the primary reason for home health services is for therapy (for example, Musculoskeletal Rehabilitation) and other clinical groups where the

[5] https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c10.pdf

primary reason for home health services is for nursing (for example, Complex Nursing Interventions), home health remains a multidisciplinary benefit and payment is bundled to cover all necessary home health services identified on the individualized home health plan of care. Therefore, regardless of the clinical group assignment, HHAs are required, in accordance with the home health CoPs at § 484.60(a)(2), to ensure that the individualized home health plan of care addresses all care needs, including the disciplines to provide such care. Under the PDGM, the clinical group is just one variable in the overall case-mix adjustment for a home health period of care.

Finally, we note that we will update the Interactive Grouper Tool posted on both the HHA Center webpage (https://www.cms.gov/center/provider-type/home-health-agency-hha-center.html) and the dedicated PDGM webpage (https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/HH-PDGM.html). This Interactive Grouper Tool will include all of the ICD-10 diagnosis codes used in the PDGM and may be used by HHAs to generate PDGM case-mix weights for their patient census. This tool is for informational and illustrative purposes only. HHAs can also request a Home Health Claims-OASIS Limited Data Set (LDS) to accompany the CY 2020 HH PPS proposed and final rules to support HHAs in evaluating the effects of the PDGM. The Home Health Claims-OASIS LDS file can be requested by following the instructions on the following CMS website:

https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/Data-Disclosures-Data-Agreements/DUA_-_NewLDS.html.

d. Functional Impairment Level

Under the PDGM, each 30-day period of care will be placed into one of three functional impairment levels, low, medium, or high, based on responses to certain OASIS functional items as listed in Table 7.

TABLE 7: OASIS ITEMS USED FOR FUNCTIONAL IMPAIRMENT LEVEL IN THE PDGM

OASIS Item	Description
M1033	Risk for Hospitalization*
M1800	Grooming
M1810	Current ability to dress upper body safely
M1820	Current ability to dress lower body safely
M1830	Bathing
M1840	Toilet transferring
M1850	Transferring
M1860	Ambulation and locomotion

*Excluding responses 8, 9, and 10

Responses to these OASIS items are grouped together into response categories with similar resource use and each response category has associated points. A more detailed description as to how these response categories were established can be found in the technical report, "Overview of the Home Health Groupings Model" posted on the Home Health Center webpage. [6] The sum of these points' results in a functional impairment level score used to group 30-day periods of care into a functional impairment level with similar resource use. The scores associated with the functional impairment levels vary by clinical group to account for differences in resource utilization. For CY 2020, we used CY 2018 claims data to update the functional points and functional impairment levels by clinical group. The updated OASIS functional points table and the table of functional impairment levels by clinical group for CY 2020 are listed in Tables 4 and 5, respectively. For ease of use, instead of listing the response categories and the associated points (as shown in Table 28 in the CY 2019 HH PPS final rule, 83 FR 56478), we have reformatted the OASIS Functional Item Response Points (Table 8) to identify how the OASIS functional items used for

[6] https://downloads.cms.gov/files/hhgm%20technical%20report%20120516%20sxf.pdf

the functional impairment level are assigned points under the PDGM. In the CY 2020 HH PPS final rule, we will update the points for the OASIS functional item response categories and the functional impairment levels by clinical group using the most recent, available claims data.

TABLE 8: CY 2020 OASIS POINTS FOR THOSE ITEMS ASSOCIATED WITH INCREASED RESOURCE USE USING A REDUCED SET OF OASIS ITEMS

	Responses	Points (2018)	Percent of Periods in 2018 with this Response Category
M1800: Grooming	0 or 1	0	39.6%
	2 or 3	5	60.4%
M1810: Current Ability to Dress Upper Body	0 or 1	0	37.5%
	2 or 3	6	62.5%
M1820: Current Ability to Dress Lower Body	0 or 1	0	18.1%
	2	6	60.5%
	3	12	21.4%
M1830: Bathing	0 or 1	0	4.6%
	2	3	16.6%
	3 or 4	12	54.0%
	5 or 6	20	24.9%
M1840: Toilet Transferring	0 or 1	0	66.3%
	2, 3 or 4	5	33.7%
M1850: Transferring	0	0	2.5%
	1	3	32.3%
	2, 3, 4 or 5	6	65.2%
M1860: Ambulation/Locomotion	0 or 1	0	6.2%
	2	9	22.6%
	3	11	55.9%
	4, 5 or 6	23	15.3%
M1032: Risk of Hospitalization	Three or fewer items marked (Excluding responses 8, 9 or 10)	0	81.2%
	Four or more items marked (Excluding responses 8, 9 or 10)	11	18.8%

Source: CY 2018 home health claims and OASIS data.

TABLE 9: CY 2020 THRESHOLDS FOR FUNCTIONAL IMPAIRMENT LEVELS BY CLINICAL GROUP

Clinical Group	Level of Impairment	Points (2018 Data)
MMTA - Other	Low	0-32
	Medium	33-49
	High	50+
Behavioral Health	Low	0-35
	Medium	36-52
	High	53+

Clinical Group	Level of Impairment	Points (2018 Data)
Complex Nursing Interventions	Low	0-38
	Medium	39-57
	High	58+
Musculoskeletal Rehabilitation	Low	0-38
	Medium	39-51
	High	52+
Neuro Rehabilitation	Low	0-44
	Medium	45-59
	High	60+
Wound	Low	0-41
	Medium	42-60
	High	61+
MMTA - Surgical Aftercare	Low	0-37
	Medium	38-51
	High	52+
MMTA - Cardiac and Circulatory	Low	0-35
	Medium	36-51
	High	52+
MMTA - Endocrine	Low	0-35
	Medium	36-51
	High	52+
MMTA - Gastrointestinal tract and Genitourinary System	Low	0-40
	Medium	41-54
	High	55+
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	Low	0-35
	Medium	36-51
	High	52+
MMTA - Respiratory	Low	0-37
	Medium	38-51
	High	52+

Source: CY 2018 home health claims and OASIS data.

The functional impairment level will remain the same for the first and second 30-day periods of care unless there has been a significant change in condition which warranted an "other follow-up" assessment prior to the second 30-day period of care. For each 30-day period of care, the Medicare claims processing system will look for the most recent OASIS assessment based on the claims "from date." The proposed CY 2020 functional points table and the functional impairment level thresholds table will be posted on the HHA Center webpage at https://www.cms.gov/center/provider-type/home-health-agency-hha-center.html as well as on the

dedicated PDGM webpage at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/HH-PDGM.html.

e. Comorbidity Adjustment

Thirty-day periods will receive a comorbidity adjustment category based on the presence of certain secondary diagnoses reported on home health claims. These diagnoses are based on a home-health specific list of clinically and statistically significant secondary diagnosis subgroups with similar resource use, meaning the diagnoses have at least as high as the median resource use and represent more that 0.1 percent of 30-day periods of care. Home health 30-day periods of care can receive a comorbidity adjustment under the following circumstances:

- *Low comorbidity adjustment:* There is a reported secondary diagnosis on the home health-specific comorbidity subgroup list that is associated with higher resource use.
- *High comorbidity adjustment:* There are two or more secondary diagnoses on the home health-specific comorbidity subgroup interaction list that are associated with higher resource use when both are reported together compared to if they were reported separately. That is, the two diagnoses may interact with one another, resulting in higher resource use.
- *No comorbidity adjustment:* A 30-day period of care will receive no comorbidity adjustment if no secondary diagnoses exist or none meet the criteria for a low or high comorbidity adjustment.

In CY 2020, there are 12 low comorbidity adjustment subgroups as identified in Table 10 and 34 high comorbidity adjustment interaction subgroups as identified in Table 11. In the CY 2020 HH PPS final rule, we will update the comorbidity subgroups and interaction subgroups using the most recent, available claims data.

TABLE 10: LOW COMORBIDITY ADJUSTMENT SUBGROUPS FOR CY 2020

Comorbidity Subgroup	Description
Cerebral 4	Includes sequelae of cerebral vascular diseases
Circulatory 10	Includes varicose veins with ulceration
Circulatory 9	Includes acute and chronic embolisms and thrombosis
Heart 10	Includes cardiac dysrhythmias
Heart 11	Includes heart failure
Neoplasms 1	Includes oral cancers
Neuro 10	Includes peripheral and polyneuropathies
Neuro 5	Includes Parkinson's disease
Neuro 7	Includes hemiplegia, paraplegia, and quadriplegia
Skin 1	Includes cutaneous abscess, cellulitis, lymphangitis
Skin 3	Includes diseases of arteries, arterioles, and capillaries with ulceration and non-pressure, chronic ulcers
Skin 4	Includes Stages Two through Four and Unstageable pressure ulcers

Source: CY 2018 Medicare claims data for episodes ending on or before December 31, 2018.

TABLE 11: HIGH COMORBIDITY ADJUSTMENT INTERACTION SUBGROUPS FOR CY 2020

Comorbidity Subgroup Interaction	Comorbidity Subgroup	Description	Comorbidity Subgroup	Description
1	Behavioral 2	Includes depression and bipolar disorder	Skin 3	Includes diseases of arteries, arterioles, and capillaries with ulceration and non-pressure, chronic ulcers
2	Cerebral 4	Includes sequelae of cerebral vascular diseases	Circulatory 4	Includes hypertensive chronic kidney disease
3	Cerebral 4	Includes sequelae of cerebral vascular diseases	Heart 11	Includes heart failure
4	Cerebral 4	Includes sequelae of cerebral vascular diseases	Neuro 10	Includes peripheral and polyneuropathies
5	Circulatory 4	Includes hypertensive chronic kidney disease	Skin 1	Includes cutaneous abscess, cellulitis, lymphangitis
6	Circulatory 4	Include hypertensive chronic kidney disease	Skin 3	Includes diseases of arteries, arterioles, and capillaries with ulceration and non-pressure, chronic ulcers
7	Circulatory 4	Include hypertensive chronic kidney disease	Skin 4	Includes Stages Two through Four and Unstageable pressure ulcers
8	Circulatory 7	Includes atherosclerosis	Skin 3	Includes diseases of arteries, arterioles, and capillaries with ulceration and non-pressure, chronic ulcers
9	Endocrine 3	Includes diabetes with complications	Neuro 5	Includes Parkinson's disease
10	Endocrine 3	Includes diabetes with complications	Neuro 7	Includes hemiplegia, paraplegia, and quadriplegia
11	Endocrine 3	Includes diabetes with complications	Skin 1	Includes cutaneous abscess, cellulitis, lymphangitis
12	Endocrine 3	Includes diabetes with complications	Skin 3	Includes diseases of arteries, arterioles, and capillaries with ulceration and non-pressure, chronic ulcers
13	Heart 10	Includes cardiac dysrhythmias	Skin 3	Includes diseases of arteries, arterioles, and capillaries with ulceration and non-pressure, chronic ulcers
14	Heart 10	Includes cardiac dysrhythmias	Skin 4	Includes Stages Two through Four and Unstageable pressure ulcers
15	Heart 11	Includes heart failure	Neuro 10	Includes peripheral and polyneuropathies
16	Heart 11	Includes heart failure	Neuro 5	Includes Parkinson's disease
17	Heart 11	Includes heart failure	Skin 1	Includes cutaneous abscess, cellulitis, lymphangitis
18	Heart 11	Includes heart failure	Skin 3	Includes diseases of arteries, arterioles, and capillaries with ulceration and non-pressure, chronic ulcers
19	Heart 11	Includes heart failure	Skin 4	Includes Stages Two through Four and Unstageable pressure ulcers
20	Heart 12	Includes other heart diseases	Skin 3	Includes diseases of arteries, arterioles, and capillaries with ulceration and non-pressure, chronic ulcers
21	Heart 12	Includes other heart diseases	Skin 4	Includes Stages Two through Four and Unstageable pressure ulcers
22	Neuro 10	Includes peripheral and polyneuropathies	Neuro 5	Includes Parkinson's disease
23	Neuro 10	Includes peripheral and polyneuropathies	Skin 3	Includes diseases of arteries, arterioles, and capillaries with ulceration and non-pressure, chronic ulcers
24	Neuro 3	Includes dementias	Skin 3	Includes diseases of arteries, arterioles, and capillaries with ulceration and non-pressure, chronic ulcers
25	Neuro 3	Includes dementias	Skin 4	Includes Stages Two through Four and Unstageable pressure ulcers
26	Neuro 5	Includes Parkinson's disease	Renal 3	Includes nephrogenic diabetes insipidus
27	Neuro 7	Includes hemiplegia, paraplegia, and quadriplegia	Renal 3	Includes nephrogenic diabetes insipidus
28	Renal 1	Includes Chronic kidney disease and ESRD	Skin 3	Includes diseases of arteries, arterioles, and capillaries with ulceration and non-pressure, chronic ulcers
29	Renal 1	Includes Chronic kidney disease and ESRD	Skin 4	Includes Stages Two through Four and Unstageable pressure ulcers
30	Renal 3	Includes nephrogenic diabetes insipidus	Skin 4	Includes Stages Two through Four and Unstageable pressure ulcers
31	Resp 5	Includes COPD and asthma	Skin 3	Includes diseases of arteries, arterioles, and capillaries with ulceration and non-pressure, chronic ulcers
32	Resp 5	Includes COPD and asthma	Skin 4	Includes Stages Two through Four and Unstageable pressure ulcers
33	Skin 1	Includes cutaneous abscess, cellulitis, lymphangitis	Skin 3	Includes diseases of arteries, arterioles, and capillaries with ulceration and non-pressure, chronic ulcers
34	Skin 3	Includes diseases of arteries, arterioles, and capillaries with ulceration and non-pressure, chronic ulcers	Skin 4	Includes Stages Two through Four and Unstageable pressure ulcers

Source: CY 2018 Medicare claims data for episodes ending on or before December 31, 2018.

A 30-day period of care can have a low comorbidity adjustment or a high comorbidity adjustment, but not both. A 30-day period of care can receive only one low comorbidity adjustment regardless of the number of secondary diagnoses reported on the home health claim that fell into one of the individual comorbidity subgroups or one high comorbidity adjustment regardless of the number of comorbidity group interactions, as applicable. The low comorbidity adjustment amount will be the same across the subgroups and the high comorbidity adjustment will be the same across the subgroup interactions. The proposed CY 2020 low comorbidity adjustment subgroups and the high comorbidity adjustment interaction subgroups including those diagnoses within each of these comorbidity adjustments will be posted on the HHA Center webpage at https://www.cms.gov/center/provider-type/home-health-agency-hha-center.html as well as on the dedicated PDGM webpage at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/HH-PDGM.html.

B. Implementation of a 30-day Unit of Payment for CY 2020

Under section 1895(b)(3)(A)(iv) of the Act, we are required to calculate a 30-day payment amount for CY 2020 in a budget-neutral manner such that estimated aggregate expenditures under the HH PPS during CY 2020 are equal to the estimated aggregate expenditures that otherwise would have been made under the HH PPS during CY 2020 in the absence of the change to a 30-day unit of payment. Section 1895(b)(3)(A)(iv) of the Act also requires that in calculating a 30-day payment amount in a budget-neutral manner to the Secretary must make assumptions about behavior changes that could occur as a result of the implementation of the 30-day unit of payment. In addition, in calculating a 30-day payment amount in a budget-neutral manner, we must take into account behavior changes that could occur as a result of the case-mix adjustment factors that are implemented in CY 2020. We are also required to calculate a budget-neutral 30-day payment amount before the provisions of section

1895(b)(3)(B) of the Act are applied; that is, before the home health applicable percentage increase, the adjustment if quality data are not reported, and the productivity adjustment.

In the CY 2019 HH PPS proposed rule (83 FR 32389), we proposed three assumptions about behavior change that could occur in CY 2020 as a result of the implementation of the 30-day unit of payment and the implementation of the PDGM case-mix adjustment methodology:

- Clinical Group Coding: A key component of determining payment under the PDGM is the 30-day period of care's clinical group assignment, which is based on the principal diagnosis code for the patient as reported by the HHA on the home health claim. Therefore, we proposed to assume that HHAs will change their documentation and coding practices and would put the highest paying diagnosis code as the principal diagnosis code in order to have a 30-day period of care be placed into a higher-paying clinical group. While we do not support or condone coding practices or the provision of services solely to maximize payment, we often take into account in proposed rules the potential behavior effects of policy changes should they be finalized and implemented.

- Comorbidity Coding: The PDGM further adjusts payments based on patients' secondary diagnoses as reported by the HHA on the home health claim. While the OASIS only allows HHAs to designate 1 primary diagnosis and 5 secondary diagnoses, the home health claim allows HHAs to designate 1 principal diagnosis and 24 secondary diagnoses. Therefore, we proposed to assume that by taking into account additional ICD-10-CM diagnosis codes listed on the home health claim (that exceed the 6 allowed on the OASIS), more 30-day periods of care will receive a comorbidity adjustment than periods otherwise would have received if we only used the OASIS diagnosis codes for payment. The comorbidity adjustment in the PDGM can increase payment by up to 20 percent.

- LUPA Threshold: Rather than being paid the per-visit amounts for a 30-day period of

care subject to the low-utilization payment adjustment (LUPA) under the proposed PDGM, we proposed to assume that for one-third of LUPAs that are 1 to 2 visits away from the LUPA threshold, HHAs will provide 1 to 2 extra visits to receive a full 30-day payment.[7] LUPAs are paid when there are a low number of visits furnished in a 30-day period of care. Under the PDGM, the LUPA threshold ranges from 2-6 visits depending on the case-mix group assignment for a particular period of care (see section III.D. of this proposed rule for the LUPA thresholds that correspond to the 432 case-mix groups under the PDGM).

While some commenters supported these three behavior assumptions in calculating the budget-neutral 30-day payment amount, many commenters disagreed with these assumptions stating that they seem arbitrary, overly complex, and that they lack any foundation in evidence-based data. Other commenters expressed concern that the behavior assumptions would result in too high of a payment reduction and that this could create potential access issues. However, in the CY 2019 HH PPS final rule, we explained why we believe the three behavior assumptions are appropriate based on previously obtained data and precedent for adjusting home health prospective payments based on assumed behavior changes. We believe that our examples and past experiences described in more detail in the CY 2019 HH PPS final rule (83 FR 56456) demonstrate that there is a substantive connection between the data and the behavior assumptions made. Furthermore, the Medicare Payment Advisory Commission (MedPAC) provided comments on the CY 2019 HH PPS proposed rule and expressed their support for the behavior assumptions, stating that past experience with the home health PPS demonstrates that HHAs have changed coding, utilization, and the mix of services provided in reaction to new payment incentives. Similarly, in its March, 2019 Report to Congress, MedPAC stated that behavior

[7] Current data suggest that what would be about 1/3 of the LUPA episodes with visits near the LUPA threshold move up to become non-LUPA episodes. We assume this experience will continue under the PDGM, with about 1/3 of those episodes 1 or 2 visits below the thresholds moving up to become non-LUPA episodes.

assumptions are necessary to offset the spending increase expected in 2020 resulting from the behavior changes.[8]

With regards to our assumption that HHAs would code the highest-paying diagnosis code as primary for the clinical grouping assignment, this assumption is based on decades of past experience under the case-mix system for the HH PPS and other case-mix systems. For example, we summarized previous data regarding the substantial increase in payments when transitioning from the diagnosis-related groups (DRGs) to the Medicare Severity (MS)-DRGs that were not related to actual changes in patient severity. Subsequent analysis of inpatient hospital claims data supported prospective payment adjustments to account for documentation and coding effects was detailed in both the FY 2010 and FY 2011 IPPS final rules (74 FR 43770 and 75 FR 50356). We also noted that in the first year of the Inpatient Rehabilitation Facility (IRF) PPS, there were instances where case-mix increases resulted from documentation and coding-induced changes (72 FR 47181). Similarly, we cited multiple instances where CMS analyzed the 2008 case-mix methodology refinements that resulted in the 153-group HH PPS case-mix model to measure change in case-mix, both real and nominal (74 FR 40958 and 75 FR 43238). We stated that our analysis subsequent to these refinements to the current case-mix methodology show an average of approximately 2 percent nominal case-mix growth per year (82 FR 35274).

For the comorbidity coding assumption, we stated that using the home health claim for the comorbidity adjustment as opposed to the OASIS provides more opportunity to report all comorbid conditions that may affect the plan of care. The OASIS item set only allows HHAs to report up to five secondary diagnoses, while the home health claim (837I institutional claim

[8] MedPAC Report to Congress, Home Care Services, chapter 9, March, 2019. http://www.medpac.gov/docs/default-source/reports/mar19_medpac_ch9_sec.pdf?sfvrsn=0

format-electronic version of the UB-04) allows HHAs to report up to 24 secondary diagnoses. Furthermore, ICD-10 coding guidelines require reporting of all secondary (additional) diagnoses that affect the plan of care. Because the comorbidity adjustment can increase payment by up to 20 percent, it is a reasonable assumption that HHAs would encourage the accurate reporting of secondary diagnoses affecting the home health plan of care to more accurately identify the conditions affecting resource use.

Finally, regarding the LUPA threshold assumption, in the CY 2019 HH PPS final rule, we referenced data from the FY 2001 HH PPS final rule where the episode file showed that approximately 16 percent of episodes would have received a LUPA (meaning the 60-day episode had 4 or fewer visits). We also stated that currently only about 7 percent of all 60-day episodes receive a LUPA, meaning that it appears that HHAs changed their practice patterns such that, upon implementation of the HH PPS, more than half of 60-day episodes that would have been LUPAs received the full 60-day episode payment amount. Additionally, while the LUPA thresholds vary for each of the 432 case-mix groups, many of these groups have a LUPA threshold of two, meaning if the HHA provides more than one visit in a 30-day period, it will receive the full 30-day payment amount. Given that many groups have only a two-visit threshold, we believe it to be a reasonable assumption that some HHAs would provide a second visit to receive the full 30-day payment amount. In the CY 2019 HH PPS final rule, we finalized the three behavior assumptions in calculating a 30-day budget-neutral payment amount given the ample evidence-based data supporting such assumptions (83 FR 56461). In response to comments regarding the impact of the behavior assumptions on payments and any potential access issues, in the CY 2019 HH PPS final rule (83 FR 56461), we stated that we expect that HHAs would continue to provide home health services in accordance with the home health

Conditions of Participation regarding the provision of services as established on the individualized home health plan of care. We stated that we expect the provision of services to be made to best meet the patient's care needs. We also noted that we would monitor any changes in utilization patterns, beneficiary impact, and provider behavior to see if any refinements to the PDGM would be warranted, or if any concerns are identified that may signal the need for appropriate program integrity measures.

In order to calculate the CY 2020 proposed budget neutral 30-day payment amounts in this proposed rule, both with and without behavior assumptions, we first calculated the total, aggregate amount of expenditures that would occur under the current case-mix adjustment methodology (as described in section III.D. of this rule) and the 60-day episode unit of payment using the CY 2019 payment parameters (for example, CY 2019 payment rates, case-mix weights, and outlier fixed-dollar loss ratio). That resulted in a total aggregate expenditures target amount of $16.2 billion.[9] We then calculated what the 30-day payment amount would need to be set at in CY 2020, with and without behavior assumptions, while taking into account needed changes to the outlier fixed-dollar loss ratio under the PDGM in order to pay out no more than 2.5 percent of total HH PPS payments as outlier payments (refer to section III.F. of this proposed rule) and in order for Medicare to pay out $16.2 billion in total expenditures in CY 2020 with the

[9] The initial 2018 analytic file included 6,606,602 60-day episodes ($18.3 billion in total expenditures). Of these, 962,949 (14.6 percent) were excluded because they could not be linked to OASIS assessments or because of the claims data cleaning process reasons listed in section III.F.1 of this proposed rule. We note that of the 962,949 claims excluded, 513,998 were excluded because they were RAPs without a final claim or they were claims with zero payment amounts, resulting in $17.4 billion in total expenditures. After removing all 962,949 excluded claims, the 2018 analytic file consisted of 5,643,653 60-day episodes ($16.3 billion in total expenditures). 60-day episodes of duration longer than 30 days were divided into two 30-day periods in order to calculate the 30-day payment amounts. As noted in section III.F.1. of this proposed rule, there were instances where 30-day periods were excluded from the 2018 analytic file (for example, we could not match the period to a start of care or resumption of care OASIS to determine the functional level under the PDGM, the 30-day period did not have any skilled visits, or because information necessary to calculate payment was missing from claim record). The final 2018 analytic file used to calculate budget neutrality consisted of 9,127,459 30-day periods ($16.2 billion in total expenditures) drawn from 5,338,939 60-day episodes.

application of a 30-day unit of payment under the PDGM. Table 12 includes the proposed, estimated 30-day budget-neutral payment amount for CY 2020 both with and without the behavior assumptions. These payment amounts do not include the CY 2020 home health payment update of 1.5 percent.

TABLE 12: CY 2020 PROPOSED, ESTIMATED 30-DAY BUDGET-NEUTRAL PAYMENT AMOUNTS

Behavior Assumption	30-day Budget Neutral (BN) Standard Amount	Percent Change from No Behavior Assumptions [1]	FDL Ratio
No Behavior Assumptions	$1,907.11		0.56
LUPA Threshold (1/3 of LUPAs 1-2 visits away from threshold get extra visits and become case-mix adjusted)	$1,871.67	-1.86%	0.59
Clinical Group Coding [2] (among available diagnoses, one leading to highest payment clinical grouping classification designated as principal)	$1,794.42	-5.91%	0.60
Comorbidity Coding (assigns comorbidity level based on comorbidities appearing on HHA claims and not just OASIS)	$1,900.05	-0.37%	0.56
Clinical Group Coding + Comorbidity Coding + LUPA Threshold	$1,754.37	-8.01%	0.63

Notes:
[1] Adding all the percent decreases for each behavior assumption results in a total percent decrease of -8.14 percent. However, there is overlap and interactions between the behavior assumptions and when combined, the budget-neutral payment amount results in a -8.01 percent decrease from the payment amount without these assumptions applied.
[2] The clinical group coding assumption has a higher percent decrease (-5.91 percent) in this year's proposed rule compared to the percent decrease in the CY 2019 HH PPS proposed rule (-4.28 percent). This is because the CY 2019 clinical coding assumption was based on the six proposed clinical groups and the CY 2020 clinical coding assumption is based on the finalized 12 clinical groups.

If no behavior assumptions were made, we estimate that the CY 2020 30-day payment amount needed to achieve budget neutrality would be $1,907.11. Applying the clinical group and comorbidity coding assumptions, and the LUPA threshold assumption, as required by section 1895(b)(3)(A)(iv) of the Act, will result in the need to decrease the CY 2020 estimated budget-neutral 30-day payment amount to $1,754.37 (a 8.01 percent decrease from $1,907.11). The CY 2020 estimated 30-day budget-neutral payment amount would be slightly more than the CY 2019 estimated 30-day budget-neutral payment amount calculated in last year's rule (that is, if the PDGM was implemented in CY 2019), which we estimated to be $1,753.68. However, the CY 2019 estimated 30-day payment amount of $1,753.68 included the CY 2019 market basket update of 2.1 percent whereas the CY 2020 estimated 30-day budget neutral payment amount of $1,754.37 does not include the 1.5 percent home health legislated payment

update for CY 2020. Applying the proposed CY 2020 Wage Index Budget Neutrality Factor and the 1.5 percent home health update would increase the CY 2020 national, standardized 30-day payment amount to $1,791.73 and is further described in section III.E. of this proposed rule. The CY 2020 proposed estimated payment rate of $1,791.73 is approximately 14 percent more than the estimated CY 2020 30-day period cost of $1,577.52, as shown in Table 5 of this proposed rule. We invite comments on the CY 2020 proposed, estimated 30-day budget-neutral payment amount with the behavior assumptions as described previously in this proposed rule and in Table 12.

The 30-day payment amount will be for 30-day periods of care beginning on and after January 1, 2020. Because CY 2020 is the first year of the PDGM and the change to a 30-day unit of payment, there will be a transition period to account for those home health episodes of care that span the implementation date. Therefore, for 60-day episodes (that is, not LUPA episodes) that begin on or before December 31, 2019 and end on or after January 1, 2020 (episodes that would span the January 1, 2020 implementation date), payment made under the Medicare HH PPS will be the CY 2020 national, standardized 60-day episode payment amount as described in section III.X. of this proposed rule. For home health periods of care that begin on or after January 1, 2020, the unit of service will be a 30-day period and payment made under the Medicare HH PPS will be the CY 2020 national, standardized prospective 30-day payment amount as described in section III.X. of this proposed rule. For home health units of service that begin on or after December 3, 2020 through December 31, 2020 and end on or after January 1, 2021, the HHA will be paid the CY 2021 national, standardized prospective 30-day payment amount.

We note that we are also required under section 1895(b)(3)(D)(i) of the Act, as added by section 51001(a)(2)(B) of the BBA of 2018, to analyze data for CYs 2020 through 2026, after implementation of the 30-day unit of payment and new case-mix adjustment methodology, to annually determine the impact of differences between assumed behavior changes and actual behavior changes on estimated aggregate expenditures. We interpret actual behavior change to encompass both behavior changes that were previously outlined, as assumed by CMS when determining the budget-neutral 30-day payment amount for CY 2020, and other behavior changes not identified at the time the 30-day payment amount for CY

2020 is determined. The data from CYs 2020 through 2026 will be available to determine whether a prospective adjustment (increase or decrease) is needed no earlier than in years 2022 through 2028 rulemaking. However, we will analyze data after implementation of the PDGM to determine if there are any notable and consistent trends to warrant whether any changes to the national, standardized 30-day payment rate should be done earlier than CY 2022.

As noted previously, under section 1895(b)(3)(D)(ii) of the Act, we are required to provide one or more permanent adjustments to the 30-day payment amount on a prospective basis, if needed, to offset increases or decreases in estimated aggregate expenditures as calculated under section 1895(b)(3)(D)(i) of the Act. Clause (iii) of section 1895(b)(3)(D) of the Act requires the Secretary to make temporary adjustments to the 30-day payment amount, on a prospective basis, in order to offset increases or decreases in estimated aggregate expenditures, as determined under clause (i) of such section. The temporary adjustments allow us to recover excess spending or give back the difference between actual and estimated spending (if actual is less than estimated) not addressed by permanent adjustments. However, any permanent or temporary adjustments to the 30-day payment amount to offset increases or decreases in estimated aggregate expenditures as calculated under section 1895(b)(3)(D)(i) and (iii) of the Act would be subject to proposed notice and comment rulemaking.

We are soliciting comments on the behavior assumptions finalized in the CY 2019 HH PPS final rule regarding any potential issues that may result from taking these assumptions into account when establishing the initial 30-day payment amount for CY 2020. We reiterate that if CMS underestimates the reductions to the 30-day payment amount necessary to offset behavior changes and maintain budget neutrality, larger adjustments to the 30-day payment amount would be required in the future, by law, to ensure budget neutrality. Likewise, if CMS overestimates the reductions, we are required to make the appropriate payment adjustments accordingly as described previously.

We wish to remind stakeholders again that CMS will provide, upon request, a Home Health Claims-OASIS LDS file to accompany the CY 2020 proposed and final rules to support HHAs in evaluating the effects of the PDGM. The Home Health Claims-OASIS LDS file can be requested by following the instructions on the following CMS website https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/Data-Disclosures-Data-Agreements/DUA_-_NewLDS.html. Additionally, we will post CY 2020 provider-level impacts and an updated Interactive Grouper Tool on the HHA Center webpage [10] and the PDGM dedicated webpage [11] to provide HHAs with ample tools to help them understand the impact of the PDGM and the change to a 30-day unit of payment.

C. Proposed CY 2020 HH PPS Case-Mix Weights for 60-Day Episodes of Care that Span the Implementation Date of the PDGM

In the CY 2015 HH PPS final rule (79 FR 66072), we finalized a policy to annually recalibrate the HH PPS case-mix weights—adjusting the weights relative to one another—using the most current, complete data available. Annual recalibration of the HH PPS case-mix weights ensures that the case-mix weights reflect, as accurately as possible, current home health resource use and changes in utilization patterns. In this proposed rule, we are detailing implementation of the PDGM and a change in the unit of home health payment to 30-day periods of care as described in section III.A and III.B. of this proposed rule. As such, we are recalibrating the CY 2020 case-mix weights for 30-day periods of care using the PDGM methodology as described in section III.D. of the proposed rule. However, these recalibrated case-mix weights are not applicable for those 60-day episodes of care that begin on or before December 31, 2019 and end

10 https://www.cms.gov/center/provider-type/home-health-agency-hha-center.html
11 https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/HH-PDGM.html

on or after January 1, 2020. Therefore, we are not proposing to separately recalibrate the case-mix weights for those 60-day episodes that span the January 1, 2020 implementation date.

Instead, we are proposing that these 60-day episodes would be paid the national, standardized 60-day episode payment amount as described in section III.E. of this rule and will be case-mix adjusted using the CY 2019 case-mix weights as listed in Table 6 in the CY 2019 HH PPS final rule (83 FR 56422) and posted on the HHA Center webpage.[12] We believe that this is a reasonable approach for case-mix adjusting these 60-day episodes of care that span the January 1, 2020 implementation date. With the implementation of a new case-mix adjustment methodology and a move to a 30-day unit of payment, we believe this approach would be less burdensome for HHAs as they will not have to download a new, separate 153-group case-mix weight data file, in addition to the 432 case-mix weight data file for CY 2020. For those 60-day episodes that end after January 1, 2020, but where there is a continued need for home health services, we are proposing that any subsequent periods of care would be paid the 30-day national, standardized payment amount with the appropriate CY 2020 PDGM case-mix weight applied. We are soliciting comments on this proposal regarding payment for those 60-day episodes of care that span the implementation date of the PDGM and the change to a 30-day unit of payment.

D. Proposed CY 2020 PDGM Low-Utilization Payment Adjustment (LUPA) Thresholds and PDGM Case-Mix Weights

1. Proposed CY 2020 PDGM LUPA Thresholds

Under the current 153-group payment system, a 60-day episode with four or fewer visits is paid the national per-visit amount by discipline, adjusted by the appropriate wage index based on the site of service of the beneficiary, instead of the full 60-day episode payment amount. Such

12 https://www.cms.gov/center/provider-type/home-health-agency-hha-center.html

payment adjustments are called Low Utilization Payment Adjustments (LUPAs). In the current payment system, approximately 7 to 8 percent of episodes are LUPAs.

LUPAs will still be paid upon implementation of the PDGM. However, the approach to calculating the LUPA thresholds has changed due to the change in the unit of payment to 30-day periods of care from 60-day episodes. As detailed in the CY 2019 HH PPS proposed rule (83 FR 32411), there are substantially more home health periods of care with four or fewer visits in a 30-day period than in 60-day episodes; therefore, we believe that the LUPA thresholds for 30-day periods of care should be correspondingly adjusted to target approximately the same percentage of LUPA episodes as under the current HH PPS case-mix system, which is approximately 7 to 8 percent of all episodes. To target approximately the same percentage of LUPAs under the PDGM, LUPA thresholds are set at the 10^{th} percentile value of visits or 2 visits, whichever is higher, for each payment group. This means that the LUPA threshold for each 30-day period of care varies depending on the PDGM payment group to which it is assigned. In the CY 2019 HH PPS final rule (83 FR 56492), we finalized that the LUPA thresholds for each PDGM payment group will be reevaluated every year based on the most current utilization data available at the time of rulemaking. Therefore, we used CY 2018 Medicare home health claims (as of March 27, 2019) linked to OASIS assessment data for this proposed rule. The proposed LUPA thresholds for the CY 2020 PDGM payment groups with the corresponding Health Insurance Prospective Payment System (HIPPS) codes and the case-mix weights are listed in Table 8. Under the PDGM, if the LUPA threshold is met, the 30-day period of care will be paid the full 30-day period payment. If a 30-day period of care does not meet the PDGM LUPA visit threshold, as detailed previously, then payment will be made using the CY 2020 per-visit payment amounts. For example, if the LUPA visit threshold is four, and a 30-day period of care has four or more visits, it is paid the full 30-day period payment amount; if the period of care has three or less visits, payment is made using the per-visit payment amounts.

2. Proposed CY 2020 PDGM Case-Mix Weights

Section 1895(b)(4)(B) of the Act requires the Secretary to establish appropriate case mix adjustment factors for home health services in a manner that explains a significant amount of the variation

in cost among different units of services. As finalized in the CY 2019 HH PPS final rule (83 FR 56502), the PDGM places patients into meaningful payment categories based on patient characteristics (principal diagnosis, functional level, comorbid conditions, referral source and timing). The PDGM case-mix methodology results in 432 unique case-mix groups called HHRGs.

To generate the CY 2020 PDGM case-mix weights, we utilized a data file based on home health 30-day periods of care, as reported in CY 2018 Medicare home health claims (as of March 2019) linked to OASIS assessment data to obtain patient characteristics. These data are the most current and complete data available at this time. The claims data provides visit-level data and data on whether NRS was provided during the period and the total charges of NRS. We determine the case-mix weight for each of the 432 different PDGM payment groups by regressing resource use on a series of indicator variables for each of the categories using a fixed effects model as described in the steps detailed in this section of this proposed rule.

Step 1: Estimate a regression model to assign a functional impairment level to each 30-day period. The regression model estimates the relationship between a 30-day period's resource use and the functional status and risk of hospitalization items included in the PDGM which are obtained from certain OASIS items. We measure resource use with the cost-per-minute + NRS approach that uses information from home health cost reports. Other variables in the regression model include the 30-day period's admission source; clinical group; and 30-day period timing. We also include home health agency level fixed effects in the regression model. After estimating the regression model using 30-day periods, we divide the coefficients that correspond to the functional status and risk of hospitalization items by 10 and round to the nearest whole number. Those rounded numbers are used to compute a functional score for each 30-day period by summing together the rounded numbers for the functional status and risk of hospitalization items that are applicable to each 30-day period. Next, each 30-day period is assigned to a functional impairment level (low, medium, or high) depending on the 30-day period's total functional score. Each clinical group has a separate set of functional thresholds used to assign 30-day periods into a low, medium or high functional impairment level. We set those thresholds so that we assign roughly a

third of 30-day periods within each clinical group to each functional impairment level (low, medium, or high).

Step 2: Next, a second regression model estimates the relationship between a 30-day period's resource use and indicator variables for the presence of any of the comorbidities and comorbidity interactions that were originally examined for inclusion in the PDGM. Like the first regression model, this model also includes home health agency level fixed effects and includes control variables for each 30-day period's admission source, clinical group, timing, and functional impairment level. After we estimate the model, we assign comorbidities to the low comorbidity adjustment if any comorbidities have a coefficient that is statistically significant (p-value of .05 or less) and which have a coefficient that is larger than the 50th percentile of positive and statistically significant comorbidity coefficients. If two comorbidities in the model and their interaction term have coefficients that sum together to exceed $150 and the interaction term is statistically significant (p-value of .05 or less), we assign the two comorbidities together to the high comorbidity adjustment.

Step 3: After Step 2, each 30-day period is assigned to a clinical group, admission source category, episode timing category, functional impairment level, and comorbidity adjustment category. For each combination of those variables (which represent the 432 different payment groups that comprise the PDGM), we then calculate the 10th percentile of visits across all 30-day periods within a particular payment group. If a 30-day period's number of visits is less than the 10th percentile for their payment group, the 30-day period is classified as a Low Utilization Payment Adjustment (LUPA). If a payment group has a 10th percentile of visits that is less than two, we set the LUPA threshold for that payment group to be equal to two. That means if a 30-day period has one visit, it is classified as a LUPA and if it has two or more visits, it is not classified as a LUPA.

Step 4: Finally, we take all non-LUPA 30-day periods and regress resource use on the 30-day period's clinical group, admission source category, episode timing category, functional impairment level, and comorbidity adjustment category. The regression includes fixed effects at the level of the home health agency. After we estimate the model, the model coefficients are used to predict each 30-day

period's resource use. To create the case-mix weight for each 30-day period, the predicted resource use is divided by the overall resource use of the 30-day periods used to estimate the regression.

The case-mix weight is then used to adjust the base payment rate to determine each 30-day period's payment. Table 13 shows the coefficients of the payment regression used to generate the weights, and the coefficients divided by average resource use.

TABLE 13 – COEFFICIENT OF PAYMENT REGRESSION AND COEFFICIENT DIVIDED BY AVERAGE RESOURCE USE FOR PDGM PAYMENT GROUP

Variable	Coefficient	Coefficient Divided by Average Resource Use
MMTA - Other - Medium Functional	$224.06	0.1394
MMTA - Other - High Functional	$424.32	0.2639
MMTA - Surgical Aftercare - Low Functional	-$164.97	-0.1026
MMTA - Surgical Aftercare - Medium Functional	$97.62	0.0607
MMTA - Surgical Aftercare - High Functional	$352.85	0.2195
MMTA - Cardiac and Circulatory - Low Functional	-$28.23	-0.0176
MMTA - Cardiac and Circulatory - Medium Functional	$201.40	0.1253
MMTA - Cardiac and Circulatory - High Functional	$385.14	0.2396
MMTA - Endocrine - Low Functional	$185.56	0.1154
MMTA - Endocrine - Medium Functional	$445.53	0.2771
MMTA - Endocrine - High Functional	$614.49	0.3822
MMTA - Gastrointestinal tract and Genitourinary system - Low Functional	-$79.59	-0.0495
MMTA - Gastrointestinal tract and Genitourinary system - Medium Functional	$165.41	0.1029
MMTA - Gastrointestinal tract and Genitourinary system - High Functional	$304.62	0.1895
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases - Low Functional	-$33.68	-0.0209
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases - Medium Functional	$178.77	0.1112
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases - High Functional	$356.17	0.2215
MMTA - Respiratory - Low Functional	-$65.41	-0.0407
MMTA - Respiratory - Medium Functional	$157.38	0.0979
MMTA - Respiratory - High Functional	$324.59	0.2019
Behavioral Health - Low Functional	-$123.88	-0.0771
Behavioral Health - Medium Functional	$142.04	0.0884
Behavioral Health - High Functional	$283.29	0.1762
Complex - Low Functional	-$75.97	-0.0473
Complex - Medium Functional	$238.65	0.1485
Complex - High Functional	$317.49	0.1975
MS Rehab - Low Functional	$126.23	0.0785
MS Rehab - Medium Functional	$297.36	0.1850
MS Rehab - High Functional	$540.40	0.3362
Neuro - Low Functional	$299.56	0.1863
Neuro - Medium Functional	$554.05	0.3446
Neuro - High Functional	$722.23	0.4493
Wound - Low Functional	$344.91	0.2145
Wound - Medium Functional	$591.71	0.3681
Wound - High Functional	$791.36	0.4923
Community - Late	-$659.24	-0.4101
Institutional - Early	$283.91	0.1766
Institutional - Late	$61.68	0.0384
Comorbidity Adjustment - Has at least one comorbidity from comorbidity list, no interaction from interaction list	$96.49	0.0600
Comorbidity Adjustment - Has at least one interaction from interaction list	$304.67	0.1895
Constant	$1,617.59	
Average Resource Use	$1,607.62	
Number of 30-day Periods	8,456,330	
Adjusted R-Squared	0.3084	

Table 14 presents the HIPPS code, the LUPA threshold, and the case-mix weight for each Home Health Resource Group (HHRG) in the regression model.

TABLE 14 – PROPOSED CY 2020 PDGM LUPA THRESHOLD AND CASE MIX WEIGHT FOR EACH HHRG PAYMENT GROUP

HIPPS	Clinical Group and Functional Level	Timing and Admission Source	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Visit Threshold (10^{th} percentile or 2 - whichever is higher)	CY 2020 Weights
1FC11	Behavioral Health - High	Early - Community	0	4	1.1824
1FC21	Behavioral Health - High	Early - Community	1	4	1.2424
1FC31	Behavioral Health - High	Early - Community	2	4	1.3719
2FC11	Behavioral Health - High	Early - Institutional	0	4	1.3590
2FC21	Behavioral Health - High	Early - Institutional	1	4	1.4190
2FC31	Behavioral Health - High	Early - Institutional	2	4	1.5485
3FC11	Behavioral Health - High	Late - Community	0	2	0.7723
3FC21	Behavioral Health - High	Late - Community	1	2	0.8324
3FC31	Behavioral Health - High	Late - Community	2	3	0.9619
4FC11	Behavioral Health - High	Late - Institutional	0	3	1.2208
4FC21	Behavioral Health - High	Late - Institutional	1	4	1.2808
4FC31	Behavioral Health - High	Late - Institutional	2	3	1.4103
1FA11	Behavioral Health - Low	Early - Community	0	3	0.9291
1FA21	Behavioral Health - Low	Early - Community	1	4	0.9892
1FA31	Behavioral Health - Low	Early - Community	2	3	1.1187
2FA11	Behavioral Health - Low	Early - Institutional	0	3	1.1058
2FA21	Behavioral Health - Low	Early - Institutional	1	3	1.1658
2FA31	Behavioral Health - Low	Early - Institutional	2	3	1.2953
3FA11	Behavioral Health - Low	Late - Community	0	2	0.5191
3FA21	Behavioral Health - Low	Late - Community	1	2	0.5791
3FA31	Behavioral Health - Low	Late - Community	2	2	0.7086
4FA11	Behavioral Health - Low	Late - Institutional	0	2	0.9675
4FA21	Behavioral Health - Low	Late - Institutional	1	2	1.0275
4FA31	Behavioral Health - Low	Late - Institutional	2	2	1.1570
1FB11	Behavioral Health - Medium	Early - Community	0	4	1.0946
1FB21	Behavioral Health - Medium	Early - Community	1	4	1.1546
1FB31	Behavioral Health - Medium	Early - Community	2	4	1.2841
2FB11	Behavioral Health - Medium	Early - Institutional	0	4	1.2712
2FB21	Behavioral Health - Medium	Early - Institutional	1	4	1.3312
2FB31	Behavioral Health - Medium	Early - Institutional	2	4	1.4607
3FB11	Behavioral Health - Medium	Late - Community	0	2	0.6845
3FB21	Behavioral Health - Medium	Late - Community	1	2	0.7445
3FB31	Behavioral Health - Medium	Late - Community	2	2	0.8740
4FB11	Behavioral Health - Medium	Late - Institutional	0	3	1.1329
4FB21	Behavioral Health - Medium	Late - Institutional	1	3	1.1930
4FB31	Behavioral Health - Medium	Late - Institutional	2	3	1.3224
1DC11	Complex - High	Early - Community	0	3	1.2037
1DC21	Complex - High	Early - Community	1	2	1.2637
1DC31	Complex - High	Early - Community	2	2	1.3932
2DC11	Complex - High	Early - Institutional	0	4	1.3803
2DC21	Complex - High	Early - Institutional	1	4	1.4403
2DC31	Complex - High	Early - Institutional	2	4	1.5698
3DC11	Complex - High	Late - Community	0	2	0.7936
3DC21	Complex - High	Late - Community	1	2	0.8536
3DC31	Complex - High	Late - Community	2	2	0.9831
4DC11	Complex - High	Late - Institutional	0	3	1.2421

HIPPS	Clinical Group and Functional Level	Timing and Admission Source	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Visit Threshold (10^{th} percentile or 2 - whichever is higher)	CY 2020 Weights
4DC21	Complex - High	Late - Institutional	1	3	1.3021
4DC31	Complex - High	Late - Institutional	2	3	1.4316
1DA11	Complex - Low	Early - Community	0	3	0.9589
1DA21	Complex - Low	Early - Community	1	3	1.0190
1DA31	Complex - Low	Early - Community	2	2	1.1485
2DA11	Complex - Low	Early - Institutional	0	3	1.1356
2DA21	Complex - Low	Early - Institutional	1	4	1.1956
2DA31	Complex - Low	Early - Institutional	2	4	1.3251
3DA11	Complex - Low	Late - Community	0	2	0.5489
3DA21	Complex - Low	Late - Community	1	2	0.6089
3DA31	Complex - Low	Late - Community	2	2	0.7384
4DA11	Complex - Low	Late - Institutional	0	2	0.9973
4DA21	Complex - Low	Late - Institutional	1	2	1.0573
4DA31	Complex - Low	Late - Institutional	2	2	1.1868
1DB11	Complex - Medium	Early - Community	0	3	1.1547
1DB21	Complex - Medium	Early - Community	1	3	1.2147
1DB31	Complex - Medium	Early - Community	2	3	1.3442
2DB11	Complex - Medium	Early - Institutional	0	4	1.3313
2DB21	Complex - Medium	Early - Institutional	1	4	1.3913
2DB31	Complex - Medium	Early - Institutional	2	4	1.5208
3DB11	Complex - Medium	Late - Community	0	2	0.7446
3DB21	Complex - Medium	Late - Community	1	2	0.8046
3DB31	Complex - Medium	Late - Community	2	2	0.9341
4DB11	Complex - Medium	Late - Institutional	0	3	1.1930
4DB21	Complex - Medium	Late - Institutional	1	3	1.2530
4DB31	Complex - Medium	Late - Institutional	2	3	1.3825
1GC11	MMTA - Surgical Aftercare - High	Early - Community	0	4	1.2257
1GC21	MMTA - Surgical Aftercare - High	Early - Community	1	5	1.2857
1GC31	MMTA - Surgical Aftercare - High	Early - Community	2	5	1.4152
2GC11	MMTA - Surgical Aftercare - High	Early - Institutional	0	4	1.4023
2GC21	MMTA - Surgical Aftercare - High	Early - Institutional	1	5	1.4623
2GC31	MMTA - Surgical Aftercare - High	Early - Institutional	2	5	1.5918
3GC11	MMTA - Surgical Aftercare - High	Late - Community	0	2	0.8156
3GC21	MMTA - Surgical Aftercare - High	Late - Community	1	2	0.8756
3GC31	MMTA - Surgical Aftercare - High	Late - Community	2	2	1.0051
4GC11	MMTA - Surgical Aftercare - High	Late - Institutional	0	4	1.2641
4GC21	MMTA - Surgical Aftercare - High	Late - Institutional	1	4	1.3241
4GC31	MMTA - Surgical Aftercare - High	Late - Institutional	2	4	1.4536
1GA11	MMTA - Surgical Aftercare - Low	Early - Community	0	3	0.9036
1GA21	MMTA - Surgical Aftercare - Low	Early - Community	1	4	0.9636
1GA31	MMTA - Surgical Aftercare - Low	Early - Community	2	4	1.0931
2GA11	MMTA - Surgical Aftercare - Low	Early - Institutional	0	3	1.0802
2GA21	MMTA - Surgical Aftercare - Low	Early - Institutional	1	4	1.1402
2GA31	MMTA - Surgical Aftercare - Low	Early - Institutional	2	4	1.2697
3GA11	MMTA - Surgical Aftercare - Low	Late - Community	0	2	0.4935
3GA21	MMTA - Surgical Aftercare - Low	Late - Community	1	2	0.5535
3GA31	MMTA - Surgical Aftercare - Low	Late - Community	2	2	0.6830
4GA11	MMTA - Surgical Aftercare - Low	Late - Institutional	0	3	0.9420
4GA21	MMTA - Surgical Aftercare - Low	Late - Institutional	1	3	1.0020
4GA31	MMTA - Surgical Aftercare - Low	Late - Institutional	2	4	1.1315
1GB11	MMTA - Surgical Aftercare - Medium	Early - Community	0	4	1.0669
1GB21	MMTA - Surgical Aftercare - Medium	Early - Community	1	4	1.1270
1GB31	MMTA - Surgical Aftercare - Medium	Early - Community	2	5	1.2564
2GB11	MMTA - Surgical Aftercare - Medium	Early - Institutional	0	4	1.2435

HIPPS	Clinical Group and Functional Level	Timing and Admission Source	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Visit Threshold (10^{th} percentile or 2 - whichever is higher)	CY 2020 Weights
2GB21	MMTA - Surgical Aftercare - Medium	Early - Institutional	1	5	1.3036
2GB31	MMTA - Surgical Aftercare - Medium	Early - Institutional	2	5	1.4331
3GB11	MMTA - Surgical Aftercare - Medium	Late - Community	0	2	0.6569
3GB21	MMTA - Surgical Aftercare - Medium	Late - Community	1	2	0.7169
3GB31	MMTA - Surgical Aftercare - Medium	Late - Community	2	2	0.8464
4GB11	MMTA - Surgical Aftercare - Medium	Late - Institutional	0	3	1.1053
4GB21	MMTA - Surgical Aftercare - Medium	Late - Institutional	1	4	1.1653
4GB31	MMTA - Surgical Aftercare - Medium	Late - Institutional	2	4	1.2948
1HC11	MMTA - Cardiac - High	Early - Community	0	5	1.2458
1HC21	MMTA - Cardiac - High	Early - Community	1	5	1.3058
1HC31	MMTA - Cardiac - High	Early - Community	2	5	1.4353
2HC11	MMTA - Cardiac - High	Early - Institutional	0	4	1.4224
2HC21	MMTA - Cardiac - High	Early - Institutional	1	4	1.4824
2HC31	MMTA - Cardiac - High	Early - Institutional	2	5	1.6119
3HC11	MMTA - Cardiac - High	Late - Community	0	2	0.8357
3HC21	MMTA - Cardiac - High	Late - Community	1	2	0.8957
3HC31	MMTA - Cardiac - High	Late - Community	2	3	1.0252
4HC11	MMTA - Cardiac - High	Late - Institutional	0	4	1.2841
4HC21	MMTA - Cardiac - High	Late - Institutional	1	4	1.3442
4HC31	MMTA - Cardiac - High	Late - Institutional	2	4	1.4737
1HA11	MMTA - Cardiac - Low	Early - Community	0	4	0.9886
1HA21	MMTA - Cardiac - Low	Early - Community	1	4	1.0487
1HA31	MMTA - Cardiac - Low	Early - Community	2	4	1.1782
2HA11	MMTA - Cardiac - Low	Early - Institutional	0	4	1.1652
2HA21	MMTA - Cardiac - Low	Early - Institutional	1	4	1.2253
2HA31	MMTA - Cardiac - Low	Early - Institutional	2	4	1.3548
3HA11	MMTA - Cardiac - Low	Late - Community	0	2	0.5786
3HA21	MMTA - Cardiac - Low	Late - Community	1	2	0.6386
3HA31	MMTA - Cardiac - Low	Late - Community	2	3	0.7681
4HA11	MMTA - Cardiac - Low	Late - Institutional	0	3	1.0270
4HA21	MMTA - Cardiac - Low	Late - Institutional	1	3	1.0870
4HA31	MMTA - Cardiac - Low	Late - Institutional	2	3	1.2165
1HB11	MMTA - Cardiac - Medium	Early - Community	0	5	1.1315
1HB21	MMTA - Cardiac - Medium	Early - Community	1	5	1.1915
1HB31	MMTA - Cardiac - Medium	Early - Community	2	5	1.3210
2HB11	MMTA - Cardiac - Medium	Early - Institutional	0	4	1.3081
2HB21	MMTA - Cardiac - Medium	Early - Institutional	1	5	1.3681
2HB31	MMTA - Cardiac - Medium	Early - Institutional	2	5	1.4976
3HB11	MMTA - Cardiac - Medium	Late - Community	0	2	0.7214
3HB21	MMTA - Cardiac - Medium	Late - Community	1	2	0.7814
3HB31	MMTA - Cardiac - Medium	Late - Community	2	3	0.9109
4HB11	MMTA - Cardiac - Medium	Late - Institutional	0	3	1.1699
4HB21	MMTA - Cardiac - Medium	Late - Institutional	1	3	1.2299
4HB31	MMTA - Cardiac - Medium	Late - Institutional	2	4	1.3594
1IC11	MMTA - Endocrine - High	Early - Community	0	5	1.3884
1IC21	MMTA - Endocrine - High	Early - Community	1	5	1.4485
1IC31	MMTA - Endocrine - High	Early - Community	2	5	1.5780
2IC11	MMTA - Endocrine - High	Early - Institutional	0	4	1.5650
2IC21	MMTA - Endocrine - High	Early - Institutional	1	5	1.6251
2IC31	MMTA - Endocrine - High	Early - Institutional	2	4	1.7546
3IC11	MMTA - Endocrine - High	Late - Community	0	3	0.9784
3IC21	MMTA - Endocrine - High	Late - Community	1	3	1.0384
3IC31	MMTA - Endocrine - High	Late - Community	2	3	1.1679
4IC11	MMTA - Endocrine - High	Late - Institutional	0	3	1.4268

HIPPS	Clinical Group and Functional Level	Timing and Admission Source	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Visit Threshold (10^{th} percentile or 2 - whichever is higher)	CY 2020 Weights
4IC21	MMTA - Endocrine - High	Late - Institutional	1	3	1.4868
4IC31	MMTA - Endocrine - High	Late - Institutional	2	4	1.6163
1IA11	MMTA - Endocrine - Low	Early - Community	0	4	1.1216
1IA21	MMTA - Endocrine - Low	Early - Community	1	4	1.1817
1IA31	MMTA - Endocrine - Low	Early - Community	2	4	1.3111
2IA11	MMTA - Endocrine - Low	Early - Institutional	0	3	1.2982
2IA21	MMTA - Endocrine - Low	Early - Institutional	1	4	1.3583
2IA31	MMTA - Endocrine - Low	Early - Institutional	2	4	1.4878
3IA11	MMTA - Endocrine - Low	Late - Community	0	2	0.7116
3IA21	MMTA - Endocrine - Low	Late - Community	1	2	0.7716
3IA31	MMTA - Endocrine - Low	Late - Community	2	3	0.9011
4IA11	MMTA - Endocrine - Low	Late - Institutional	0	3	1.1600
4IA21	MMTA - Endocrine - Low	Late - Institutional	1	3	1.2200
4IA31	MMTA - Endocrine - Low	Late - Institutional	2	3	1.3495
1IB11	MMTA - Endocrine - Medium	Early - Community	0	5	1.2833
1IB21	MMTA - Endocrine - Medium	Early - Community	1	5	1.3434
1IB31	MMTA - Endocrine - Medium	Early - Community	2	4	1.4729
2IB11	MMTA - Endocrine - Medium	Early - Institutional	0	4	1.4599
2IB21	MMTA - Endocrine - Medium	Early - Institutional	1	4	1.5200
2IB31	MMTA - Endocrine - Medium	Early - Institutional	2	5	1.6495
3IB11	MMTA - Endocrine - Medium	Late - Community	0	3	0.8733
3IB21	MMTA - Endocrine - Medium	Late - Community	1	3	0.9333
3IB31	MMTA - Endocrine - Medium	Late - Community	2	3	1.0628
4IB11	MMTA - Endocrine - Medium	Late - Institutional	0	3	1.3217
4IB21	MMTA - Endocrine - Medium	Late - Institutional	1	3	1.3817
4IB31	MMTA - Endocrine - Medium	Late - Institutional	2	4	1.5112
1JC11	MMTA - GI/GU - High	Early - Community	0	4	1.1957
1JC21	MMTA - GI/GU - High	Early - Community	1	3	1.2557
1JC31	MMTA - GI/GU - High	Early - Community	2	3	1.3852
2JC11	MMTA - GI/GU - High	Early - Institutional	0	4	1.3723
2JC21	MMTA - GI/GU - High	Early - Institutional	1	4	1.4323
2JC31	MMTA - GI/GU - High	Early - Institutional	2	4	1.5618
3JC11	MMTA - GI/GU - High	Late - Community	0	2	0.7856
3JC21	MMTA - GI/GU - High	Late - Community	1	2	0.8456
3JC31	MMTA - GI/GU - High	Late - Community	2	2	0.9751
4JC11	MMTA - GI/GU - High	Late - Institutional	0	3	1.2341
4JC21	MMTA - GI/GU - High	Late - Institutional	1	3	1.2941
4JC31	MMTA - GI/GU - High	Late - Institutional	2	4	1.4236
1JA11	MMTA - GI/GU - Low	Early - Community	0	3	0.9567
1JA21	MMTA - GI/GU - Low	Early - Community	1	3	1.0167
1JA31	MMTA - GI/GU - Low	Early - Community	2	3	1.1462
2JA11	MMTA - GI/GU - Low	Early - Institutional	0	3	1.1333
2JA21	MMTA - GI/GU - Low	Early - Institutional	1	4	1.1933
2JA31	MMTA - GI/GU - Low	Early - Institutional	2	4	1.3228
3JA11	MMTA - GI/GU - Low	Late - Community	0	2	0.5466
3JA21	MMTA - GI/GU - Low	Late - Community	1	2	0.6066
3JA31	MMTA - GI/GU - Low	Late - Community	2	2	0.7361
4JA11	MMTA - GI/GU - Low	Late - Institutional	0	3	0.9951
4JA21	MMTA - GI/GU - Low	Late - Institutional	1	3	1.0551
4JA31	MMTA - GI/GU - Low	Late - Institutional	2	3	1.1846
1JB11	MMTA - GI/GU - Medium	Early - Community	0	4	1.1091
1JB21	MMTA - GI/GU - Medium	Early - Community	1	4	1.1691
1JB31	MMTA - GI/GU - Medium	Early - Community	2	4	1.2986
2JB11	MMTA - GI/GU - Medium	Early - Institutional	0	4	1.2857

HIPPS	Clinical Group and Functional Level	Timing and Admission Source	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Visit Threshold (10^{th} percentile or 2 - whichever is higher)	CY 2020 Weights
2JB21	MMTA - GI/GU - Medium	Early - Institutional	1	4	1.3457
2JB31	MMTA - GI/GU - Medium	Early - Institutional	2	4	1.4752
3JB11	MMTA - GI/GU - Medium	Late - Community	0	2	0.6990
3JB21	MMTA - GI/GU - Medium	Late - Community	1	2	0.7590
3JB31	MMTA - GI/GU - Medium	Late - Community	2	2	0.8885
4JB11	MMTA - GI/GU - Medium	Late - Institutional	0	3	1.1475
4JB21	MMTA - GI/GU - Medium	Late - Institutional	1	3	1.2075
4JB31	MMTA - GI/GU - Medium	Late - Institutional	2	4	1.3370
1KC11	MMTA - Infectious - High	Early - Community	0	3	1.2278
1KC21	MMTA - Infectious - High	Early - Community	1	3	1.2878
1KC31	MMTA - Infectious - High	Early - Community	2	3	1.4173
2KC11	MMTA - Infectious - High	Early - Institutional	0	3	1.4044
2KC21	MMTA - Infectious - High	Early - Institutional	1	4	1.4644
2KC31	MMTA - Infectious - High	Early - Institutional	2	4	1.5939
3KC11	MMTA - Infectious - High	Late - Community	0	2	0.8177
3KC21	MMTA - Infectious - High	Late - Community	1	2	0.8777
3KC31	MMTA - Infectious - High	Late - Community	2	2	1.0072
4KC11	MMTA - Infectious - High	Late - Institutional	0	3	1.2661
4KC21	MMTA - Infectious - High	Late - Institutional	1	3	1.3261
4KC31	MMTA - Infectious - High	Late - Institutional	2	3	1.4556
1KA11	MMTA - Infectious - Low	Early - Community	0	3	0.9853
1KA21	MMTA - Infectious - Low	Early - Community	1	3	1.0453
1KA31	MMTA - Infectious - Low	Early - Community	2	4	1.1748
2KA11	MMTA - Infectious - Low	Early - Institutional	0	3	1.1619
2KA21	MMTA - Infectious - Low	Early - Institutional	1	3	1.2219
2KA31	MMTA - Infectious - Low	Early - Institutional	2	4	1.3514
3KA11	MMTA - Infectious - Low	Late - Community	0	2	0.5752
3KA21	MMTA - Infectious - Low	Late - Community	1	2	0.6352
3KA31	MMTA - Infectious - Low	Late - Community	2	2	0.7647
4KA11	MMTA - Infectious - Low	Late - Institutional	0	2	1.0236
4KA21	MMTA - Infectious - Low	Late - Institutional	1	3	1.0836
4KA31	MMTA - Infectious - Low	Late - Institutional	2	3	1.2131
1KB11	MMTA - Infectious - Medium	Early - Community	0	3	1.1174
1KB21	MMTA - Infectious - Medium	Early - Community	1	4	1.1774
1KB31	MMTA - Infectious - Medium	Early - Community	2	4	1.3069
2KB11	MMTA - Infectious - Medium	Early - Institutional	0	4	1.2940
2KB21	MMTA - Infectious - Medium	Early - Institutional	1	4	1.3540
2KB31	MMTA - Infectious - Medium	Early - Institutional	2	5	1.4835
3KB11	MMTA - Infectious - Medium	Late - Community	0	2	0.7073
3KB21	MMTA - Infectious - Medium	Late - Community	1	2	0.7674
3KB31	MMTA - Infectious - Medium	Late - Community	2	2	0.8968
4KB11	MMTA - Infectious - Medium	Late - Institutional	0	3	1.1558
4KB21	MMTA - Infectious - Medium	Late - Institutional	1	3	1.2158
4KB31	MMTA - Infectious - Medium	Late - Institutional	2	4	1.3453
1AC11	MMTA - Other - High	Early - Community	0	5	1.2701
1AC21	MMTA - Other - High	Early - Community	1	5	1.3302
1AC31	MMTA - Other - High	Early - Community	2	5	1.4597
2AC11	MMTA - Other - High	Early - Institutional	0	5	1.4468
2AC21	MMTA - Other - High	Early - Institutional	1	5	1.5068
2AC31	MMTA - Other - High	Early - Institutional	2	5	1.6363
3AC11	MMTA - Other - High	Late - Community	0	2	0.8601
3AC21	MMTA - Other - High	Late - Community	1	3	0.9201
3AC31	MMTA - Other - High	Late - Community	2	3	1.0496
4AC11	MMTA - Other - High	Late - Institutional	0	4	1.3085

HIPPS	Clinical Group and Functional Level	Timing and Admission Source	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Visit Threshold (10^{th} percentile or 2 - whichever is higher)	CY 2020 Weights
4AC21	MMTA - Other - High	Late - Institutional	1	4	1.3685
4AC31	MMTA - Other - High	Late - Institutional	2	3	1.4980
1AA11	MMTA - Other - Low	Early - Community	0	4	1.0062
1AA21	MMTA - Other - Low	Early - Community	1	4	1.0662
1AA31	MMTA - Other - Low	Early - Community	2	4	1.1957
2AA11	MMTA - Other - Low	Early - Institutional	0	3	1.1828
2AA21	MMTA - Other - Low	Early - Institutional	1	4	1.2428
2AA31	MMTA - Other - Low	Early - Institutional	2	4	1.3723
3AA11	MMTA - Other - Low	Late - Community	0	2	0.5961
3AA21	MMTA - Other - Low	Late - Community	1	2	0.6562
3AA31	MMTA - Other - Low	Late - Community	2	3	0.7856
4AA11	MMTA - Other - Low	Late - Institutional	0	3	1.0446
4AA21	MMTA - Other - Low	Late - Institutional	1	3	1.1046
4AA31	MMTA - Other - Low	Late - Institutional	2	3	1.2341
1AB11	MMTA - Other - Medium	Early - Community	0	5	1.1456
1AB21	MMTA - Other - Medium	Early - Community	1	5	1.2056
1AB31	MMTA - Other - Medium	Early - Community	2	5	1.3351
2AB11	MMTA - Other - Medium	Early - Institutional	0	5	1.3222
2AB21	MMTA - Other - Medium	Early - Institutional	1	5	1.3822
2AB31	MMTA - Other - Medium	Early - Institutional	2	5	1.5117
3AB11	MMTA - Other - Medium	Late - Community	0	2	0.7355
3AB21	MMTA - Other - Medium	Late - Community	1	2	0.7955
3AB31	MMTA - Other - Medium	Late - Community	2	3	0.9250
4AB11	MMTA - Other - Medium	Late - Institutional	0	3	1.1839
4AB21	MMTA - Other - Medium	Late - Institutional	1	3	1.2440
4AB31	MMTA - Other - Medium	Late - Institutional	2	4	1.3735
1LC11	MMTA - Respiratory - High	Early - Community	0	4	1.2081
1LC21	MMTA - Respiratory - High	Early - Community	1	4	1.2681
1LC31	MMTA - Respiratory - High	Early - Community	2	4	1.3976
2LC11	MMTA - Respiratory - High	Early - Institutional	0	4	1.3847
2LC21	MMTA - Respiratory - High	Early - Institutional	1	4	1.4447
2LC31	MMTA - Respiratory - High	Early - Institutional	2	4	1.5742
3LC11	MMTA - Respiratory - High	Late - Community	0	2	0.7980
3LC21	MMTA - Respiratory - High	Late - Community	1	2	0.8581
3LC31	MMTA - Respiratory - High	Late - Community	2	3	0.9876
4LC11	MMTA - Respiratory - High	Late - Institutional	0	3	1.2465
4LC21	MMTA - Respiratory - High	Late - Institutional	1	4	1.3065
4LC31	MMTA - Respiratory - High	Late - Institutional	2	3	1.4360
1LA11	MMTA - Respiratory - Low	Early - Community	0	4	0.9655
1LA21	MMTA - Respiratory - Low	Early - Community	1	4	1.0255
1LA31	MMTA - Respiratory - Low	Early - Community	2	4	1.1550
2LA11	MMTA - Respiratory - Low	Early - Institutional	0	4	1.1421
2LA21	MMTA - Respiratory - Low	Early - Institutional	1	4	1.2021
2LA31	MMTA - Respiratory - Low	Early - Institutional	2	4	1.3316
3LA11	MMTA - Respiratory - Low	Late - Community	0	2	0.5554
3LA21	MMTA - Respiratory - Low	Late - Community	1	2	0.6155
3LA31	MMTA - Respiratory - Low	Late - Community	2	2	0.7450
4LA11	MMTA - Respiratory - Low	Late - Institutional	0	3	1.0039
4LA21	MMTA - Respiratory - Low	Late - Institutional	1	3	1.0639
4LA31	MMTA - Respiratory - Low	Late - Institutional	2	3	1.1934
1LB11	MMTA - Respiratory - Medium	Early - Community	0	4	1.1041
1LB21	MMTA - Respiratory - Medium	Early - Community	1	5	1.1641
1LB31	MMTA - Respiratory - Medium	Early - Community	2	5	1.2936
2LB11	MMTA - Respiratory - Medium	Early - Institutional	0	4	1.2807

HIPPS	Clinical Group and Functional Level	Timing and Admission Source	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Visit Threshold (10^{th} percentile or 2 - whichever is higher)	CY 2020 Weights
2LB21	MMTA - Respiratory - Medium	Early - Institutional	1	5	1.3407
2LB31	MMTA - Respiratory - Medium	Early - Institutional	2	5	1.4702
3LB11	MMTA - Respiratory - Medium	Late - Community	0	2	0.6940
3LB21	MMTA - Respiratory - Medium	Late - Community	1	2	0.7541
3LB31	MMTA - Respiratory - Medium	Late - Community	2	2	0.8835
4LB11	MMTA - Respiratory - Medium	Late - Institutional	0	3	1.1425
4LB21	MMTA - Respiratory - Medium	Late - Institutional	1	3	1.2025
4LB31	MMTA - Respiratory - Medium	Late - Institutional	2	4	1.3320
1EC11	MS Rehab - High	Early - Community	0	5	1.3424
1EC21	MS Rehab - High	Early - Community	1	5	1.4024
1EC31	MS Rehab - High	Early - Community	2	5	1.5319
2EC11	MS Rehab - High	Early - Institutional	0	6	1.5190
2EC21	MS Rehab - High	Early - Institutional	1	6	1.5790
2EC31	MS Rehab - High	Early - Institutional	2	6	1.7085
3EC11	MS Rehab - High	Late - Community	0	2	0.9323
3EC21	MS Rehab - High	Late - Community	1	2	0.9923
3EC31	MS Rehab - High	Late - Community	2	3	1.1218
4EC11	MS Rehab - High	Late - Institutional	0	4	1.3807
4EC21	MS Rehab - High	Late - Institutional	1	4	1.4407
4EC31	MS Rehab - High	Late - Institutional	2	5	1.5702
1EA11	MS Rehab - Low	Early - Community	0	5	1.0847
1EA21	MS Rehab - Low	Early - Community	1	5	1.1447
1EA31	MS Rehab - Low	Early - Community	2	5	1.2742
2EA11	MS Rehab - Low	Early - Institutional	0	5	1.2613
2EA21	MS Rehab - Low	Early - Institutional	1	5	1.3213
2EA31	MS Rehab - Low	Early - Institutional	2	5	1.4508
3EA11	MS Rehab - Low	Late - Community	0	2	0.6746
3EA21	MS Rehab - Low	Late - Community	1	2	0.7347
3EA31	MS Rehab - Low	Late - Community	2	3	0.8642
4EA11	MS Rehab - Low	Late - Institutional	0	4	1.1231
4EA21	MS Rehab - Low	Late - Institutional	1	4	1.1831
4EA31	MS Rehab - Low	Late - Institutional	2	4	1.3126
1EB11	MS Rehab - Medium	Early - Community	0	5	1.1912
1EB21	MS Rehab - Medium	Early - Community	1	5	1.2512
1EB31	MS Rehab - Medium	Early - Community	2	5	1.3807
2EB11	MS Rehab - Medium	Early - Institutional	0	5	1.3678
2EB21	MS Rehab - Medium	Early - Institutional	1	6	1.4278
2EB31	MS Rehab - Medium	Early - Institutional	2	6	1.5573
3EB11	MS Rehab - Medium	Late - Community	0	2	0.7811
3EB21	MS Rehab - Medium	Late - Community	1	2	0.8411
3EB31	MS Rehab - Medium	Late - Community	2	3	0.9706
4EB11	MS Rehab - Medium	Late - Institutional	0	4	1.2295
4EB21	MS Rehab - Medium	Late - Institutional	1	4	1.2896
4EB31	MS Rehab - Medium	Late - Institutional	2	4	1.4191
1BC11	Neuro - High	Early - Community	0	5	1.4555
1BC21	Neuro - High	Early - Community	1	5	1.5155
1BC31	Neuro - High	Early - Community	2	5	1.6450
2BC11	Neuro - High	Early - Institutional	0	5	1.6321
2BC21	Neuro - High	Early - Institutional	1	6	1.6921
2BC31	Neuro - High	Early - Institutional	2	5	1.8216
3BC11	Neuro - High	Late - Community	0	2	1.0454
3BC21	Neuro - High	Late - Community	1	3	1.1054
3BC31	Neuro - High	Late - Community	2	3	1.2349
4BC11	Neuro - High	Late - Institutional	0	4	1.4938

HIPPS	Clinical Group and Functional Level	Timing and Admission Source	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Visit Threshold (10^{th} percentile or 2 - whichever is higher)	CY 2020 Weights
4BC21	Neuro - High	Late - Institutional	1	4	1.5539
4BC31	Neuro - High	Late - Institutional	2	4	1.6833
1BA11	Neuro - Low	Early - Community	0	5	1.1925
1BA21	Neuro - Low	Early - Community	1	5	1.2526
1BA31	Neuro - Low	Early - Community	2	5	1.3821
2BA11	Neuro - Low	Early - Institutional	0	5	1.3691
2BA21	Neuro - Low	Early - Institutional	1	5	1.4292
2BA31	Neuro - Low	Early - Institutional	2	5	1.5587
3BA11	Neuro - Low	Late - Community	0	2	0.7825
3BA21	Neuro - Low	Late - Community	1	2	0.8425
3BA31	Neuro - Low	Late - Community	2	2	0.9720
4BA11	Neuro - Low	Late - Institutional	0	3	1.2309
4BA21	Neuro - Low	Late - Institutional	1	4	1.2909
4BA31	Neuro - Low	Late - Institutional	2	4	1.4204
1BB11	Neuro - Medium	Early - Community	0	5	1.3508
1BB21	Neuro - Medium	Early - Community	1	5	1.4109
1BB31	Neuro - Medium	Early - Community	2	5	1.5404
2BB11	Neuro - Medium	Early - Institutional	0	6	1.5275
2BB21	Neuro - Medium	Early - Institutional	1	6	1.5875
2BB31	Neuro - Medium	Early - Institutional	2	6	1.7170
3BB11	Neuro - Medium	Late - Community	0	2	0.9408
3BB21	Neuro - Medium	Late - Community	1	2	1.0008
3BB31	Neuro - Medium	Late - Community	2	3	1.1303
4BB11	Neuro - Medium	Late - Institutional	0	4	1.3892
4BB21	Neuro - Medium	Late - Institutional	1	4	1.4492
4BB31	Neuro - Medium	Late - Institutional	2	5	1.5787
1CC11	Wound - High	Early - Community	0	5	1.4985
1CC21	Wound - High	Early - Community	1	5	1.5585
1CC31	Wound - High	Early - Community	2	5	1.6880
2CC11	Wound - High	Early - Institutional	0	4	1.6751
2CC21	Wound - High	Early - Institutional	1	5	1.7351
2CC31	Wound - High	Early - Institutional	2	5	1.8646
3CC11	Wound - High	Late - Community	0	3	1.0884
3CC21	Wound - High	Late - Community	1	3	1.1484
3CC31	Wound - High	Late - Community	2	3	1.2779
4CC11	Wound - High	Late - Institutional	0	3	1.5368
4CC21	Wound - High	Late - Institutional	1	4	1.5969
4CC31	Wound - High	Late - Institutional	2	4	1.7263
1CA11	Wound - Low	Early - Community	0	5	1.2207
1CA21	Wound - Low	Early - Community	1	5	1.2808
1CA31	Wound - Low	Early - Community	2	4	1.4103
2CA11	Wound - Low	Early - Institutional	0	4	1.3974
2CA21	Wound - Low	Early - Institutional	1	4	1.4574
2CA31	Wound - Low	Early - Institutional	2	4	1.5869
3CA11	Wound - Low	Late - Community	0	2	0.8107
3CA21	Wound - Low	Late - Community	1	3	0.8707
3CA31	Wound - Low	Late - Community	2	3	1.0002
4CA11	Wound - Low	Late - Institutional	0	3	1.2591
4CA21	Wound - Low	Late - Institutional	1	3	1.3191
4CA31	Wound - Low	Late - Institutional	2	3	1.4486
1CB11	Wound - Medium	Early - Community	0	5	1.3743
1CB21	Wound - Medium	Early - Community	1	5	1.4343
1CB31	Wound - Medium	Early - Community	2	5	1.5638
2CB11	Wound - Medium	Early - Institutional	0	5	1.5509

HIPPS	Clinical Group and Functional Level	Timing and Admission Source	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Visit Threshold (10th percentile or 2 - whichever is higher)	CY 2020 Weights
2CB21	Wound - Medium	Early - Institutional	1	5	1.6109
2CB31	Wound - Medium	Early - Institutional	2	5	1.7404
3CB11	Wound - Medium	Late - Community	0	3	0.9642
3CB21	Wound - Medium	Late - Community	1	3	1.0242
3CB31	Wound - Medium	Late - Community	2	3	1.1537
4CB11	Wound - Medium	Late - Institutional	0	4	1.4126
4CB21	Wound - Medium	Late - Institutional	1	4	1.4727
4CB31	Wound - Medium	Late - Institutional	2	4	1.6022

Source: CY 2018 Medicare claims data for episodes ending on or before December 31, 2018 (as of March 27, 2019) for which we had a linked OASIS assessment. LUPA episodes, outlier episodes, and episodes with PEP adjustments were excluded.

E. Proposed CY 2020 Home Health Payment Rate Updates

1. Proposed CY 2020 Home Health Market Basket Update for HHAs

Section 1895(b)(3)(B) of the Act requires that the standard prospective payment amounts for CY 2020 be increased by a factor equal to the applicable home health market basket update for those HHAs that submit quality data as required by the Secretary. In the CY 2019 HH PPS final rule (83 FR 56425), we finalized a rebasing of the home health market basket to reflect 2016 Medicare cost report (MCR) data, the latest available and complete data on the actual structure of HHA costs. As such, based on the rebased 2016-based home health market basket, we finalized that the labor-related share is 76.1 percent and the non-labor-related share is 23.9 percent. A detailed description of how we rebased the HHA market basket is available in the CY 2019 HH PPS final rule (83 FR 56425 through 56436).

Section 1895(b)(3)(B) of the Act, requires that, in CY 2015 and in subsequent calendar years, except CY 2018 (under section 411(c) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114-10, enacted April 16, 2015)), and except in CY 2020 (under section 53110 of the Bipartisan Budget Act of 2018 (BBA) (Pub. L. 115-123, enacted February 9, 2018)), the market basket percentage under the HHA prospective payment system, as described in section 1895(b)(3)(B) of the Act, be annually adjusted by changes in economy-wide productivity. Section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment to be equal to the 10-year moving average of change in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, calendar year, cost reporting period, or other

annual period) (the ''MFP adjustment''). The Bureau of Labor Statistics (BLS) is the agency that publishes the official measure of private nonfarm business MFP. Please see http://www.bls.gov/mfp, to obtain the BLS historical published MFP data.

The proposed home health update percentage for CY 2020 would have been based on the estimated home health market basket update, specified at section 1895(b)(3)(B)(iii) of the Act, of 3.0 percent (based on IHS Global Insight Inc.'s first-quarter 2019 forecast with historical data through fourth-quarter 2018). Due to the requirements specified at section 1895(b)(3)(B)(vi) of the Act prior to the enactment of the BBA of 2018, the estimated CY 2020 home health market basket update of 3.0 percent would have been reduced by a MFP adjustment, as mandated by the section 3401 of the Patient Protection and Affordable Care Act (the Affordable Care Act) (Pub. L. 111-148) and currently estimated to be 0.4 percentage point for CY 2020. In effect, the proposed home health payment update percentage for CY 2020 would have been a 2.6 percent increase. However, section 53110 of the BBA of 2018 amended section 1895(b)(3)(B) of the Act, such that for home health payments for CY 2020, the home health payment update is required to be 1.5 percent. The MFP adjustment is not applied to the BBA of 2018 mandated 1.5 percent payment update. Section 1895(b)(3)(B)(v) of the Act requires that the home health update be decreased by 2 percentage points for those HHAs that do not submit quality data as required by the Secretary. For HHAs that do not submit the required quality data for CY 2020, the home health payment update would be -0.5 percent (1.5 percent minus 2 percentage points).

2. CY 2020 Home Health Wage Index

Sections 1895(b)(4)(A)(ii) and (b)(4)(C) of the Act require the Secretary to provide appropriate adjustments to the proportion of the payment amount under the HH PPS that account for area wage differences, using adjustment factors that reflect the relative level of wages and wage-related costs applicable to the furnishing of HH services. Since the inception of the HH PPS, we have used inpatient hospital wage data in developing a wage index to be applied to HH payments. We propose to continue this practice for CY 2020, as we continue to believe that, in the absence of HH-specific wage data that accounts for area differences, using inpatient hospital wage data is appropriate and reasonable for the HH

PPS. Specifically, we propose to use the FY 2020 pre-floor, pre-reclassified hospital wage index as the CY 2020 wage adjustment to the labor portion of the HH PPS rates. For CY 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 apply the appropriate wage index value to the labor portion of the HH PPS rates based on the site of service for the beneficiary (defined by section 1861(m) of the Act as the beneficiary's place of residence).

To address those geographic areas in which there are no inpatient hospitals, and thus, no hospital wage data on which to base the calculation of the CY 2020 HH PPS wage index, we propose to continue to use the same methodology discussed in the CY 2007 HH PPS final rule (71 FR 65884) to address those geographic areas in which there are no inpatient hospitals. For rural areas that do not have inpatient hospitals, we propose to use the average wage index from all contiguous Core Based Statistical Areas (CBSAs) as a reasonable proxy. Currently, the only rural area without a hospital from which hospital wage data could be derived is Puerto Rico. However, for rural Puerto Rico, we do 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 propose to continue to use the most recent wage index previously available for that area. For urban areas without inpatient hospitals, we use the average wage index of all urban areas within the state as a reasonable proxy for the wage index for that CBSA. For CY 2020, the urban areas without inpatient hospital wage data are Hinesville, GA (CBSA 25980) and Carson City, NV (CBSA 16180). The CY 2020 wage index value for Hinesville, GA is 0.8237 and the wage index value for Carson City, NV is 1.0518.

On February 28, 2013, OMB issued Bulletin No. 13-01, announcing revisions to the delineations of MSAs, Micropolitan Statistical Areas, and CBSAs, and guidance on uses of the delineation of these areas. In the CY 2015 HH PPS final rule (79 FR 66085 through 66087), we adopted the OMB's new area delineations using a 1-year transition.

On August 15, 2017, OMB issued Bulletin No. 17-01 in which it announced that one Micropolitan Statistical Area, Twin Falls, Idaho, now qualifies as a Metropolitan Statistical Area. The new CBSA (46300) comprises the principal city of Twin Falls, Idaho in Jerome County, Idaho and Twin Falls County, Idaho. The CY 2020 HH PPS wage index value for CBSA 46300, Twin Falls, Idaho, will be 0.8252. Bulletin No. 17-01 is available at https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2017/b-17-01.pdf.[13]

The most recent OMB Bulletin (No. 18-04) was published on September 14, 2018 and is available at https://www.whitehouse.gov/wp-content/uploads/2018/09/Bulletin-18-04.pdf.[14]

The revisions contained in OMB Bulletin No. 18-04 have no impact on the geographic area delineations that are used to wage adjust HH PPS payments.

The CY 2020 wage index is available on the CMS website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Home-Health-Prospective-Payment-System-Regulations-and-Notices.html. We were recently made aware of a minor calculation error in the file used to compute the home health wage index values. We are also posting the corrected wage index values in the same file, on the same website and we will correct this error when computing the home health wage index values and payment rates for the final rule.

3. Comment Solicitation

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

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13 "Revised Delineations of Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and Guidance on Uses of the Delineations of These Areas". OMB BULLETIN NO. 17-01. August 15, 2017. https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2017/b-17-01.pdf

14 Revised Delineations of Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and Guidance on Uses of the Delineations of These Areas". OMB BULLETIN NO. 18-04. September 14, 2018 https://www.whitehouse.gov/wp-content/uploads/2018/09/Bulletin-18-04.pdf

4. CY 2020 Annual Payment Update

a. Background

The Medicare HH PPS has been in effect since October 1, 2000. As set forth in the July 3, 2000 final rule (65 FR 41128), the base unit of payment under the Medicare HH PPS was a national, standardized 60-day episode payment rate. As finalized in the CY 2019 HH PPS final rule (83 FR 56406) and as described in section III.B of this proposed rule, the unit of home health payment will change from a 60-day episode to a 30-day period effective for those 30-day periods beginning on or after January 1, 2020. However, the standardized 60-day payment rate will apply to case-mix adjusted episodes (that is, not LUPAs) beginning on or before December 31, 2019 and ending on or before February 28, 2020. As such, the latest date such a 60-day crossover episode could end on is February 28, 2020. Those 60-day episodes that begin on or before December 31, 2019, but are LUPA episodes, will be paid the national, per-visit payment rates as shown in Table 23.

As set forth in § 484.220, we adjust the national, standardized prospective payment rates by a case-mix relative weight and a wage index value based on the site of service for the beneficiary. To provide appropriate adjustments to the proportion of the payment amount under the HH PPS to account for area wage differences, we apply the appropriate wage index value to the labor portion of the HH PPS rates. In the CY 2019 HH PPS final rule (83 FR 56435), we finalized to rebase and revise the home health market basket to reflect 2016 Medicare cost report (MCR) data, the latest available and most complete data on the actual structure of HHA costs. We also finalized a revision to the labor-related share to reflect the 2016-based home health market basket Compensation (Wages and Salaries plus Benefits) cost weight. We finalized that for CY 2019 and subsequent years, the labor-related share would be 76.1 percent and the non-labor-related share would be 23.9 percent. The following are the steps we take to compute the case-mix and wage-adjusted 60-day episode (for those episodes that span the implementation date of January 1, 2020) and 30-day period rates for CY 2020:

- Multiply the national, standardized 60-day episode rate or 30-day period rate by the patient's applicable case-mix weight.

- Divide the case-mix adjusted amount into a labor (76.1 percent) and a non-labor portion (23.9 percent).
- Multiply the labor portion by the applicable wage index based on the site of service of the beneficiary.
- Add the wage-adjusted portion to the non-labor portion, yielding the case-mix and wage adjusted 60-day episode rate or 30-day period rate, subject to any additional applicable adjustments.

We provide annual updates of the HH PPS rate in accordance with section 1895(b)(3)(B) of the Act. Section 484.225 sets forth the specific annual percentage update methodology. In accordance with section 1895(b)(3)(B)(v) of the Act and § 484.225(i), for an HHA that does not submit HH quality data, as specified by the Secretary, the unadjusted national prospective 60-day episode rate or 30-day period rate is equal to the rate for the previous calendar year increased by the applicable HH payment update, minus 2 percentage points. Any reduction of the percentage change would apply only to the calendar year involved and would not be considered in computing the prospective payment amount for a subsequent calendar year.

Medicare pays both the national, standardized 60-day and 30-day case-mix and wage-adjusted payment amounts on a split percentage payment approach for those HHAs eligible for such payments. The split percentage payment approach includes an initial percentage payment and a final percentage payment as set forth in § 484.205(b)(1) and (2). The claim that the HHA submits for the final percentage payment determines the total payment amount for the episode or period and whether we make an applicable adjustment to the 60-day or 30-day case-mix and wage-adjusted payment amount. We refer stakeholders to section III.H. of this proposed rule regarding proposals on changes to the current split percentage policy in CY 2020 and subsequent years. The end date of the 60-day episode or 30-day period, as reported on the claim, determines which calendar year rates Medicare will use to pay the claim.

We may also adjust the 60-day or 30-day case-mix and wage-adjusted payment based on the information submitted on the claim to reflect the following:

- A low-utilization payment adjustment (LUPA) is provided on a per-visit basis as set forth in §§ 484.205(d)(1) and 484.230.
- A partial episode payment (PEP) adjustment as set forth in §§ 484.205(d)(2) and 484.235.
- An outlier payment as set forth in §§ 484.205(d)(3) and 484.240.

b. CY 2020 National, Standardized 60-Day Episode Payment Rate

Section 1895(b)(3)(A)(i) of the Act requires that the standard, prospective payment rate and other applicable amounts be standardized in a manner that eliminates the effects of variations in relative case-mix and area wage adjustments among different home health agencies in a budget neutral manner. To determine the CY 2020 national, standardized 60-day episode payment rate for those 60-day episodes that span the implementation date of the PDGM and the change to a 30-day unit of payment, we apply a wage index budget neutrality factor and the home health payment update percentage discussed in section III.F.1. of this proposed rule. We are not proposing to update the case-mix weights for the 153-group case-mix methodology in CY 2020 as outlined in section III.D. of this proposed rule. Because we would continue to use the CY 2019 case-mix weights, we do not have to apply a case-mix weight budget neutrality factor to the CY 2020 60-day episode payment rate.

To calculate the wage index budget neutrality factor, we simulated total payments for non-LUPA episodes using the proposed CY 2020 wage index and compared it to our simulation of total payments for non-LUPA episodes using the CY 2019 wage index. By dividing the total payments for non-LUPA episodes using the CY 2020 wage index by the total payments for non-LUPA episodes using the CY 2019 wage index, we obtain a wage index budget neutrality factor of 1.0062. We would apply the wage index budget neutrality factor of 1.0062 to the calculation of the CY 2019 national, standardized 60-day episode payment rate.

Next, we would update the 60-day payment rate by the CY 2020 home health payment update percentage of 1.5 percent as required by section 53110 of the BBA of 2018 and as described in section III.E.1. of this proposed rule. The CY 2020 national, standardized 60-day episode payment rate is calculated in Table 15.

TABLE 15: CY 2020 NATIONAL, STANDARDIZED 60-DAY EPISODE PAYMENT AMOUNT

CY 2019 National, Standardized 60-Day Episode Payment	Wage Index Budget Neutrality Factor	CY 2020 HH Payment Update	CY 2020 National, Standardized 60-Day Episode Payment
$3,154.27	X 1.0062	X 1.015	$3,221.43

The CY 2020 national, standardized 60-day episode payment rate for an HHA that does not submit the required quality data is updated by the CY 2020 home health payment update of 1.5 percent minus 2 percentage points and is shown in Table 16.

TABLE 16: CY 2020 NATIONAL, STANDARDIZED 60-DAY EPISODE PAYMENT AMOUNT FOR HHAS THAT DO NOT SUBMIT THE QUALITY DATA

CY 2019 National, Standardized 60-Day Episode Payment	Wage Index Budget Neutrality Factor	CY 2020 HH Payment Update Minus 2 Percentage Points	CY 2020 National, Standardized 60-Day Episode Payment
$3,154.27	X 1.0062	X 0.995	$3,157.96

c. CY 2020 Non-routine Medical Supply (NRS) Payment Rates for CY 2020 60-day Episodes of Care

All medical supplies (routine and non-routine) must be provided by the HHA while the patient is under a home health plan of care. Examples of supplies that can be considered non-routine include dressings for wound care, IV supplies, ostomy supplies, catheters, and catheter supplies. Payments for NRS are computed by multiplying the relative weight for a particular severity level by the NRS conversion factor. To determine the CY 2020 NRS conversion factor, we updated the CY 2019 NRS conversion factor ($54.20) by the CY 2020 home health payment update percentage of 1.5 percent. We did not apply a standardization factor as the NRS payment amount calculated from the conversion factor is not wage or case-mix adjusted when the final claim payment amount is computed. The proposed NRS conversion factor for CY 2020 is shown in Table 17.

TABLE 17: CY 2020 NRS CONVERSION FACTOR

CY 2019 NRS Conversion Factor	CY 2020 HH Payment Update	CY 2020 NRS Conversion Factor
$54.20	X 1.015	$55.01

Using the CY 2020 NRS conversion factor, the payment amounts for the six severity levels are shown in Table 18.

TABLE 18: CY 2020 NRS PAYMENT AMOUNTS

Severity Level	Points (Scoring)	Relative Weight	CY 2020 NRS Payment Amounts
1	0	0.2698	$14.84
2	1 to 14	0.9742	$53.59
3	15 to 27	2.6712	$146.94
4	28 to 48	3.9686	$218.31
5	49 to 98	6.1198	$336.65
6	99+	10.5254	$579.00

For HHAs that do not submit the required quality data, we updated the CY 2019 NRS conversion factor ($54.20) by the CY 2019 home health payment update percentage of 1.5 percent minus 2 percentage points. To determine the CY 2020 NRS conversion factor for HHAs that do not submit the required quality data we multiplied the CY 2019 NRS conversion factor ($54.20) by the CY 2020 HH Payment Update (0.995) to determine the CY 2020 NRS conversion factor ($53.93). The proposed CY 2020 NRS conversion factor for HHAs that do not submit quality data is shown in Table 19.

TABLE 19: CY 2020 NRS CONVERSION FACTOR FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

CY 2019 NRS Conversion Factor	CY 2020 HH Payment Update Percentage Minus 2 Percentage Points	CY 2020 NRS Conversion Factor
$54.20	X 0.995	$53.93

The payment amounts for the various severity levels based on the updated conversion factor for HHAs that do not submit quality data are calculated in Table 20.

TABLE 20: CY 2020 NRS PAYMENT AMOUNTS FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

Severity Level	Points (Scoring)	Relative Weight	CY 2020 NRS Payment Amounts
1	0	0.2698	$ 14.55
2	1 to 14	0.9742	$ 52.54
3	15 to 27	2.6712	$ 144.06
4	28 to 48	3.9686	$ 214.03
5	49 to 98	6.1198	$ 330.04
6	99+	10.5254	$ 567.63

In CY 2020, the NRS payment amounts apply to only those 60-day episodes that begin on or before December 31, 2019 but span the implementation of the PDGM and the 30-day unit of payment on January 1, 2020 (ending on February 28, 2020). Under the PDGM, NRS payments are included in the 30-day base payment rate.

d. CY 2020 National, Standardized 30-Day period Payment Amount

Section 1895(b)(3)(A)(i) of the Act requires that the standard prospective payment rate and other applicable amounts be standardized in a manner that eliminates the effects of variations in relative case-mix and area wage adjustments among different home health agencies in a budget-neutral manner. To determine the CY 2020 national, standardized 30-day period payment rate, we apply a wage index budget neutrality factor; and the home health payment update percentage discussed in section III.E.1. of this proposed rule.

To calculate the wage index budget neutrality factor, we simulated total payments for non-LUPA episodes using the proposed CY 2020 wage index and compared it to our simulation of total payments for non-LUPA episodes using the CY 2019 wage index. By dividing the total payments for non-LUPA episodes using the CY 2020 wage index by the total payments for non-LUPA episodes using the CY 2019 wage index, we obtain a wage index budget neutrality factor of 1.0062. We would apply the wage index budget neutrality factor of 1.0062 to the calculation of the CY 2019 national, standardized 30-day period payment rate as described in section III.B. of this proposed rule.

We note that in past years, a case-mix budget neutrality factor was annually applied to the HH PPS base rates to account for the change between the previous year's case-mix weights and the newly recalibrated case-mix weights. Since CY 2020 is the first year of PDGM, there is no way to do a case-mix budget neutrality factor in this manner. However, in future years under the PDGM, we would apply a case-mix budget neutrality factor with the annual payment update in order to account for the change between the previous year's PDGM case-mix weights.

Next, we would update the 30-day payment rate by the CY 2020 home health payment update percentage of 1.5 percent as required by section 53110 of the BBA of 2018 and as described in section III.F.1. of this proposed rule. The CY 2020 national, standardized 30-day period payment rate is calculated in Table 21.

TABLE 21: CY 2020 NATIONAL, STANDARDIZED 30-DAY PERIOD PAYMENT AMOUNT

CY 2020 30-day Budget Neutral (BN) Standard Amount	Wage Index Budget Neutrality Factor	CY 2020 HH Payment Update	CY 2020 National, Standardized 30-Day Period Payment
$1,754.37	X 1.0062	X 1.015	$1,791.73

The CY 2020 national, standardized 30-day episode payment rate for an HHA that does not submit the required quality data is updated by the CY 2020 home health payment update of 1.5 percent minus 2 percentage points and is shown in Table 22.

TABLE 22: CY 2020 NATIONAL, STANDARDIZED 30-DAY PERIOD PAYMENT AMOUNT FOR HHAS THAT DO NOT SUBMIT THE QUALITY DATA

CY 2019 National, Standardized 30-Day Period Payment	Wage Index Budget Neutrality Factor	CY 2020 HH Payment Update Minus 2 Percentage Points	CY 2020 National, Standardized 30-Day Period Payment
$1,754.37	X 1.0062	X 0.995	$1,756.42

e. CY 2020 National Per-Visit Rates for both 60-day Episodes of Care and 30-day Periods of Care

The national per-visit rates are used to pay LUPAs and are also used to compute imputed costs in outlier calculations. The per-visit rates are paid by type of visit or HH discipline. The six HH disciplines are as follows:

- Home health aide (HH aide).
- Medical Social Services (MSS).
- Occupational therapy (OT).
- Physical therapy (PT).
- Skilled nursing (SN).
- Speech-language pathology (SLP).

To calculate the CY 2020 national per-visit rates, we started with the CY 2019 national per-visit rates. Then we applied a wage index budget neutrality factor to ensure budget neutrality for LUPA per-visit payments. We calculated the wage index budget neutrality factor by simulating total payments for LUPA episodes using the CY 2020 wage index and comparing it to simulated total payments for LUPA episodes using the CY 2019 wage index. By dividing the total payments for LUPA episodes using the CY 2020 wage index by the total payments for LUPA episodes using the CY 2019 wage index, we obtained a wage index budget neutrality factor of 1.0066. We apply the wage index budget neutrality factor of 1.0066 in order to calculate the CY 2020 national per-visit rates.

The LUPA per-visit rates are not calculated using case-mix weights. Therefore, no case-mix weights budget neutrality factor is needed to ensure budget neutrality for LUPA payments. Lastly, the per-visit rates for each discipline are updated by the CY 2020 home health payment update percentage of 1.5 percent. The national per-visit rates are adjusted by the wage index based on the site of service of the beneficiary. The per-visit payments for LUPAs are separate from the LUPA add-on payment amount, which is paid for episodes that occur as the only episode or initial episode in a sequence of adjacent episodes. The CY 2020 national per-visit rates for HHAs that submit the required quality data are updated by the CY 2020 HH payment update percentage of 1.5 percent and are shown in Table 23.

TABLE 23: CY 2020 NATIONAL PER-VISIT PAYMENT AMOUNTS

HH Discipline	CY 2019 Per-Visit Payment	Wage Index Budget Neutrality Factor	CY 2020 HH Payment Update	CY 2020 Per-Visit Payment
Home Health Aide	$66.34	X 1.0065	X 1.015	$ 67.77
Medical Social Services	$234.82	X 1.0065	X 1.015	$239.89
Occupational Therapy	$161.24	X 1.0065	X 1.015	$164.72
Physical Therapy	$160.14	X 1.0065	X 1.015	$163.60
Skilled Nursing	$146.50	X 1.0065	X 1.015	$149.66
Speech-Language Pathology	$174.06	X 1.0065	X 1.015	$177.82

The CY 2020 per-visit payment rates for HHAs that do not submit the required quality data are updated by the CY 2020 HH payment update percentage of 1.5 percent minus 2 percentage points and are shown in Table 24.

TABLE 24: CY 2020 NATIONAL PER-VISIT PAYMENT AMOUNTS FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

HH Discipline	CY 2019 Per-Visit Rates	Wage Index Budget Neutrality Factor	CY 2020 HH Payment Update Minus 2 Percentage Points	CY 2020 Per-Visit Rates
Home Health Aide	$66.34	X 1.0065	X 0.995	$66.44
Medical Social Services	$234.82	X 1.0065	X 0.995	$235.16
Occupational Therapy	$161.24	X 1.0065	X 0.995	$161.48
Physical Therapy	$160.14	X 1.0065	X 0.995	$160.38
Skilled Nursing	$146.50	X 1.0065	X 0.995	$146. 71
Speech- Language Pathology	$174.06	X 1.0065	X 0.995	$174.32

f. Rural Add-On Payments for CYs 2020 Through 2022

1. Background

Section 421(a) of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA) (Pub. L. 108-173) required, for HH services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Act), for episodes or visits ending on or after April 1, 2004, and before April 1, 2005, that the Secretary increase the payment amount that otherwise would have been made under section 1895 of the Act for the services by 5 percent. Section 5201 of the Deficit Reduction Act of 2003 (DRA)

(Pub. L 108-171) amended section 421(a) of the MMA. The amended section 421(a) of the MMA required, for HH services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Act), on or after January 1, 2006, and before January 1, 2007, that the Secretary increase the payment amount otherwise made under section 1895 of the Act for those services by 5 percent.

Section 3131(c) of the Affordable Care Act amended section 421(a) of the MMA to provide an increase of 3 percent of the payment amount otherwise made under section 1895 of the Act for HH services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Act), for episodes and visits ending on or after April 1, 2010, and before January 1, 2016. Section 210 of the MACRA amended section 421(a) of the MMA to extend the rural add-on by providing an increase of 3 percent of the payment amount otherwise made under section 1895 of the Act for HH services provided in a rural area (as defined in section 1886(d)(2)(D) of the Act), for episodes and visits ending before January 1, 2018.

Section 50208(a) of the BBA of 2018 amended section 421(a) of the MMA to extend the rural add-on by providing an increase of 3 percent of the payment amount otherwise made under section 1895 of the Act for HH services provided in a rural area (as defined in section 1886(d)(2)(D) of the Act), for episodes and visits ending before January 1, 2019.

2. Rural Add-on Payments for CYs 2020 Through 2022

Section 50208(a)(1)(D) of the BBA of 2018 added a new subsection (b) to section 421 of the MMA to provide rural add-on payments for episodes or visits ending during CYs 2019 through 2022. It also mandated implementation of a new methodology for applying those payments. Unlike previous rural add-ons, which were applied to all rural areas uniformly, the extension provided varying add-on amounts depending on the rural county (or equivalent area) classification by classifying each rural county (or equivalent area) into one of three distinct categories: (1) rural counties and equivalent areas in the highest quartile of all counties and equivalent areas based on the number of Medicare home health episodes furnished per 100 individuals who are entitled to, or enrolled for, benefits under Part A of Medicare or enrolled for benefits under part B of Medicare only, but not enrolled in a Medicare Advantage plan under part C of Medicare (the ‘‘High utilization’’ category); (2) rural counties and equivalent areas with a

population density of 6 individuals or fewer per square mile of land area and are not included in the ''High utilization'' category (the ''Low population density'' category); and (3) rural counties and equivalent areas not in either the ''High utilization'' or ''Low population density'' categories (the ''All other'' category).

In the CY 2019 HH PPS final rule (83 FR 56443), CMS finalized policies for the rural add-on payments for CY 2019 through CY 2022, in accordance with section 50208 of the BBA of 2018. The CY 2019 HH PPS proposed rule (83 FR 32373) described the provisions of the rural add-on payments, the methodology for applying the new payments, and outlined how we categorized rural counties (or equivalent areas) based on claims data, the Medicare Beneficiary Summary File and Census data. The data used to categorize each county or equivalent area is available in the Downloads section associated with the publication of this rule at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Home-Health-Prospective-Payment-System-Regulations-and-Notices.html. In addition, an Excel file containing the rural county or equivalent area name, their Federal Information Processing Standards (FIPS) state and county codes, and their designation into one of the three rural add-on categories is available for download.

The HH PRICER module, located within CMS' claims processing system, will increase the proposed CY 2020 60-day and 30-day base payment rates described in section III.E. of this proposed rule by the appropriate rural add-on percentage prior to applying any case-mix and wage index adjustments. The CY 2020 through 2022 rural add-on percentages outlined in law are shown in Table 25.

TABLE 25: HH PPS RURAL ADD-ON PERCENTAGES, CYs 2020-2022

Category	CY 2020	CY 2021	CY 2022
High utilization	0.5%	None	None
Low population density	3.0%	2.0%	1.0%
All other	2.0%	1.0%	None

g. Low-Utilization Payment Adjustment (LUPA) Add-On Factors and Partial Payment Adjustments

Currently, LUPA episodes qualify for an add-on payment when the episode is the first or only episode in a sequence of adjacent episodes. As stated in the CY 2008 HH PPS final rule, LUPA add-on payments are made because the national per-visit payment rates do not adequately account for the front-loading of costs for the first LUPA episode of care as the average visit lengths in these initial LUPAs are 16 to 18 percent higher than the average visit lengths in initial non-LUPA episodes (72 FR 49848). LUPA episodes that occur as the only episode or as an initial episode in a sequence of adjacent episodes are adjusted by applying an additional amount to the LUPA payment before adjusting for area wage differences. In the CY 2014 HH PPS final rule (78 FR 72305), we changed the methodology for calculating the LUPA add-on amount by finalizing the use of three LUPA add-on factors: 1.8451 for SN; 1.6700 for PT; and 1.6266 for SLP. We multiply the per-visit payment amount for the first SN, PT, or SLP visit in LUPA episodes that occur as the only episode or an initial episode in a sequence of adjacent episodes by the appropriate factor to determine the LUPA add-on payment amount.

In the CY 2019 HH PPS final rule (83 FR 56440), we finalized our policy of continuing to multiply the per-visit payment amount for the first skilled nursing, physical therapy, or speech-language pathology visit in LUPA periods that occur as the only period of care or the initial 30-day period of care in a sequence of adjacent 30-day periods of care by the appropriate add-on factor (1.8451 for SN, 1.6700 for PT, and 1.6266 for SLP) to determine the LUPA add-on payment amount for 30-day periods of care under the PDGM. For example, using the proposed CY 2020 per-visit payment rates for those HHAs that submit the required quality data, for LUPA periods that occur as the only period or an initial period in a sequence of adjacent periods, if the first skilled visit is SN, the payment for that visit will be $276.14 (1.8451 multiplied by $149.66), subject to area wage adjustment.

Also in the CY 2019 HH PPS final rule (83 FR 56516), we finalized our policy that the process for partial payment adjustments for 30-day periods of care will remain the same as the process for 60-day episodes. The partial episode payment (PEP) adjustment is a proportion of the period payment and is based on the span of days including the start-of-care date (for example, the date of the first billable

service) through and including the last billable service date under the original plan of care before the intervening event in a home health beneficiary's care defined as a--

- Beneficiary elected transfer, or
- Discharge and return to home health that would warrant, for purposes of payment, a new OASIS assessment, physician certification of eligibility, and a new plan of care.

When a new 30-day period begins due to an intervening event, the original 30-day period will be proportionally adjusted to reflect the length of time the beneficiary remained under the agency's care prior to the intervening event. The proportional payment is the partial payment adjustment. The partial payment adjustment will be calculated by using the span of days (first billable service date through and including the last billable service date) under the original plan of care as a proportion of the 30-day period. The proportion will then be multiplied by the original case-mix and wage index to produce the 30-day payment.

F. Proposed Payments for High-Cost Outliers under the HH PPS

1. Background

Section 1895(b)(5) of the Act allows for the provision of an addition or adjustment to the home health payment amount otherwise made in the case of outliers because of unusual variations in the type or amount of medically necessary care. Under the HH PPS, outlier payments are made for episodes whose estimated costs exceed a threshold amount for each Home Health Resource Group (HHRG). The episode's estimated cost was established as the sum of the national wage-adjusted per-visit payment amounts delivered during the episode. The outlier threshold for each case-mix group or partial episode payment (PEP) adjustment is defined as the 60-day episode payment or PEP adjustment for that group plus a fixed-dollar loss (FDL) amount. For the purposes of the HH PPS, the FDL amount is calculated by multiplying the HH FDL ratio by a case's wage-adjusted national, standardized 60-day episode payment rate, which yields an FDL dollar amount for the case. The outlier threshold amount is the sum of the wage and case-mix adjusted PPS episode amount and wage-adjusted FDL amount. The outlier payment is defined to be a proportion of the wage-adjusted estimated cost that surpasses the wage-adjusted

threshold. The proportion of additional costs over the outlier threshold amount paid as outlier payments is referred to as the loss-sharing ratio.

As we noted in the CY 2011 HH PPS final rule (75 FR 70397 through 70399), section 3131(b)(1) of the Affordable Care Act amended section 1895(b)(3)(C) of the Act to require that the Secretary reduce the HH PPS payment rates such that aggregate HH PPS payments were reduced by 5 percent. In addition, section 3131(b)(2) of the Affordable Care Act amended section 1895(b)(5) of the Act by re-designating the existing language as section 1895(b)(5)(A) of the Act and revising the language to state that the total amount of the additional payments or payment adjustments for outlier episodes could not exceed 2.5 percent of the estimated total HH PPS payments for that year. Section 3131(b)(2)(C) of the Affordable Care Act also added section 1895(b)(5)(B) of the Act, which capped outlier payments as a percent of total payments for each HHA for each year at 10 percent.

As such, beginning in CY 2011, we reduced payment rates by 5 percent and targeted up to 2.5 percent of total estimated HH PPS payments to be paid as outliers. To do so, we first returned the 2.5 percent held for the target CY 2010 outlier pool to the national, standardized 60-day episode rates, the national per visit rates, the LUPA add-on payment amount, and the NRS conversion factor for CY 2010. We then reduced the rates by 5 percent as required by section 1895(b)(3)(C) of the Act, as amended by section 3131(b)(1) of the Affordable Care Act. For CY 2011 and subsequent calendar years we targeted up to 2.5 percent of estimated total payments to be paid as outlier payments, and apply a 10 percent agency-level outlier cap.

In the CY 2017 HH PPS proposed and final rules (81 FR 43737 through 43742 and 81 FR 76702), we described our concerns regarding patterns observed in home health outlier episodes. Specifically, we noted that the methodology for calculating home health outlier payments may have created a financial incentive for providers to increase the number of visits during an episode of care in order to surpass the outlier threshold; and simultaneously created a disincentive for providers to treat medically complex beneficiaries who require fewer but longer visits. Given these concerns, in the CY 2017 HH PPS final rule (81 FR 76702), we finalized changes to the methodology used to calculate outlier

payments, using a cost-per-unit approach rather than a cost-per-visit approach. This change in methodology allows for more accurate payment for outlier episodes, accounting for both the number of visits during an episode of care and also the length of the visits provided. Using this approach, we now convert the national per-visit rates into per 15-minute unit rates. These per 15-minute unit rates are used to calculate the estimated cost of an episode to determine whether the claim will receive an outlier payment and the amount of payment for an episode of care. In conjunction with our finalized policy to change to a cost-per-unit approach to estimate episode costs and determine whether an outlier episode should receive outlier payments, in the CY 2017 HH PPS final rule we also finalized the implementation of a cap on the amount of time per day that would be counted toward the estimation of an episode's costs for outlier calculation purposes (81 FR 76725). Specifically, we limit the amount of time per day (summed across the six disciplines of care) to 8 hours (32 units) per day when estimating the cost of an episode for outlier calculation purposes.

We plan to publish the cost-per-unit amounts for CY 2020 in the rate update change request, which is issued after the publication of the CY 2020 HH PPS final rule. We note that in the CY 2017 HH PPS final rule (81 FR 76724), we stated that we did not plan to re-estimate the average minutes per visit by discipline every year. Additionally, we noted that the per-unit rates used to estimate an episode's cost will be updated by the home health update percentage each year, meaning we would start with the national per-visit amounts for the same calendar year when calculating the cost-per-unit used to determine the cost of an episode of care (81 FR 76727). We note that we will continue to monitor the visit length by discipline as more recent data become available, and we may propose to update the rates as needed in the future.

In the CY 2019 HH PPS final rule (83 FR 56521), we finalized a policy to maintain the current methodology for payment of high-cost outliers upon implementation of the PDGM beginning in CY 2020 and that we will calculate payment for high-cost outliers based upon 30-day periods of care. The calculation of the proposed fixed-dollar loss ratio for CY 2020 for both the 60-day episodes that span the

implementation date, and for 30-day periods of care beginning on and after January 1, 2020 is detailed in this section.

2. Proposed Fixed Dollar Loss (FDL) Ratio for CY 2020

For a given level of outlier payments, there is a trade-off between the values selected for the FDL ratio and the loss-sharing ratio. A high FDL ratio reduces the number of episodes or periods that can receive outlier payments, but makes it possible to select a higher loss-sharing ratio, and therefore, increase outlier payments for qualifying outlier episodes or periods. Alternatively, a lower FDL ratio means that more episodes or periods can qualify for outlier payments, but outlier payments per episode or per period must then be lower.

The FDL ratio and the loss-sharing ratio must be selected so that the estimated total outlier payments do not exceed the 2.5 percent aggregate level (as required by section 1895(b)(5)(A) of the Act). Historically, we have used a value of 0.80 for the loss-sharing ratio which, we believe, preserves incentives for agencies to attempt to provide care efficiently for outlier cases. With a loss-sharing ratio of 0.80, Medicare pays 80 percent of the additional estimated costs that exceed the outlier threshold amount.

In the CY 2019 HH PPS final rule (83 FR 56439), we finalized a FDL ratio of 0.51 to pay up to, but no more than, 2.5 percent of total payments as outlier payments. For CY 2020, we are not proposing to update the FDL ratio for those 60-day episodes that span the implementation date of the PDGM; we would keep the FDL ratio for 60-day episodes in CY 2020 at 0.51. For this CY 2020 proposed rule, simulating payments using preliminary CY 2018 claims data (as of January 2019) and the CY 2019 HH PPS payment rates, we estimate that outlier payments in CY 2019 would comprise 2.42 percent of total payments for those 60-day episodes that span into 2020 and are paid under the national, standardized 60-day payment rate (with an FDL of 0.51) and 2.5 percent of total payments for PDGM 30-day periods using the 30-day budget-neutral payment amount as detailed in section III.B. of this proposed rule (with an FDL of 0.63). Given the statutory requirement that total outlier payments not exceed 2.5 percent of the total payments estimated to be made under the HH PPS, we are proposing that the FDL ratio for 30-day periods of care in CY 2020 would need to be set at 0.63 for 30-day periods of care based on our

simulations looking at both 60-day episodes that would span into CY 2020 and 30-day periods. We note that in the final rule, we will update our estimate of outlier payments as a percent of total HH PPS payments using the most current and complete year of HH PPS data (CY 2018 claims data as of June 30, 2019 or later) and therefore, we may adjust the final FDL ratio accordingly. We invite public comments on the proposed change to the FDL ratio for CY 2020.

G. Proposed Changes to the Split-Percentage Payment Approach for HHAs in CY 2020 and Subsequent Years

1. Background

In the current HH PPS, there is a split-percentage payment approach to the 60-day episode of care. The first bill, a Request for Anticipated Payment (RAP), is submitted at the beginning of the initial episode for 60 percent of the anticipated final claim payment amount. The second, final bill is submitted at the end of the 60-day episode for the remaining 40 percent. For all subsequent episodes for beneficiaries who receive continuous home health care, the episodes are paid at a 50/50 percentage payment split. RAP submissions are operationally significant, as the RAP establishes the beneficiary's primary HHA by alerting the claims processing system consolidating billing edits.

In the CY 2018 HH PPS proposed rule (82 FR 35270), we solicited comments as to whether the split-percentage payment approach would still be needed for HHAs to maintain adequate cash flow if the unit of payment changes from a 60-day episode to a 30-day period; ways to phase-out the split-percentage payment approach, including reducing the percentage of upfront payment incrementally over a period of time; and if the split-percentage payment approach was ultimately eliminated, whether submission of a Notice of Admission (NOA) within 5 days of the start of care would be needed to establish the primary HHA so the claims processing system would be alerted to a home health period of care. Commenters generally expressed support for continuing the split-percentage payment approach in the future under the proposed alternative case-mix model. While we solicited comments on the possibility of phasing-out the split-percentage payment approach in the future and the need for a NOA, commenters did not provide suggestions for a phase-out approach, but stated that they did not agree with requiring a NOA, given their

experience with a similar process under the Medicare hospice benefit. We did not finalize the change to a 30-day unit of payment in the CY 2018 HH PPS final rule to allow CMS more time to examine the effects of such change to a 30-day unit of payment and to an alternate case-mix methodology.

Section 1895(b)(2)(B) of the Act, as added by section 51001(a) of the BBA of 2018, requires that CMS move to a 30-day payment period from a 60-day payment period, effective January 1, 2020. As such, in the CY 2019 HH PPS proposed rule (83 FR 32391), we proposed a change to the split-percentage payment approach where newly-enrolled HHAs, meaning HHAs that were certified for participation in Medicare on or after January 1, 2019, would not receive split-percentage payments beginning in CY 2020. We also proposed that HHAs that are certified for participation in Medicare effective on or after January 1, 2019, would still be required to submit a "no pay" RAP at the beginning of care in order to establish the home health period of care, as well as every 30 days thereafter. Additionally, we proposed that existing HHAs, that is, HHAs certified for participation in Medicare effective prior to January 1, 2019, would continue to receive split-percentage payments upon implementation of the PDGM and the 30-day unit of payment in CY 2020. For split-percentage payments to be made, we proposed that existing HHAs would have to submit a RAP at the beginning of each 30-day period of care and a final claim would be submitted at the end of each 30-day period of care. For the first 30-day period of care, we proposed that the split-percentage payment would be 60/40 and all subsequent 30-day periods of care would be a split-percentage payment of 50/50.

Many commenters supported all or parts of the split-percentage payment proposals. Some commenters stated that elimination of the split-percentage payments would align better with a 30-day payment and would simplify home health claims submissions. Other commenters generally expressed support for continuing the split-percentage payment approach under the PDGM and disagreed with any future phase-out because of a potential impact on cash flow. Others supported eventual elimination of split-percentage payments but wanted ample time to adapt to the PDGM and suggested a multi-year phase-out approach. Some commenters supported elimination of split-percentage payments for late periods of care but suggested that the split-percentage payments should continue for early periods to

ensure an upfront payment for newly admitted home health patients. Ultimately, we finalized all of the split-percentage payments proposals in the CY 2019 HH PPS final rule (83 FR 56463), discussed previously.

2. CY 2019 HH PPS Final Rule Title Error Correction

In the CY 2019 HH PPS final rule with comment (83 FR 56628), we finalized that newly-enrolled HHAs, that is HHAs certified for participation in Medicare effective on or after January 1, 2019, will not receive split-percentage payments beginning in CY 2020. HHAs that are certified for participation in Medicare effective on or after January 1, 2019, will still be required to submit a ''no pay'' Request for Anticipated Payment (RAP) at the beginning of a period of care in order to establish the home health period of care, as well as every 30 days thereafter. Existing HHAs, meaning those HHAs that are certified for participation in Medicare with effective dates prior to January 1, 2019, would continue to receive split-percentage payments upon implementation of the PDGM and the change to a 30-day unit of payment in CY 2020. We finalized the corresponding regulations text changes at § 484.205(g)(2), which sets forth the policy for split-percentage payments for periods of care on or after January 1, 2020.

However, after the final rule was published, we note that there was an error in titling when the CY 2019 HH PPS final rule went to the Federal Register. Specifically, paragraph (g)(2)(ii) is incorrectly titled "Split percentage payments on or after January 1, 2019". The title of this paragraph implies that split percentage payments are made to newly-enrolled HHAs on or after January 1, 2019, which is contradictory to the finalized policy on split percentage-payments for newly enrolled HHAs beginning in CY 2020. As such, we are proposing to make a correction to the regulations text at § 484.205(g)(2)(iii) to accurately reflect the finalized policy that newly-enrolled HHAs will not receive split-percentage payments beginning in CY 2020. The regulation at § 484.205(g)(2)(iii), as it relates to split percentage payments for newly-enrolled HHAs under the HH PPS beginning in CY 2020, is separate from the placement of new HHAs into a provisional period of enhanced oversight under the authority of section 6401(a)(3) of the Affordable Care Act, which amended section 1866(j)(3) of the Act. The provisional period of enhanced oversight became effective in February 2019. More information regarding the

provisional period of enhanced oversight can be found at the following link: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE19005.pdf

3. CY 2020 and Subsequent Years

CMS continues to believe that, as a result of a reduced timeframe for the unit of payment from a 60-day episode of care to a 30-day period of care, a split-percentage payment approach may not be needed for HHAs to maintain an adequate cash flow. We also believe that a one-time submission of a NOA followed by home health claims submission on a 30-day basis may streamline claims processing for HHAs. Additionally, our analysis has shown that approximately 5 percent of RAPs are not submitted until the end of a 60-day episode of care, 10 percent of RAPs are not submitted until 36 days after the start of the 60-day episode of care, and the median length of days for RAP submission is 12 days from the start of the 60-day episode of care (82 FR 35307). We believe that these data are inconsistent with the stated justification for RAPs maintaining adequate cash flow, especially given the change from a 60- to 30-day unit of payment, and increases complexity for HHAs in their claim submission processing. With the change to monthly billing in CY 2020, HHAs should have the ability to maintain an ongoing cash flow, which we believe mitigates concerns for the continued need of a split-percentage payment.

We did not finalize any changes to RAP payments for existing HHAs in the CY 2019 HH PPS final rule (83 FR 56462), we stated that we would monitor RAP submissions, service utilization, payment and quality trends which may change as a result of implementing the PDGM and a 30-day unit of payment. We also stated if changes in practice and/or coding patterns or RAPs submissions arise, we may propose additional changes in policy.

We have observed that RAP payments pose a significant program integrity risk to the Medicare program, as the current RAP structure pays HHAs 50 to 60 percent of the total episode payment upfront. Currently, RAP payments are automatically recouped against other payments if the claim for a given episode does not follow the RAP submission in the later of: (1) 120 days from the start of the episode; or

(2) 60 days from the payment date of the RAP. As stated in the CY 2019 HH PPS proposed rule (83 FR 32391), some fraud schemes have involved HHAs collecting RAP payments, never submitting final claims, and ceasing business before CMS is aware of the need to take action.

Under a typical RAP fraud scenario, a large amount of RAPs are submitted in a short period of time, which could potentially result in payments of millions of dollars within days of the submissions. The 60-day or 120-day time period before a RAP cancellation is triggered in the Fiscal Intermediary Standard System (FISS) is long enough to allow a provider to continue to submit RAPs before we can identify that the final claims are not being submitted and services are not being rendered, and yet is too short for us to perform the necessary investigative steps, such as medical reviews, site verifications, and beneficiary interviews, to determine if fraudulent actions have been conducted. The current payment regulations also allow discharges and readmissions during a home health payment episode, which means that some HHAs can submit multiple RAPs for the same provider/patient combination during the same episode of care.

This type of fraud scheme has been most prevalent among existing providers. As a variation on this scheme, individuals with the intent of perpetuating this fraud enter the Medicare program by acquiring existing HHAs, allowing them to circumvent Medicare's screening and enrollment process. For example, during the screening process, we deny enrollment if owners listed on the enrollment form have certain criminal backgrounds. However, some providers who acquire HHAs fail to disclose ownership changes and as a result, the newly purchased HHA is not subject to the normal enrollment screening process leaving us blind to potentially problematic criminal histories. There are cases where we would have denied enrollment based on a new owner's prior criminal background, but we approve the enrollment of the purchasing entity due to the intentional omission of the new owner and his criminal history. More specifically, individuals intent on perpetrating the HH RAP fraud have taken advantage of the acquisition of existing agencies through Changes of Ownership (CHOWs) and Changes of Information, failing to disclose ownership changes for those HH entities to CMS. A CHOW results in the transfer of a previous owner's Medicare Identification Number and provider agreement (including the

previous owner's outstanding Medicare debts) to a new owner and must be reported within 30 days. A Change of Information must be submitted for various types of changes of information on an enrollment. For instance, a change in ownership other than a CHOW—such as the sale of stock from one of several 5 percent or more owners, who is no longer an owner, to a new individual who has become a 5 percent or more owner—also must be reported within 30 days of the change (see § 424.516(e)). Based on our investigations, individuals perpetrating the RAP fraud fail to disclose ownership or informational changes, which results in the changes not being reflected in the Provider Enrollment, Chain, and Ownership System **(**PECOS), the online Medicare provider and suppler enrollment system that allows registered users to securely and electronically submit and manage Medicare enrollment information. The lack of information concerning changes in ownership contributes to the perpetuation of HH RAP fraud.

CMS has monitored numerous schemes like this where an existing HHA undergoes an unreported ownership change and CMS identifies a massive spike in RAP submissions with no final claims ever being submitted. These types of RAP fraud cases are difficult to investigate because the actual owners perpetrating the fraud are often not the owners identified in PECOS due to a failure to disclose ownership changes. This complicates investigations and results in the need for additional resources to perform extensive manual research of Secretary of States' (SOS) and licensing agencies' websites. In several cases, the individuals perpetrating the fraud have been found to be located outside the country.

The following are examples of HHAs that were identified for billing large amounts of RAPs after a CHOW, or the acquisition of an existing agency, from 2014 to the present.

- Example 1: One prior investigation illustrates an individual intent on perpetrating the HH RAP fraud who took advantage of the acquisition of an existing agency. The investigation was initiated based on a lead generated by the Fraud Prevention System (FPS). Per PECOS, the provider had an effective date that was followed by a CHOW. The investigation was aided by a whistleblower coming forward who stated that the new owners of the agency completed the transaction with the intent to submit large quantities of fraudulent claims with the expressed purpose of receiving inappropriate payment from

Medicare. Notwithstanding the quick actions taken to prevent further inappropriate payments, the fraud scheme resulted in improper payments of RAPs and final claims in the amount of $1.3 million.

- Example 2: One investigation, CY 2019 HH PPS proposed rule (83 FR 32391), involved a HHA located in Michigan that submitted home health claims for beneficiaries located in California and Florida. Further analysis found that after a CHOW the HHA submitted RAPs with no final claims. CMS discovered that the address of record for the HHA was vacant for an extended period of time. In addition, we determined that although the HHA had continued billing and receiving payments for RAP claims, it had not submitted a final claim in 10 months. Ultimately, the HHA submitted a total of $50,234,430 in RAP claims and received $37,204,558 in RAP payments.

- Example 3: A HHA submitted a significant spike in the number of RAPs following an ownership change. The investigation identified that in the period following the CHOW there were RAP payments totaling $12 million and thousands of RAPs that were submitted for which apparently no services were rendered.

- Example 4: An Illinois HHA was identified through analysis of CHOW information. Three months after, the HHA had a CHOW, the provider submitted a spike in RAP suppressions. All payments to the provider were suspended. Notwithstanding, the provider was paid $3.6 million in RAPs.

We have attempted to address these types of vulnerabilities through extensive monitoring and investigations. However, there continues to be cases of individual HHAs causing large RAP fraud losses.

In the CY 2019 HH PPS final rule (83 FR 56462), we stated our plan to continue to closely monitor RAP submissions, service utilization, payment, and quality trends which may change as a result of implementing of the PDGM and a 30-day unit of payment in order to address unusual billing patterns and potential fraud related to RAP payments to existing providers. In light of the issues outlined in this section, we have determined that the program integrity concerns based upon the current RAP structure are significant enough to revisit the continued need for RAP payments for existing HHAs and propose a phase-out approach to RAP payments.

Therefore, we are proposing a reduction of the split-percentage payment in CY 2020 for existing HHAs and elimination of split-percentage payments for all providers in CY 2021, along with corresponding regulations text changes at § 484.205. Specifically, we are proposing, for existing HHAs (that is, HHAs certified for participation in Medicare with effective dates prior to January 1, 2019): (1) to reduce the split-percentage payment from the current 60/50 percent (dependent on whether the RAP is for a new or subsequent period of care) to 20 percent in CY 2020 for all 30-day HH periods of care (both initial and subsequent periods of care); and (2) full elimination of the split-percentage payments for all providers in CY 2021. We believe that the proposed phase-out approach of split-percentage payments with a reduction to a 20 percent split-percentage payment in CY 2020 allows HHAs time to adjust to a no-RAP environment and provides sufficient time for software and business process changes for a CY 2021 implementation. The current split-percentage payments are 60/40 (for initial episodes of care) and 50/50 (for subsequent episodes of care); therefore, we believe that the reduction in the split-percentage payment must be sufficient enough in order to mitigate the perpetuation of fraud schemes. As such, we believe a reduction to the split percentage payment to 20 percent would achieve this purpose. However, the 20 percent split percentage payment would still provide some upfront payment as HHAs transition from receiving split-percentage payments to receiving full payments on a 30-day basis.

Additionally, we are proposing that newly enrolled HHAs, that is, HHAs enrolled in Medicare on or after January 1, 2019 (and would not receive split-percentage payments beginning in CY 2020), would continue to submit "no-pay" RAPs at the beginning of every 30-day period in CY 2020. Beginning in CY 2021, we are proposing that all HHAs would receive the full 30-day period of care payment once the final claim is submitted to CMS.

Beginning in CY 2021, we are also proposing that all HHAs submit a one-time submission of a NOA within 5 calendar days of the start of care to establish that the beneficiary is under a Medicare home health period of care. The NOA would be used to trigger HH consolidated billing edits, required by law under section 1842(b)(6)(F) of the Act, and would allow for other providers and the CMS claims processing systems to know that the beneficiary is in a HH period of care. We are proposing that the

NOA be submitted only at the beginning of the first 30-day period of care (that is, the NOA would not have to be submitted for each subsequent 30-day period of care) to establish that the beneficiary is under a home health period of care. However, if there is any beneficiary discharge from home health services and subsequent readmission, a new NOA would need to be submitted within 5 calendar days of an initial 30-day period of care.

When we solicited comments in the CY 2019 HH PPS proposed rule (83 FR 32390) on requiring HHAs to submit a NOA within 5 days of the start of care if the split-percentage payment approach was eliminated, commenters stated that they did not agree with requiring a NOA given the experience with a similar Notice of Election (NOE) process under the Medicare hospice benefit where there were submission issues causing untimely filed NOEs. However, implementation of the Electronic Data Interchange (EDI) submission of hospice Notices of Election (NOE) in January 2018 has alleviated the issues related to the submission of the hospice NOE by increasing efficiency and information exchange coordination. As such, we are proposing that the home health NOA process would be through an EDI submission, similar to that used for submission of the hospice NOE. An EDI submission occurs when NOEs or NOAs are submitted through an electronic data interchange for the purpose of minimizing data entry errors. Because there is already a Medicare claims processing notification of a benefit admission process in place, we believe that this should make the home health NOA process more consistent and timely for HHAs.

Furthermore, because of the reduced timeframe for the unit of payment from a 60-day episode of care to a 30-day period of care and the proposed elimination of RAPs, NOAs would be needed for home health period of care identification (83 FR 32390). Without such notification triggering the home health consolidated billing edits establishing the home health period of care in the common working file (CWF), there could be an increase in claims denials. Subsequently, this potentially could result in an increase in appeals and an increase in situations where other providers, including other HHAs, would not have easily accessible information on whether a patient was already being treated by another HHA. In the CY 2019 HH PPS final rule, while some commenters expressed their concern about potential submission issues and

claims delays which could result from the potential use of a NOA, one national association was in support of such proposal. The association strongly recommended CMS require HHAs to submit a NOA within 5 calendar days from the start of care to ensure that the proper agency is established as the primary HHA for the beneficiary and so that the claims processing system is alerted that a beneficiary is under an HHA period of care to enforce the consolidated billing edits required by law.

We are proposing that failure to submit a timely NOA would result in a reduction to the 30-day Medicare payment amount, from the start of care date to the NOA filing date, as is done similarly in hospice. As hospice is paid a bundled per diem payment amount for each day a beneficiary is under a hospice election, Medicare will not cover and pay for the days of hospice care from the hospice admission date to the date the NOE is submitted to the Medicare contractor. Therefore, we are proposing that the penalty for not submitting a timely home health NOA would result in Medicare not paying for those days of home health services from the start of care date to the NOA filing date.

Since payment under home health is a bundled payment, which includes a national, standardized 30-day period payment rate adjusted for case-mix and geographic wage differences, we are proposing that the payment reduction would be applied to the case-mix and wage-adjusted 30-day period payment amount, including NRS. As such, we are proposing that the penalty for not submitting a timely NOA would be a 1/30 reduction off of the full 30-day period payment amount for each day until the date the NOA is submitted (that is, from the start of care date through the day before the NOA is submitted, as the day of submission would be a covered day). The reduction (R) to the full 30-day period payment amount would be calculated as follows:

- The number of days (d) from the start of care until the NOA is submitted divided by 30 days;
- The fraction from step 1 is multiplied by the case-mix and wage adjusted 30-day period payment amount (P).

The formula for the reduction would be $R= (d/30) \times P$.

There would be no NOA penalty if the NOA is submitted timely (that is, within the first 5 calendar days starting with the start of care date). Likewise, we propose that for periods of care in which an HHA fails

to submit a timely NOA, no LUPA payments would be made for days that fall within the period of care prior to the submission of the NOA. We are proposing that these days would be a provider liability, the payment reduction could not exceed the total payment of the claim, and that the provider may not bill the beneficiary for these days. Once the NOA is received, all claims for both initial and subsequent episodes of care would compare the receipt date of the NOA to the HH period of care start date to determine whether a late NOA reduction applies.

However, we are also proposing that if an exceptional circumstance is experienced by the HHA, CMS may waive the consequences of failure to submit a timely-filed NOA. For instance, if a HHA requests a waiver of the payment consequences due to an exceptional circumstance, the home health agency would fully document and furnish any requested documentation to CMS, through their corresponding MAC, for a determination of exception. We are proposing that these exceptional circumstances would be the same as those in place for the hospice NOE. That is, we are proposing that an exceptional circumstance for such waiver would be, but is not limited to the following:

- Fires, floods, earthquakes, or similar unusual events that inflict extensive damage to the home health agency's ability to operate.
- A CMS or Medicare contractor systems issue that is beyond the control of the home health agency.
- A newly Medicare-certified home health agency that is notified of that certification after the Medicare certification date, or which is awaiting its user ID from its Medicare contractor.
- Other situations determined by CMS to not be under the control of the home health agency.

We are soliciting comments on our proposals to phase-out the split percentage payments beginning in CY 2020 with the elimination of split-percentage payments in CY 2021 for existing HHAs (that is, those HHAs certified to participate in Medicare prior to January 1, 2019). We note that in the CY 2019 HH PPS final rule (83 FR 56463), we finalized that HHAs certified for participation in Medicare on and after January 1, 2019, would not receive split percentage payments beginning in CY 2020. We are also soliciting comments on the implementation of a NOA process, including the NOA timely-filing

requirement, for all HHAs, in CY 2021 and subsequent years; and the corresponding regulation text changes at § 484.205.

H. Proposed Regulatory Change to Allow Therapist Assistants to Perform Maintenance Therapy

As referenced in our regulations at § 409.44(c)(2)(iii), in order for therapy visits to be covered in the home health setting one of three criteria must be met: there must be an expectation that the beneficiary's condition will improve materially in a reasonable (and generally predictable) period of time based on the physician's assessment of the beneficiary's restoration potential and unique medical condition; the unique clinical condition of a patient requires the specialized skills, knowledge, and judgment of a qualified therapist to design or establish a safe and effective maintenance program required in connection with the patient's specific illness or injury; or the unique clinical condition of a patient requires the specialized skills of a qualified therapist to perform a safe and effective maintenance program required in connection with the patient's specific illness or injury. The regulations at § 409.44(c)(2)(iii)(C) state that where the clinical condition of the patient is such that the complexity of the therapy services required to maintain function involves the use of complex and sophisticated therapy procedures to be delivered by the therapist himself/herself (and not an assistant) or the clinical condition of the patient is such that the complexity of the therapy services required to maintain function must be delivered by the therapist himself/herself (and not an assistant) in order to ensure the patient's safety and to provide an effective maintenance program, then those reasonable and necessary services shall be covered.

In contrast to restorative therapy, provided when the goals of care are geared towards patient improvement, maintenance therapy is provided when improvement is not feasible in order to prevent or slow further decline/deterioration of the patient's condition. While a therapist assistant is able to perform restorative therapy under the Medicare home health benefit, the regulations at § 409.44(c)(2)(iii)(C) state that only a qualified therapist, and not an assistant, can perform maintenance therapy. Of note, the CY 2011 HH PPS final rule (75 FR 70372) reorganized the text regarding this regulation, but did not re-evaluate the policy.

The regulations at § 484.115(g) and (i) state that qualified occupational and physical therapist assistants are licensed as assistants unless licensure does not apply, are registered or certified, if applicable, as assistants by the state in which practicing, and have graduated from an approved curriculum for therapist assistants, and passed a national examination for therapist assistants. In states where licensure does not apply, therapist assistants must meet certain education and/or proficiency examination requirements. For example, physical therapist assistants (PTAs) in general, practice in accordance with physical therapy state practice acts, providing many of the services that a physical therapist (PT) provides, such as therapeutic exercise, mobilization, and passive manipulation.[15] Services must be commensurate with the PTA's education, training, and experience, and must be under the direction of a supervising PT. Additionally, Medicare allows services furnished by therapist assistants to be included as part of the covered services under a benefit when provided under the direction and supervision of a qualified therapist.[16] The regulations at § 409.44(c) set out the skilled service requirements for physical therapy, speech-language pathology services, and occupational therapy under the home health benefit. In accordance with § 409.44(c)(1)(i), a patient must be under a physician plan of care with documented therapy goals established by a qualified therapist in conjunction with the physician. Additionally, in accordance with § 409.44(c)(2)(i)(A) and (B), the patient's function must be initially assessed and reassessed at least every 30 calendar days by a qualified therapist. As such, under the Medicare home health benefit, a therapist assistant can furnish services covered under a home health plan of care, when provided under the direction and supervision of a qualified therapist, responsible for establishing the plan of care and assessing and reassessing the patient.

While Medicare allows for skilled maintenance therapy in a SNF, HH, and other outpatient settings, the type of clinician that can provide the therapy services vary by setting. In some settings both the therapist and the therapist assistant can deliver the skilled maintenance therapy services, and in other settings, only the therapist can deliver the skilled maintenance therapy services. For example, Medicare

15 https://www.laptboard.org/index.cfm/rules/practiceact
16 https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf

regulations allow therapist assistants to provide maintenance therapy in a SNF, but not in the home health setting. Furthermore, commenters on the CY 2019 Physician Fee Schedule final rule (83 FR 59654) noted concerns about shortages of therapists and finalized payment for outpatient therapy services for which payment is made for services that are furnished by a therapist assistant. As such, this rule recognizes that therapist assistants play a valuable role in the provision of needed therapy services.

We believe it would be appropriate to allow therapist assistants to perform maintenance therapy services under a maintenance program established by a qualified therapist under the home health benefit, if acting within the therapy scope of practice defined by state licensure laws. The qualified therapist would still be responsible for the initial assessment; plan of care; maintenance program development and modifications; and reassessment every 30 days, in addition to supervising the services provided by the therapist assistant. We believe this would allow home health agencies more latitude in resource utilization. Furthermore, allowing assistants to perform maintenance therapy would be consistent with other post-acute care settings, including SNFs. Thus, we are proposing to modify the regulations at § 409.44(c)(2)(iii)(C) to allow therapist assistants (rather than only therapists) to perform maintenance therapy under the Medicare home health benefit. We are soliciting comments regarding this proposal and we also welcome feedback on whether this proposal would require therapists to provide more frequent patient reassessment or maintenance program review when the services are being performed by a therapist assistant. We are also soliciting comments on whether we should revise the description of the therapy codes to indicate maintenance services performed by a physical or occupational therapist assistant (G0151 and G0157) versus a qualified therapist, or simply remove the therapy code indicating the establishment or delivery of a safe and effective physical therapy maintenance program, by a physical therapist (G0159). We welcome comments on the importance of tracking whether a visit is for maintenance or restorative therapy or whether it would be appropriate to only identify whether the service is furnished by a qualified therapist or an assistant. Finally, we seek comments on any possible effects on the quality of care that could result by allowing therapist assistants to perform maintenance therapy.

I. Proposed Changes to the Home Health Plan of Care Regulations at §409.43

As a condition for payment of Medicare home health services, the regulations at § 409.43(a), home health plan of care content requirements, state that the plan of care must contain those items listed in § 484.60(a) that specify the standards relating to a plan of care that an HHA must meet in order to participate in the Medicare program. The home health conditions of participation (CoPs) at § 484.60(a) set forth the content requirements of the individualized home health plan of care. In the January 13, 2017 final rule, "Medicare and Medicaid Program: Conditions of Participation for Home Health Agencies" (82 FR 4504), we finalized changes to the plan of care requirements under the home health CoPs by reorganizing the existing plan of care content requirements at § 484.18(a), adding two additional plan of care content requirements, and moving the plan of care content requirements to § 484.60(a). Specifically, in addition to the longstanding plan of care content requirements previously listed at § 484.18(a), a home health plan of care must also include the following:

- A description of the patient's risk for emergency department visits and hospital readmission, and all necessary interventions to address the underlying risk factors; and
- Information related to any advanced directives.

The new content requirements for the plan of care at § 484.60(a) became effective January 13, 2018 (82 FR 31729) and the Interpretive Guidelines to accompany the new CoPs were released on August 31, 2018. Since implementation of the new home health CoP plan of care requirements, we clarified in subregulatory guidance in the Medicare Benefit Policy Manual, chapter 7,[17] that the plan of care must include the identification of the responsible discipline(s) providing home health services, and the frequency and duration of all visits, as well as those items required by the CoPs that establish the need for such services (§ 484.60(a)(2)(iii) and (iv)).

However, the current requirements at § 409.43(a) may be overly prescriptive and may interfere with timely payment for otherwise eligible episodes of care. To mitigate these potential issues, we are proposing to change the regulations text at § 409.43(a). Specifically, we are proposing to change the regulations text to state that for HHA services to be covered, the individualized plan of care must specify

[17] https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c07.pdf

the services necessary to meet the patient-specific needs identified in the comprehensive assessment. In addition, the plan of care must include the identification of the responsible discipline(s) and the frequency and duration of all visits as well as those items listed in 42 CFR 484.60(a) that establish the need for such services. All care provided must be in accordance with the plan of care. While these newly-added plan of care items at § 484.60(a) remain CoP, we believe that violations for missing required items are best addressed through the survey process, rather than through claims denials for otherwise eligible periods of care. We are soliciting comments on this proposal to change to the regulations text at § 409.43 to state that the home health plan of care must include those items listed in 42 CFR 484.60(a) that establish the need for such services.

IV. Proposed Provisions of the Home Health Value-Based Purchasing (HHVBP) Model

A. Background

As authorized by section 1115A of the Act and finalized in the CY 2016 HH PPS final rule (80 FR 68624) and in the regulations at 42 CFR part 484, subpart F, we began testing the HHVBP Model on January 1, 2016. The HHVBP Model has an overall purpose of improving the quality and delivery of home health care services to Medicare beneficiaries. The specific goals of the Model are to: (1) provide incentives for better quality care with greater efficiency; (2) study new potential quality and efficiency measures for appropriateness in the home health setting; and (3) enhance the current public reporting process.

Using the randomized selection methodology finalized in the CY 2016 HH PPS final rule, we selected nine states for inclusion in the HHVBP Model, representing each geographic area across the nation. All Medicare-certified Home Health Agencies (HHAs) providing services in Arizona, Florida, Iowa, Maryland, Massachusetts, Nebraska, North Carolina, Tennessee, and Washington are required to compete in the Model. The HHVBP Model uses the waiver authority under section 1115A(d)(1) of the Act to adjust Medicare payment rates under

section 1895(b) of the Act based on the competing HHAs' performance on applicable measures. The maximum payment adjustment percentage increases incrementally, upward or downward, over the course of the HHVBP Model in the following manner: (1) 3 percent in CY 2018; (2) 5 percent in CY 2019; (3) 6 percent in CY 2020; (4) 7 percent in CY 2021; and (5) 8 percent in CY 2022. Payment adjustments are based on each HHA's Total Performance Score (TPS) in a given performance year (PY), which is comprised of performance on: (1) a set of measures already reported via the Outcome and Assessment Information Set (OASIS), completed Home Health Consumer Assessment of Healthcare Providers and Systems (HHCAHPS) surveys, and select claims data elements; and (2) three New Measures for which points are achieved for reporting data.

In the CY 2017 HH PPS final rule (81 FR 76741 through 76752), CY 2018 HH PPS final rule (83 FR 51701 through 51706), and CY 2019 HH PPS final rule (83 FR 56527 through 56547), we finalized changes to the HHVBP Model. Some of those changes included adding and removing measures from the applicable measure set, revising our methodology for calculating benchmarks and achievement thresholds at the state level, creating an appeals process for recalculation requests, and revising our methodologies for weighting measures and assigning improvement points.

B. Public Reporting of Total Performance Scores and Percentile Rankings under the HHVBP Model

As stated previously and discussed in prior rulemaking, one of the goals of the HHVBP Model is to enhance the current public reporting processes for home health. In the CY 2016 HH PPS final rule, we finalized our proposed reporting framework for the HHVBP Model, including both the annual and quarterly reports that are made available to competing HHAs and a separate,

publicly available quality report (80 FR 68663 through 68665). We stated that such publicly available performance reports would inform home health industry stakeholders (consumers, physicians, hospitals) as well as all competing HHAs delivering care to Medicare beneficiaries within selected state boundaries on their level of quality relative to both their peers and their own past performance, and would also provide an opportunity to confirm that the beneficiaries referred for home health services are being provided the best quality of care available. We further stated that we intended to make public competing HHAs' TPSs with the intention of encouraging providers and other stakeholders to utilize quality ranking when selecting an HHA. As summarized in the CY 2016 final rule (80 FR 68665), overall, commenters generally encouraged the transparency of data pertaining to the HHVBP Model. Commenters offered that to the extent possible, accurate comparable data would provide HHAs the ability to improve care delivery and patient outcomes, while better predicting and managing quality performance and payment updates.

We have continued to discuss and solicit comments on the scope of public reporting under the HHVBP Model in subsequent rulemaking. In the CY 2017 final rule (81 FR 76751 through 76752), we discussed the public display of total performance scores, stating that annual publicly available performance reports would be a means of developing greater transparency of Medicare data on quality and aligning the competitive forces within the market to deliver care based on value over volume. We stated our belief that the public reporting of competing HHAs' performance scores under the HHVBP Model would support our continued efforts to empower consumers by providing more information to help them make health care decisions, while also encouraging providers to strive for higher levels of quality. We explained that we have employed a variety of means (CMS Open Door Forums, webinars, a dedicated help desk, and a

web-based forum where training and learning resources are regularly posted) to facilitate direct communication, sharing of information and collaboration to ensure that we maintain transparency while developing and implementing the HHVBP Model. This same care was taken with our plans to publicly report performance data, through collaboration with other CMS components that use many of the same quality measures. We also noted that section 1895(b)(3)(B)(v) of the Act requires HHAs to submit patient-level quality of care data using the OASIS and the HHCAHPS, and that section 1895(b)(3)(B)(v)(III) of the Act states that this quality data is to be made available to the public. Thus, HHAs have been required to collect OASIS data since 1999 and report HHCAHPS data since 2012.

We solicited further public comment in the CY 2019 HH PPS proposed rule (83 FR 32438) on which information from the Annual Total Performance Score and Payment Adjustment Report (Annual Report) should be made publicly available. We noted that HHAs have the opportunity to review and appeal their Annual Report as outlined in the appeals process finalized in the CY 2017 HH PPS final rule (81 FR 76747 through 76750). Examples of the information included in the Annual Report are the agency name, address, TPS, payment adjustment percentage, performance information for each measure used in the Model (for example, quality measure scores, achievement, and improvement points), state and cohort information, and percentile ranking. We stated that based on the public comments received, we would consider what information, specifically from the Annual Report, we may consider proposing for public reporting in future rulemaking.

As we summarized in the CY 2019 HH PPS final rule (83 FR 56546 through 56547), several commenters expressed support for publicly reporting information from the Annual Total Performance Score and Payment Adjustment Report, as they believed it would better inform

consumers and allow for more meaningful and objective comparisons among HHAs. Other commenters suggested that CMS consider providing the percentile ranking for HHAs along with their TPS and expressed interest in publicly reporting all information relevant to the HHVBP Model. Several commenters expressed concern with publicly displaying HHAs' TPSs, citing that the methodology is still evolving and pointing out that consumers already have access to data on the quality measures in the Model on Home Health Compare. Another commenter believed that publicly reporting data just for states included in the HHVBP Model could be confusing for consumers.

Our belief remains that publicly reporting HHVBP data would enhance the current home health public reporting processes as it would better inform beneficiaries when choosing an HHA, while incentivizing HHAs to improve quality. Although the data made public would only pertain to the final performance year of the Model, we believe that publicly reporting HHVBP data for Performance Year 5 would nonetheless incentivize HHAs to improve performance. Consistent with our discussion in prior rulemaking of the information that we are considering for public reporting under the HHVBP Model, we propose to publicly report, on the CMS Website the following two points of data from the final CY 2020 (PY) 5 Annual Report for each participating HHA in the Model that qualified for a payment adjustment for CY 2020: (1) the HHA's TPS from PY 5, and (2) the HHA's corresponding PY 5 TPS Percentile Ranking. We are considering making these data available on the HHVBP Model page of the CMS Innovation website (https://innovation.cms.gov/initiatives/home-health-value-based-purchasing-model). These data would be reported for each such competing HHA by agency name, city, state, and by the agency's CMS Certification Number (CCN). We expect that these data would be made public

after December 1, 2021, the date by which we intend to complete the CY 2020 Annual Report appeals process and issuance of the final Annual Report to each HHA.

As discussed in prior rulemaking, we believe the public reporting of such data would further enhance quality reporting under the Model by encouraging participating HHAs to provide better quality of care through focusing on quality improvement efforts that could potentially improve their TPS. In addition, we believe that publicly reporting performance data that indicates overall performance may assist beneficiaries, physicians, discharge planners, and other referral sources in choosing higher-performing HHAs within the nine Model states and allow for more meaningful and objective comparisons among HHAs on their level of quality relative to their peers.

We believe that the TPS would be more meaningful if the corresponding TPS Percentile Ranking were provided so consumers can more easily assess an HHA's relative performance. We would also provide definitions for the HHVBP TPS and the TPS Percentile Ranking methodology to ensure the public understands the relevance of these data points and how they were calculated.

Under our proposal, the data reported would be limited to one year of the Model. We believe this proposal strikes a balance between allowing for public reporting under the Model for the reasons discussed while heeding commenters' concerns about reporting performance data for earlier performance years of the HHVBP Model. We believe publicly reporting the TPS and TPS Percentile Ranking for CY 2020 would enhance quality reporting under the Model by encouraging participating HHAs to provide better quality of care and would promote transparency, and could enable beneficiaries to make better informed decisions about where to receive care.

We are soliciting comment on our proposal to publicly report the Total Performance Score and Total Performance Score Percentile Ranking from the final CY 2020 PY 5 Annual Report for each HHA in the nine Model states that qualified for a payment adjustment for CY 2020. We are also soliciting comment on our proposed amendment to § 484.315 to reflect this policy. Specifically, we are proposing to add new paragraph (d) to specify that CMS will report, for performance year 5, the TPS and the percentile ranking of the TPS for each competing HHA on the CMS Website.

C. CMS Proposal to Remove Improvement in Pain Interfering with Activity Measure (NQF #0177)

As discussed in section V.C. of this proposed rule, CMS is proposing to remove the Improvement in Pain Interfering with Activity Measure (NQF #0177) from the Home Health Quality Reporting Program (HH QRP) beginning with CY 2022. Under this proposal, HHAs would no longer be required to submit OASIS Item M1242, Frequency of Pain Interfering with Patient's Activity or Movement, for the purposes of the HH QRP beginning January 1, 2021. As HHAs would continue to be required to submit their data for this measure through CY 2020, we do not anticipate any impact on the collection of this data and the inclusion of the measure in the HHVBP Model's applicable measure set for the final performance year (CY 2020) of the Model.

V. Proposed Updates to the Home Health Care Quality Reporting Program (HH QRP)

A. Background and Statutory Authority

The HH QRP is authorized by section 1895(b)(3)(B)(v) of the Act. Section 1895(b)(3)(B)(v)(II) of the Act requires that for 2007 and subsequent years, each HHA submit to the Secretary in a form and manner, and at a time, specified by the Secretary, such data that the Secretary determines are appropriate for the measurement of health care quality. To the extent

that an HHA does not submit data in accordance with this clause, the Secretary shall reduce the home health market basket percentage increase applicable to the HHA for such year by 2 percentage points. As provided at section 1895(b)(3)(B)(vi) of the Act, depending on the market basket percentage increase applicable for a particular year, the reduction of that increase by 2 percentage points for failure to comply with the requirements of the HH QRP and further reduction of the increase by the productivity adjustment (except in 2018 and 2020) described in section 1886(b)(3)(B)(xi)(II) of the Act may result in the home health market basket percentage increase being less than 0.0 percent for a year, and may result in payment rates under the Home Health PPS for a year being less than payment rates for the preceding year.

For more information on the policies we have adopted for the HH QRP, we refer readers to the CY 2007 HH PPS final rule (71 FR 65888 through 65891), the CY 2008 HH PPS final rule (72 FR 49861 through 49864), the CY 2009 HH PPS update notice (73 FR 65356), the CY 2010 HH PPS final rule (74 FR 58096 through 58098), the CY 2011 HH PPS final rule (75 FR 70400 through 70407), the CY 2012 HH PPS final rule (76 FR 68574), the CY 2013 HH PPS final rule (77 FR 67092), the CY 2014 HH PPS final rule (78 FR 72297), the CY 2015 HH PPS final rule (79 FR 66073 through 66074), the CY 2016 HH PPS final rule (80 FR 68690 through 68695), the CY 2017 HH PPS final rule (81 FR 76752), the CY 2018 HH PPS final rule (82 FR 51711 through 51712), and the CY 2019 HH PPS final rule (83 FR 56547).

B. General Considerations Used for the Selection of Quality Measures for the HH QRP

For a detailed discussion of the considerations we historically use for measure selection for the HH QRP quality, resource use, and others measures, we refer readers to the CY 2016 HH PPS final rule (80 FR 68695 through 68696). In the CY 2019 HH PPS final rule (83 FR 56548

through 56550) we also finalized the factors we consider for removing previously adopted HH QRP measures.

C. Quality Measures Currently Adopted for the CY 2021 HH QRP

The HH QRP currently includes 19[18] measures for the CY 2021 program year, as outlined in Table 26.

TABLE 26: MEASURES CURRENTLY ADOPTED FOR THE CY 2021 HH QRP

Short Name	Measure Name & Data Source
OASIS-based	
Ambulation	Improvement in Ambulation/Locomotion (NQF #0167).
Application of Falls	Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674).
Application of Functional Assessment	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).
Bathing	Improvement in Bathing (NQF #0174).
Bed Transferring	Improvement in Bed Transferring (NQF # 0175).
DRR	Drug Regimen Review Conducted With Follow-Up for Identified Issues-Post Acute Care (PAC) HH QRP.
Drug Education	Drug Education on All Medications Provided to Patient/Caregiver during All Episodes of Care.
Dyspnea	Improvement in Dyspnea.
Influenza	Influenza Immunization Received for Current Flu Season
Oral Medications	Improvement in Management of Oral Medications (NQF #0176).
Pain	Improvement in Pain Interfering with Activity (NQF #0177).
Pressure Ulcer/Injury	Changes in Skin Integrity Post-Acute Care
Timely Care	Timely Initiation Of Care (NQF #0526).
Claims-based	
ACH	Acute Care Hospitalization During the First 60 Days of HH (NQF #0171).
DTC	Discharge to Community-Post Acute Care (PAC) Home Health (HH) Quality Reporting Program (QRP).
ED Use	Emergency Department Use without Hospitalization During the First 60 Days of HH (NQF #0173).
MSPB	Total Estimated Medicare Spending Per Beneficiary (MSPB)—Post Acute Care (PAC) HH QRP.
PPR	Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH Quality Reporting Program.
HHCAHPS-based	
CAHPS Home Health Survey	CAHPS® Home Health Care Survey (experience with care) (NQF #0517) - How often the HH team gave care in a professional way. - How well did the HH team communicate with patients. - Did the HH team discuss medicines, pain, and home safety with patients. - How do patients rate the overall care from the HHA. - Will patients recommend the HHA to friends and family.

D. Proposed Removal of HH QRP Measures Beginning with the CY 2022 HH QRP

In line with our Meaningful Measures Initiative, we are proposing to remove one measure from the HH QRP beginning with the CY 2022 HH QRP.

18 The HHCAHPS has five component questions that together are used to represent one NQF-endorsed measure.

1. Proposed Removal of the Improvement in Pain Interfering with Activity Measure (NQF #0177)

We are removing pain-associated quality measures from its quality reporting programs in an effort to mitigate any potential unintended, over-prescription of opioid medications inadvertently driven by these measures. We are proposing to remove the Improvement in Pain Interfering with Activity Measure (NQF #0177) from the HH QRP beginning with the CY 2022 HH QRP under our measure removal Factor 7: Collection or public reporting of a measure leads to negative unintended consequences other than patient harm.

In the CY 2007 HH PPS final rule (71 FR 65888 through 65891), we adopted the Improvement in Pain Interfering with Activity Measure beginning with the CY 2007 HH QRP. The measure was NQF-endorsed (NQF #0177) in March 2009. This risk-adjusted outcome measure reports the percentage of HH episodes during which the patient's frequency of pain with activity or movement improved. The measure is calculated using OASIS Item M1242, Frequency of Pain Interfering with Patient's Activity or Movement.[19]

We evaluated the Improvement in Pain Interfering with Activity Measure (NQF #0177) and determined that the measure could have unintended consequences with respect to responsible use of opioids for the management of pain. In 2018, CMS published a comprehensive roadmap, available at https://www.cms.gov/About-CMS/Agency-Information/Emergency/Downloads/Opioid-epidemic-roadmap.pdf, which outlined the agency's efforts to address national issues around prescription opioid misuse and overuse. Because the Medicare program pays for a significant amount of prescription opioids, the roadmap was designed to promote appropriate stewardship of these medications that can provide a medical

[19] Measure specifications can be found in the Home Health Process Measures Table on the Home Health Quality Measures website https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/Home-Health-Outcome-Measures-Table-OASIS-D-11-2018c.pdf

benefit but also carry a risk for patients, including those receiving home health. One key component of this strategy is to prevent new cases of opioid use disorder, through education, guidance and monitoring of opioid prescriptions. When used correctly, prescription opioids are helpful for treating pain. However, effective non-opioid pain treatments are available to providers and CMS is working to promote their use.

Although we are not aware of any scientific studies that support an association between the prior or current iterations of the Improvement in Pain Interfering with Activity Measure (NQF #0177) and opioid prescribing practices, out of an abundance of caution and to avoid any potential unintended consequences, we are proposing to remove the Improvement in Pain Interfering with Activity Measure (NQF #0177) from the HH QRP beginning with the CY 2022 HH QRP under measure removal Factor 7: Collection or public reporting of a measure leads to negative unintended consequences other than patient harm.

If finalized as proposed, HHAs would no longer be required to submit OASIS Item M1242, Frequency of Pain Interfering with Patient's Activity or Movement for the purposes of this measure beginning January 1, 2021. We are unable to remove M1242 earlier due to the timelines associated with implementing changes to OASIS. If finalized as proposed, data for this measure would be publicly reported on HH Compare until April 2020.

We are inviting public comment on this proposal.

E. Proposed New and Modified HH QRP Quality Measures Beginning with the CY 2022 HH QRP

In this proposed rule, we are proposing to adopt two process measures for the HH QRP under section 1895(b)(3)(B)(v)(IV)(aa) of the Act, both of which would satisfy section 1899B(c)(1)(E)(ii) of the Act, which requires that the quality measures specified by the Secretary

include measures with respect to the quality measure domain titled "Accurately communicating the existence of and providing for the transfer of health information and care preferences of an individual to the individual, family caregiver of the individual, and providers of services furnishing items and services to the individual, when the individual transitions from a [post-acute care] PAC provider to another applicable setting, including a different PAC provider, a hospital, a critical access hospital, or the home of the individual." Given the length of this domain title, hereafter, we will refer to this quality measure domain as "Transfer of Health Information." The two measures we are proposing to adopt are: (1) Transfer of Health Information to Provider–Post-Acute Care; and (2) Transfer of Health Information to Patient–Post-Acute Care. 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. One data element in the Transfer of Health Information to Patient–Post-Acute Care measure evaluates whether information was sent to the patient, family, and caregiver at discharge.

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

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

The proposed Transfer of Health Information to the Provider–Post-Acute Care (PAC) Measure is a process-based measure that assesses whether or not a current reconciled medication list is given to the admitting provider when a patient is discharged/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 9 percent who were discharged to SNFs.[20] 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), underscoring the importance of the measure. 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 an HHA, three percent were discharged to an IRF, and one percent were discharged to an LTCH.[21]

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.[22, 23, 24, 25, 26, 27] Poor communication and coordination across health care settings contributes to patient complications, hospital readmissions, emergency department visits, and

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20 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.
21 Ibid.
22 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.
23 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.
24 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.
25 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.
26 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.
27 Boling, P. A., "Care transitions and home health care," Clinical Geriatric Medicine, 2009, Vol.25(1), pp. 135-48.

medication errors.[28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39] Communication has been cited as the third most frequent root cause in sentinel events, which The Joint Commission defines[40] 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.[41] 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.[42, 43, 44, 45, 46, 47]

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28 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.

29 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.

30 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.

31 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

32 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.

34 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

35 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.

36 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.

37 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.

38 Lattimer, C. (2011). When it comes to transitions in patient care, effective communication can make all the difference. Generations, 35(1), 69–72.

39 Vognar, L., & Mujahid, N. (2015). Healthcare transitions of older adults: an overview for the general practitioner. Rhode Island Medical Journal (2013), 98(4), 15–18.

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

41 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.

42 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.

43 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.

44 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.

45 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.

Care transitions across health care settings have been characterized as complex, costly, and potentially hazardous, and may increase the risk for multiple adverse outcomes. [48, 49] 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.[50] The communication of health information and patient care preferences is critical to ensuring safe and effective transitions from one health care setting to another.[51, 52]

Patients in PAC settings often have complicated medication regimens and require efficient and effective communication and coordination of care between settings, including detailed transfer of medication information.[53, 54, 55] Patients in PAC settings may be vulnerable to adverse health outcomes due to insufficient medication information on the part of their health

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46 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.
47 Siefferman, J. W., Lin, E., & Fine, J. S. (2012). Patient safety at handoff in rehabilitation medicine. Physical Medicine and Rehabilitation Clinics of North America, 23(2), 241-257.
48 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.
49 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/.
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52 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.
53 Starmer A. J, Spector N. D., Srivastava R., West, D. C., Rosenbluth, G., Allen, A. D., Noble, E. L., & Landrigen, C. P., "Changes in medical errors after implementation of a handoff program," N Engl J Med, 2014, Vol. 37(1), pp. 1803-1812.
54 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
55 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.

care providers, and the higher likelihood for multiple comorbid chronic conditions, polypharmacy, and complicated transitions between care settings.[56,57] Preventable adverse drug events (ADEs) may occur after hospital discharge in a variety of settings including PAC.[58] For older patients discharged from the hospital, 80 percent of the medication errors occurring during patient handoffs relate to miscommunication between providers[59] and for those transferring to an HHA, medication errors typically relate to transmission of inaccurate discharge medication lists.[60] 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.[61, 62]

Patients in PAC settings often take 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. Medication discrepancies in PAC are common, such as those identified in transition from hospital to SNF[63] and hospital to home.[64] In

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57 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 the Inspector General, February 2014. Available at: https://oig.hhs.gov/oei/reports/oei-06-11-00370.pdf.

58 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.

59 Siefferman, J. W., Lin, E., & Fine, J. S. (2012). Patient safety at handoff in rehabilitation medicine. Physical Medicine and Rehabilitation Clinics of North America, 23(2), 241-257.

60 Hale, J., Neal, E. B., Myers, A., Wright, K. H. S., Triplett, J., Brown, L. B., & Mixon, A. S. (2015). Medication Discrepancies and Associated Risk Factors Identified in Home Health patients. Home Healthcare Now, 33(9), 493–499 https://doi.org/10.1097/NHH.0000000000000290

61 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.

62 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.

63 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.

64 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.188-96.

one small intervention study, approximately 90 percent of the sample of 101 patients experienced at least one medication discrepancy in the transition from hospital to home care.[65]

We would define a reconciled medication list as a list of the current prescribed and over the counter (OTC) medications, nutritional supplements, vitamins, and homeopathic and herbal products administered by any route to the patient/resident at the time of discharge or transfer. Medications may also include but are not limited to total parenteral nutrition (TPN) and oxygen. The current medications should include those that are: (1) active, including those that will be discontinued after discharge; and (2) those held during the stay and planned to be continued/resumed after discharge. If deemed relevant to the patient's/resident's care by the subsequent provider, medications discontinued during the stay may be included.

A reconciled medication list often includes important information about: (1) the patient/resident - including their name, date of birth, information, active diagnoses, known medication and other allergies, and known drug sensitivities and reactions; and (2) each medication, including the name, strength, dose, route of medication administration, frequency or timing, purpose/indication, any special instructions (for example, crush medications), and, for any held medications, the reason for holding the medication and when medication should resume. This information can improve medication safety. Additional information may be applicable and important to include in the medication list such as the patient's/resident's weight and date taken, height and date taken, patient's preferred language, patient's ability to self-administer medication, when the last dose of the medication was administered by the discharging provider, and when the final dose should be administered (for example, end of treatment). This is not an exhaustive list of the information that could be included in the medication list. The suggested elements detailed in the definition above are for guidance purposes only and are not a requirement for the types of information to be included in a reconciled medication list in order to meet the measure criteria.

(b) Stakeholder and TEP Input

65 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.188-96.

The proposed Transfer of Health Information to the Provider–Post-Acute Care (PAC) measure was developed after consideration of feedback we received from stakeholders and four TEPs convened by our contractors. Further, the proposed measure was developed after evaluation of data collected during two pilot tests we conducted in accordance with the CMS Measures Management System Blueprint.

Our measure development contractors convened a TEP, which met on September 27, 2016[66], January 27, 2017, and August 3, 2017[67] 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 a 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 the feasibility of implementing the measure across PAC settings. Overall, the TEP was supportive of the 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.

66 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

67 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

Our measure development contractors solicited stakeholder feedback on the proposed measure by requesting comment on the CMS Measures Management System Blueprint website, and accepted comments that were submitted from March 19, 2018 to May 3, 2018. The comments received expressed overall support for the measure. Several commenters suggested ways to improve the measure, primarily related to what types of information should be included 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 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 on the 2018 Measures Under Consideration (MUC) list for HH QRP. The NQF-convened MAP Post-Acute Care- Long Term Care (PAC LTC) Workgroup met on December 10, 2018 and provided input on this proposed Transfer of Health Information to the Provider–Post-Acute Care measure. 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/Projects/i-m/MAP/PAC-LTC_Workgroup/2019_Considerations_for_Implementing_Measures_Draft_Report.aspx.

As part of the measure development and selection process, we identified one NQF-endorsed quality measure related to the proposed measure, titled Documentation of Current Medications in the Medical Record (NQF #0419e, 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 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 measure addresses the transfer of medication information whereas the NQF-endorsed measure #0419e

assesses the documentation of medications, but not the transfer of such information. 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 #0419e does not. After review of the NQF-endorsed measure, we determined that the proposed Transfer of Health Information to Provider–Post-Acute Care 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 post-acute care assessment instruments.

Section 1899B(e)(2)(A) of the Act requires that measures specified by the Secretary under section 1899B of the Act be endorsed by the consensus-based 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 the consensus-based entity under a contract with the Secretary. For these reasons, 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 quality episodes with a discharge/transfer assessment indicating that a current reconciled medication list was provided to the admitting provider at the time of discharge/transfer.

The proposed measure denominator is the total number of quality episodes ending in discharge/transfer to an "admitting provider," which is defined as: a short-term general hospital, intermediate care, home under care of another organized home health service organization or a hospice, a hospice in an institutional facility, a SNF, an LTCH, an IRF, an inpatient psychiatric facility, or a critical access hospital (CAH). These providers were selected for inclusion in the denominator because they represent admitting providers captured by the current discharge location items on the OASIS. The proposed measure numerator is the number of HH quality episodes (Start of Care or Resumption of Care OASIS assessment and a Transfer or Discharge OASIS Assessment) indicating a current reconciled medication list was provided to the admitting provider at the time of discharge/transfer. The proposed measure also collects data on how information is exchanged in PAC facilities, informing consumers and providers on how information was transferred at discharge/transfer. Data pertaining to how information is transferred by PAC providers to other providers and/or to patients/family/caregivers will provide important information to consumers, improving shared-decision making while selecting PAC providers. For additional technical information about this proposed measure, including information about the measure calculation and the standardized items used to calculate this measure, we refer readers to the document titled, "Proposed Specifications for HH QRP Quality 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. The data source for the proposed quality measure is the OASIS assessment instrument for HH patients.

For more information about the data submission requirements we are proposing for this measure, we refer readers to section V.I.2. of this proposed rule.

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

The proposed Transfer of Health Information to the Patient–Post-Acute Care (PAC) measure is a process-based measure that assesses whether or not a current reconciled medication list was provided to the patient, family, and/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 or transitional living.

(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.[68] 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 risk to patient safety, often life-threatening.[69, 70, 71, 72, 73] 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

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[68] 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.

69 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.

70 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.

71 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.

72 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.

73 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.

complicated transitions between care settings.[74, 75] Upon discharge to home, individuals in PAC settings may be faced with numerous medication changes, new medication regimes, and follow-up details.[76,77,78] The efficient and effective communication and coordination of medication information may be critical to prevent potentially deadly adverse events. 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.[79, 80]

Finally, the transfer of a patient's discharge medication information to the patient, family, and/or caregiver is a common practice and supported by discharge planning requirements for participation in Medicare and Medicaid programs.[81, 82] 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.[83]

(b) Stakeholder and TEP Input

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74 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.

75 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.

76 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.

77 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.

78 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.

79 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.

80 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.

81 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.

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

83 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.

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.

Our measure development contractors convened a TEP which met on September 27, 2016[84], January 27, 2017, and August 3, 2017[85] 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.

84 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

85 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

Our measure development contractors solicited stakeholder feedback on the proposed measure by requesting comment on the CMS MMS Blueprint website, and accepted comments that were submitted from March 19, 2018 to May 3, 2018. Several commenters noted the importance of ensuring that the instruction provided to patients and caregivers is clear and understandable to promote transparent access to medical record information and meet the goals of the IMPACT Act. The summary report for the March 19 to May 3, 2018 public comment period titled "IMPACT- Medication Profile Transferred Public Comment Summary Report" is available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html

(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 87 percent agreement for this measure. Overall, pilot testing enabled us to verify its reliability, components of face validity, and feasibility of being implemented the proposed measure 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 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 summary report for pilot testing conducted in 2017 of a

previous version of the data element, at that time intended for benchmarking purposes only, is available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-nstruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.

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

This measure was submitted to the 2018 MUC list for HH QRP. The NQF-convened MAP PAC-LTC Workgroup met on December 10, 2018 and provided input on the use of the proposed Transfer of Health Information to the Patient–Post Acute-Care measure. 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/Projects/i-m/MAP/PAC-LTC_Workgroup/2019_Considerations_for_Implementing_Measures_Draft_Report.aspx.

Section 1899B(e)(2)(A) of the Act requires that measures specified by the Secretary under section 1899B of the Act 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 the 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 Patient–Post-Acute Care measure would be based on the proportion of quality episodes with a discharge assessment indicating that a current reconciled medication list was provided to the patient, family, and/or caregiver at the time of discharge.

The proposed measure denominator is the total number of HH quality episodes ending in discharge to a private home/apartment without any further services, a board and care home, assisted living, a group home or transitional living. These health care providers and settings were selected for inclusion in the denominator because they represent discharge locations captured by items on the OASIS. The proposed measure numerator is the number of HH quality episodes with an OASIS discharge assessment indicating a current reconciled medication list was provided to the patient, family, and/or caregiver at the time of discharge. We believe that data pertaining to how information is transferred by PAC providers to other providers and/or to patients/family/caregivers will provide important information to consumers, improving shared-decision making while selecting PAC providers. For technical information about this proposed measure including information about the measure calculation, we refer readers to the document titled "Proposed Specifications for HH 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

For more information about the data submission requirements we are proposing for this measure, we refer readers to section V.I.2. of this proposed rule.

3. Proposed Update to the Discharge to Community (DTC)–Post Acute Care (PAC) Home Health (HH) Quality Reporting Program (QRP) Measure

We are proposing to update the specifications for the DTC—PAC HH QRP measure to exclude baseline nursing facility (NF) residents from the measure. This proposed measure exclusion aligns with the proposed updates to measure exclusions for the DTC-PAC measures utilized in quality reporting programs for other PAC providers, as outlined in the FY2020 PPS proposed rules for IRFs and SNFs as well as for LTCHs in the FY2020 IPPS/LTCH PPS proposed rule. This measure assesses successful discharge to the community from an HHA, with successful discharge to the community including no unplanned re-hospitalizations and no death in the 31 days following discharge. We adopted this measure in the CY 2017 HH PPS final rule (81 FR 76765 through 76770).

The DTC-PAC HH QRP measure does not currently exclude baseline NF residents. We have now developed a methodology to identify and exclude baseline NF residents using the Minimum Data Set (MDS) and have conducted additional measure testing work. To identify baseline NF residents, we examine any historical MDS data in the 180 days preceding the qualifying prior acute care admission and index HH episode of care start date. Presence of an OBRA (Omnibus Budget Reconciliation Act)-only assessment (not a SNF PPS assessment) with no intervening community discharge between the OBRA assessment and acute care admission date flags the index HH episode of care as baseline NF resident. We assessed the impact of the

baseline NF resident exclusion on HH patient- and agency-level discharge to community rates using CY 2016 and CY 2017 Medicare FFS claims data. Baseline NF residents represented 0.13 percent of the measure population after all measure exclusions were applied. The national observed patient-level discharge to community rate was 78.05 percent when baseline NF residents were included in the measure, increasing to 78.08 percent when they were excluded from the measure. After excluding baseline NF residents to align with current or proposed exclusions in other PAC settings, the agency-level risk-standardized discharge to community rate ranged from 3.21 percent to 100 percent, with a mean of 77.39 percent and standard deviation of 17.27 percentage points, demonstrating a performance gap in this domain. That is, the results show that there is a wide range in measure results, emphasizing the opportunity for providers to improve their measure performance.

Accordingly, we are proposing to exclude baseline NF residents from the DTC–PAC HH QRP measure beginning with the CY 2021 HH QRP. We are proposing to define "baseline NF residents" for purposes of this measure as HH patients who had a long-term NF stay in the 180 days preceding their hospitalization and HH episode, with no intervening community discharge between the NF stay and qualifying hospitalization. We are currently using MDS assessments, which are required quarterly for NF residents, to identify baseline NF residents. A 180-day lookback period ensures that we will capture both quarterly OBRA assessments identifying NF residency and any discharge assessments to determine if there was a discharge to community from NF.

For additional technical information regarding the DTC–PAC HH QRP measure, including technical information about the proposed exclusion, we refer readers to the document titled "Proposed Specifications for HH 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.

F. HH QRP Quality Measures, Measure Concepts, and Standardized Patient Assessment Data Elements Under Consideration for Future Years: Request for Information

We are seeking input on the importance, relevance, appropriateness, and applicability of each of the measures, standardized patient assessment data elements (SPADEs), and measure concepts under consideration listed in the Table 27 for future years in the HH QRP.

TABLE 27: FUTURE MEASURES, MEASURE CONCEPTS, AND STANDARDIZED PATIENT ASSESSMENT DATA ELEMENTS (SPADEs) UNDER CONSIDERATION FOR THE HH QRP

Quality Measures and Measure Concepts
Potentially-preventable hospitalizations
Functional improvement and maintenance outcomes
Opioid use and frequency
Exchange of electronic health information and interoperability
Standardized Patient Assessment Data Elements (SPADEs)
Cognitive complexity, such as executive function and memory
Dementia
Bladder and bowel continence including appliance use and episodes of incontinence
Care preferences, advance care directives, and goals of care
Caregiver Status
Veteran Status
Health disparities and risk factors, including education, sex and gender identity, and sexual orientation

While we will not be responding to comment submissions in response to this Request for Information in the CY 2020 HH PPS final rule, nor will we be finalizing any of these measures, measure concepts, and SPADEs under consideration for the HH QRP in this CY 2020 HH PPS final rule, we intend to use this input to inform our future measure and SPADE development efforts.

G. Proposed Standardized Patient Assessment Data Reporting Beginning with the CY 2022 HH QRP

Section 1895(b)(3)(B)(v)(IV)(bb) of the Act requires that, for CY 2019 (beginning January 1, 2019) and each subsequent year, HHAs report standardized patient assessment data 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 HHAs, to submit SPADEs under the Medicare program. Section 1899B(b)(1)(A) of the Act requires that PAC providers must submit SPADEs under applicable reporting provisions, (which for HHAs is the HH QRP) with respect to the admissions and discharges of an individual (and more frequently as the Secretary deems appropriate), and section 1899B(b)(1)(B) 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.

In the CY 2018 HH PPS proposed rule (82 FR 35355 through 35371), we proposed to adopt SPADEs that would satisfy the first five categories. While many commenters expressed support for our adoption of SPADEs, including support for our broader standardization goal and

support for the clinical usefulness of specific proposed SPADEs in general, 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 51737 through 51740). 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 51732 through 51733).

However, we did, 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 HHAs 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) along with the additional data elements in Section GG: Functional Abilities and Goals; 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 HHAs for the calculation of quality measures (82 FR 51733 through 51735).

Since we issued the CY 2018 HH PPS final rule, HHAs 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 proposed SPADEs, as described more fully elsewhere in this proposed rule, and believe that this testing supports their use in our

PAC assessment instruments. Therefore, we are now proposing to adopt many of the same SPADEs that we previously proposed to adopt, along with other SPADEs.

We are proposing that HHAs would be required to report these SPADEs beginning with the CY 2022 HH QRP. If finalized as proposed, HHAs would be required to report this data with respect to admissions and discharges that occur between January 1, 2021 and June 30, 2021 for the CY 2022 HH QRP. Beginning with the CY 2023 HH QRP, we propose that HHAs must report data with respect to admissions and discharges that occur the successive calendar year (for example, data from FY 2021 for the CY 2023 HH QRP and data from FY 2022 for the CY 2024 HH QRP). For the purposes of the HH QRP, we are proposing that HHAs must submit SPADEs with respect to start of care (SOC), resumption of care (ROC), and discharge with the exception of Hearing, Vision, Race, and Ethnicity SPADEs, which will only be collected with respect to SOC. We are proposing to use SOC for purposes of admissions because, in the HH setting, the start of care is functionally the same as an admission.

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

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

- Overall clinical relevance;

- Interoperable exchange to facilitate care coordination during transitions in care;
- Ability to capture medical complexity and risk factors that can inform both payment and quality;
- Scientific reliability and validity, general consensus agreement for its usability.

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

The National Beta Test collected data from 3,121 patients and residents across 143 LTCHs, SNFs, IRFs, and HHAs from November 2017 to August 2018 to evaluate the feasibility, reliability, and validity of candidate data elements across PAC settings. The National Beta Test also gathered feedback on the candidate data elements from staff who administered the test protocol in order to understand usability and workflow of the candidate data elements. More information on the methods, analysis plan, and results for the National Beta Test can be found 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 previously. 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.

H. Proposed Standardized Patient Assessment Data by Category

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.[86] 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,[87] and because these assessments provide opportunity for improving quality of care.

Symptoms of dementia may improve with pharmacotherapy, occupational therapy, or physical activity,[88, 89, 90] and promising treatments for severe traumatic brain injury are currently being tested.[91] For older patients and residents diagnosed with depression, treatment options to reduce symptoms and improve quality of life include antidepressant medication and psychotherapy,[92, 93, 94, 95] and targeted services, such as therapeutic recreation, exercise, and restorative nursing, to increase opportunities for psychosocial interaction.[96]

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86 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.
87 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.
88 Casey D.A., Antimisiaris D., O'Brien J. (2010). Drugs for Alzheimer's Disease: Are They Effective? *Pharmacology & Therapeutics*, 35, 208–11.
89 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.
90 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.
91 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.
92 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.
93 Arean P.A., Cook B.L. (2002). Psychotherapy and combined psychotherapy/pharmacotherapy for late life depression. *Biological Psychiatry*, 52(3), 293-303.
94 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.
95 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.
96 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.

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; promoting effective prevention and treatment of chronic disease; strengthening person and family engagement as partners in their care; and promoting 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. 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 SPADEs 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. We describe each of the proposed cognitive function and mental status data SPADEs elsewhere in the proposed rule.

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

a. Brief Interview for Mental Status (BIMS)

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

As described in the CY 2018 HH PPS proposed rule (82 FR 35356 through 35357), dementia and cognitive impairment are associated with long-term functional dependence and, consequently, poor quality of life and increased health care costs and mortality.[97] 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.[98]

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 in SNFs and the IRF-PAI used by IRFs. For more information on the BIMS, we refer readers to the document titled, "Proposed Specifications for HH QRP Quality Measures and SPADEs," 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.

97 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.

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

The data elements that comprise the BIMS were first proposed as SPADEs in the CY 2018 HH PPS proposed rule (82 FR 35356 through 35357). 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 those commenters had noted 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 CY 2018 HH PPS proposed rule, we received public comments in support of the use of the BIMS in the HH setting. However, a commenter suggested the BIMS should be administered with respect to both admission and discharge, and another commenter encouraged its use at follow-up assessments. Another commenter expressed support for the BIMS to assess significant cognitive impairment, but a few commenters suggested alternative cognitive assessments as more appropriate for the HH settings, such as assessments that would capture mild cognitive impairment and "functional cognition."

Subsequent to receiving comments on the CY 2018 HH PPS proposed rule, the BIMS was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the BIMS to be

feasible and reliable for use with PAC patients and residents. More information about the performance of the BIMS in the National Beta Test can be found in the document titled, "Proposed Specifications for HH QRP Quality Measures and SPADEs," 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 BIMS, and 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 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. Some commenters 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 SPADEs Received After November 27, 2018 Stakeholder Meeting" is available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-

Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.

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

b. Confusion Assessment Method (CAM)

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

As described in the CY 2018 HH PPS proposed rule (82 FR 35357), 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.[99] Assessing these signs and symptoms of delirium is clinically relevant for care planning by PAC providers.

The CAM is a patient assessment instrument that screens for overall cognitive impairment, as well as distinguishes delirium or reversible confusion from other types of cognitive impairment. The CAM is currently in use in two of the PAC assessments: a four-item version of the CAM is used in the MDS in SNFs, and a six-item version of the CAM is used in the LTCH CARE Data Set (LCDS) in LTCHs. We are proposing the four-item version of the CAM that assesses acute change in mental status, inattention, disorganized thinking, and altered level of consciousness. For more information on the CAM, we refer readers to the document titled, "Proposed Specifications for HH QRP Quality Measures and SPADEs," 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 SPADEs in the CY 2018 HH PPS proposed rule (82 FR 35357). 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 on the CAM 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 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:

99 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.

https://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 CY 2018 HH PPS proposed rule, one commenter expressed support for the CAM to assess significant cognitive impairment but noted that functional cognition should also be assessed. Another commenter suggested the CAM was not suitable for the HH setting and noted that the additional cognition items would be redundant with existing assessment items in the OASIS data set.

Subsequent to receiving comments on the CY 2018 HH PPS proposed rule, the CAM was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the CAM to be feasible and reliable for use with PAC patients and residents. More information about the performance of the CAM in the National Beta Test can be found in the document titled, "Proposed Specifications for HH QRP Quality Measures and SPADEs," 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, 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 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 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 delirium, stakeholder input, and strong test results, we are proposing that the CAM data elements meet the definition of standardized patient assessment data with respect to cognitive function and mental status under section 1899B(b)(1)(B)(ii) of the Act and to adopt CAM as standardized patient assessment data for use in the HH QRP.

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

We are proposing that the Patient Health Questionnaire-2 to 9 (PHQ-2 to 9) data elements meet the definition of standardized patient assessment data with respect to cognitive function and mental status under section 1899B(b)(1)(B)(ii) of the Act. The proposed data elements are based on the PHQ-2 mood interview, which focuses on only the two cardinal symptoms of depression, and the longer PHQ-9 mood interview, which assesses presence and frequency of nine signs and symptoms of depression. The name of the data element, the PHQ-2 to 9, refers to an embedded

skip pattern that transitions patients with a threshold level of symptoms in the PHQ-2 to the longer assessment of the PHQ-9. The skip pattern is described elsewhere in this proposed rule.

As described in the CY 2018 HH PPS proposed rule (82 FR 35358 through 35359), depression is a common and under-recognized mental health condition. Assessments of depression help PAC providers better understand the needs of their patients and residents by: prompting further evaluation after establishing a diagnosis of depression; elucidating the patient's or resident's ability to participate in therapies for conditions other than depression during their stay; and identifying appropriate ongoing treatment and support needs at the time of discharge.

The proposed PHQ-2 to 9 is based on the PHQ-9 mood interview. The PHQ-2 consists of questions about only the first two symptoms addressed in the PHQ-9: depressed mood and anhedonia (inability to feel pleasure), which are the cardinal symptoms of depression. The PHQ-2 has performed well as both a screening tool for identifying depression, to assess depression severity, and to monitor patient mood over time. [100,101] 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 patients who fail to report the cardinal symptoms of depression. The design of the PHQ-2 to 9 reduces the burden that would be associated with the full PHQ-9, while ensuring that patients with indications of depressive symptoms based on the PHQ-2 receive the longer assessment.

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100 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.
101 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.

Components of the proposed data elements are currently used in the OASIS for HHAs (PHQ-2) and the MDS for SNFs (PHQ-9). We are proposing to add the additional data elements of the PHQ-9 to the OASIS to replace M1730, Depression Screening. We are proposing to alter the administration instructions for the existing and new data elements to adopt the PHQ-2 to 9 gateway logic, meaning that administration of the full PHQ-9 is contingent on patient responses to questions about the cardinal symptoms of depression. For more information on the PHQ-2 to 9, we refer readers to the document titled, "Proposed Specifications for HH QRP Quality Measures and SPADEs," 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 CY 2018 HH proposed rule (82 FR 35358 through 35359). 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 rule proposal was also informed by public input that we received 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 were supportive of the standardized assessment of mood in PAC settings, 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,[102] for patients and residents who showed signs and symptoms of depression on the PHQ-2. A summary report for to the 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 CY 2018 HH PPS proposed rule, we received public comments in support of the PHQ-2, with a few commenters noting the limitation that the PHQ-2 is not appropriate for patients who are physically or cognitively impaired.

Subsequent to receiving comments on the CY 2018 HH PPS proposed rule, the PHQ-2 to 9 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 PHQ-2 to 9 to be feasible and reliable for use with PAC patients and residents. More information about the performance of the PHQ-2 to 9 in the National Beta Test can be found in the document titled, "Proposed Specifications for CY 2020 HH 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.

102 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):348–53. doi: 10.1370/afm.1139 pmid:20644190; PubMed Central PMCID: PMC2906530.

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

2. 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; promoting effective prevention and treatment of chronic disease; strengthening person and family engagement as partners in their care; and promoting 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. We provide rationale and further support for each of the proposed data elements and in the document titled, "Proposed Specifications for CY 2020 HH 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 TEP convened by our data element contractor provided input on the data elements for special services, treatments, and interventions. In a meeting held on January 5 and 6, 2017, the 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 to 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 CY 2018 HH PPS proposed rule (82 FR 35359 through 35369) public comment period. A few commenters expressed support for the special services, treatments, and interventions data elements but requested that a vendor be contracted to support

OASIS questions and answers. A commenter noted that many of these data elements were redundant with current assessment items and encouraged CMS to eliminate the redundancy by removing items similar to the proposed data elements. Another commenter noted that collecting these data elements on patients that come to the HH setting from non-affiliated entities can be challenging. The Medicare Payment Advisory Commission supported the addition of data elements related to specific services, treatments, and interventions, but cautioned that such data elements, when used for risk adjustment, may be susceptible to inappropriate manipulation by providers and expressed that CMS may want to consider requiring a physician signature to attest that the reported service was reasonable and necessary. CMS is not proposing to require a physician signature because the existing Conditions of Participation for HHAs already require accurate reporting of patient assessment data, and a physician signature would be redundant. We reported this comment in order to accurately represent the public comments received on these proposals in the CY 2017 HH PPS proposed rule.

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

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

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

As described in the CY 2018 HH PPS proposed rule (82 FR 35359 through 35360), 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 but 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 patient is receiving

chemotherapy on the principal Chemotherapy data element, the assessor would then indicate by which route or routes (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. For more information on the Chemotherapy (IV, Oral, Other) data element, we refer readers to the document titled "Proposed Specifications for HH QRP Quality Measures and SPADEs," 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 SPADE in the CY 2018 HH PPS proposed rule (82 FR 35359 through 35360). 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 CY 2018 HH PPS proposed rule, one commenter expressed support for the Chemotherapy data element.

Subsequent to receiving comments on the CY 2018 HH PPS proposed rule, the Chemotherapy data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Chemotherapy data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Chemotherapy data element in the National Beta Test can be found in the document titled, "Proposed Specifications for HH QRP Quality Measures and SPADEs," 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 special services, treatments, and interventions. Although the TEP members did not specifically discuss the Chemotherapy data element, the TEP members supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled "SPADE Technical Expert Panel Summary (Third Convening)" is available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.

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

contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled "Input on 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 chemotherapy, stakeholder input , and strong test results, we are proposing that the Chemotherapy (IV, Oral, Other) 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 Chemotherapy (IV, Oral, Other) data element as standardized patient assessment data for use in the HH QRP.

b. Cancer Treatment: Radiation

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

As described in the CY 2018 HH PPS proposed rule (82 FR 35360), 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 for SNFs. For more information on the Radiation data element, we refer readers to the document titled, "Proposed Specifications for HH QRP Quality Measures and SPADEs," 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 standardized patient assessment data element in the CY 2018 HH PPS proposed rule (82 FR 35360). 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 CY 2018 HH PPS proposed rule, we received public comments in support of the special services, treatments, and interventions data elements in general; no additional comments were received that were specific to the Radiation data element.

Subsequent to receiving comments on the CY 2018 HH PPS proposed rule, the Radiation data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Radiation data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Radiation data element in the National Beta Test can be found in the document titled, "Proposed Specifications for HH QRP Quality Measures and SPADEs," 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. Although the TEP members did not specifically discuss the Radiation data element, the TEP members supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled "SPADE Technical Expert Panel Summary (Third Convening)" is available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled "Input on 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 radiation, stakeholder input, and strong test results, we are proposing that the Radiation data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Radiation data element as standardized patient assessment data for use in the HH QRP.

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

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

As described in the CY 2018 HH PPS proposed rule (82 FR 35360 through 35361), we proposed a data element related to oxygen therapy. 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 capture 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 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 patient is receiving oxygen therapy on the principal oxygen therapy data element, the assessor would then 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 for SNFs ("Oxygen Therapy"), previously used in the OASIS-C2 for HHAs ("Oxygen (intermittent or continuous)"), and a data element tested in the PAC PRD that focused on intensive oxygen therapy ("High O2 Concentration Delivery System with FiO2 > 40 percent"). For more information on the proposed Oxygen Therapy (Continuous, Intermittent, High-concentration oxygen delivery system) data element, we refer readers to the document titled, "Proposed Specifications for HH QRP Quality Measures and SPADEs", 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 a standardized patient assessment data element in the CY 2018 HH PPS proposed rule (82 FR 35360 through 35361). 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 CY 2018 HH PPS proposed rule, one commenter expressed support for the Oxygen Therapy (Continuous, Intermittent) data element.

Subsequent to receiving comments on the CY 2018 HH PPS proposed rule, the Oxygen Therapy data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Oxygen Therapy data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Oxygen Therapy data element in the National Beta Test can be found in the document titled, "Proposed Specifications for HH QRP Quality Measures and SPADEs", 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, although the TEP did not specifically discuss the Oxygen Therapy data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled "SPADE Technical Expert Panel Summary (Third Convening)" is available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.

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

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

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

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

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

As described in the CY 2018 HH PPS proposed rule (82 FR 35361 through 35362), 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' or residents' 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. 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 the 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 patient is receiving suctioning on the principal Suctioning data element, the assessor would then indicate the frequency (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 and residents with tracheostomies ("Trach Tube with Suctioning: Specify most intensive

frequency of suctioning during stay [Every __ hours]"). For more information on the Suctioning data element, we refer readers to the document titled, "Proposed Specifications for HH QRP Quality Measures and SPADEs", 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 elements in the CY 2018 HH PPS proposed rule (82 FR 35361 through 35362). 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 Suctioning data element currently used in the MDS in SNFs. 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 CY 2018 HH PPS proposed rule, one commenter expressed support for the Suctioning data element.

Subsequent to receiving comments on the CY 2018 HH PPS proposed rule, the Suctioning data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Suctioning data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Suctioning data element in the National Beta Test can be found in the document titled, "Proposed Specifications for HH QRP Quality Measures and SPADEs", 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. 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 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 suctioning, stakeholder input, and strong test results, we are proposing that the Suctioning (Scheduled, As needed) data element with a principal data element and two sub-elements meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Suctioning (Scheduled, As needed) data element as standardized patient assessment data for use in the HH QRP.

e. Respiratory Treatment: Tracheostomy Care

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

As described in the CY 2018 HH PPS proposed rule (82 FR 35362), 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 is also 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 for SNFs ("Tracheostomy care"). For more information on the Tracheostomy Care data element, we refer readers to the document titled "Proposed Specifications for HH QRP Quality Measures and SPADEs", 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 a standardized patient assessment data element in the CY 2018 HH PPS proposed rule (82 FR 35362). 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 on the Tracheostomy Care data element 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 CY 2018 HH PPS proposed rule, one commenter expressed support for the Tracheostomy Care data element.

Subsequent to receiving comments on the CY 2018 HH PPS proposed rule, the Tracheostomy Care data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Tracheostomy Care data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Tracheostomy Care data element in the National Beta Test can be found in the document titled, "Proposed Specifications for HH QRP Quality Measures and SPADEs", 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. Although the TEP did not specifically discuss the Tracheostomy Care data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled "SPADE Technical Expert Panel Summary (Third Convening)" is available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled "Input on 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 tracheostomy care, stakeholder input, and strong test results, we are proposing that the Tracheostomy Care data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Tracheostomy Care data element as standardized patient assessment data for use in the HH QRP.

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

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

As described in the CY 2018 HH PPS proposed rule (82 FR 35362 through 35363), 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 patient is receiving non-invasive mechanical ventilation on the principal Non-invasive Mechanical Ventilator data element, the assessor would then indicate which type (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)"). For more information on the Non-invasive Mechanical Ventilator data element, we refer readers to the document titled, "Proposed Specifications for HH QRP Quality Measures and SPADEs", 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 a standardized patient assessment data element in the CY 2018 HH PPS proposed rule (82 FR 35362 through 35363). In that proposed rule, we stated that the proposal was informed by input

we received 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, expressing 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 CY 2018 HH PPS proposed rule, one commenter expressed support for the Non-invasive Mechanical Ventilator data element.

Subsequent to receiving comments on the CY 2018 HH PPS proposed rule, the Non-invasive Mechanical Ventilator data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Non-invasive Mechanical Ventilator data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Non-invasive Mechanical Ventilator data element in the National Beta Test can be found in the document titled, "Proposed Specifications for HH QRP Quality Measures and SPADEs, 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. Although the TEP did not specifically discuss the Non-invasive Mechanical Ventilator data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled "SPADE Technical Expert Panel Summary (Third Convening)" is available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled "Input on 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 non-invasive mechanical ventilation, stakeholder input, and strong test results, we are proposing that the Non-invasive Mechanical Ventilator (BiPAP, CPAP) data element with a principal data element and two sub-elements meets the definition of standardized patient assessment data with respect to special services,

treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Non-invasive Mechanical Ventilator (BiPAP, CPAP) data element as standardized patient assessment data for use in the HH QRP.

g. Respiratory Treatment: Invasive Mechanical Ventilator

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

As described in the CY 2018 HH PPS proposed rule (82 FR 35363 through 35364), 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.[103]

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. For more information on the Invasive Mechanical Ventilator data element, we refer readers to the document titled, "Proposed Specifications for

103 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.

HH QRP Quality Measures and SPADEs, available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.

The Invasive Mechanical Ventilator data element was first proposed as a SPADE in the CY 2018 HH PPS proposed rule (82 FR 35363 through 35364). 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 on data elements that assess invasive ventilator use and weaning status that were tested in the PAC PRD ("Ventilator – Weaning" and "Ventilator – Non-Weaning") 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" 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 CY 2018 HH PPS proposed rule, one commenter expressed support for the Invasive Mechanical Ventilator data element.

Subsequent to receiving comments on the CY 2018 HH PPS proposed rule, the Invasive Mechanical Ventilator data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Invasive Mechanical Ventilator data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Invasive Mechanical Ventilator data element in the National Beta Test can be found in the document titled, "Proposed Specifications for HH QRP Quality Measures and SPADEs, 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. 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 ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present results of the National Beta Test and solicit additional comments. General input on the testing and item development process and

concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled "Input on 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 invasive mechanical ventilation, stakeholder input, and strong test results, we are proposing that the Invasive Mechanical Ventilator data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Invasive Mechanical Ventilator data element as standardized patient assessment data for use in the HH QRP.

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

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

As described in the CY 2018 HH PPS proposed rule (82 FR 35364 through 35365), when we proposed a similar set of data elements 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 tube 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 elements (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; an oral form of the medication does not exist; or the patient is unable to take the medication by mouth. IV anticoagulants refer to anti-clotting medications (that is, "blood thinners"). IV anticoagulants are commonly used for hospitalized patients who have deep venous thrombosis, pulmonary embolism, or myocardial infarction, as well as those undergoing interventional cardiac procedures. Vasoactive medications refer to the IV administration of vasoactive drugs, including vasopressors, vasodilators, and continuous medication for pulmonary edema, which increase or decrease blood pressure or heart rate. The indications, risks, and benefits of each of these classes of IV medications are distinct, making it important to assess each separately in PAC. Knowing whether or not patients and residents are receiving IV medication and the type of medication provided by each PAC provider will improve quality of care.

The IV Medications (Antibiotics, Anticoagulants, Vasoactive Medications, and Other) data element we are proposing consists of a principal data element (IV Medications) and four response option sub-elements: Antibiotics, Anticoagulants, Vasoactive Medications, and Other. The Vasoactive Medications sub-element was not proposed in the CY 2018 HH PPS proposed rule (82 FR 35364 through 35365). We added the Vasoactive Medications sub-element to our proposal in order to harmonize the proposed IV Mediciations element with the data currently collected in the LCDS.

If the assessor indicates that the patient is receiving IV medications on the principal IV Medications data element, the assessor would then indicate which types of medications (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. For more information on the IV Medications data element, we refer readers to the document titled, "Proposed Specifications for HH QRP Quality Measures and SPADEs, 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 standardized patient assessment data elements in the CY 2018 HH PPS proposed rule (82 FR 35364 through 35365). 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 on Vasoactive Medications from August 12 to September 12, 2016 supported this data element with one commenter 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 CY 2018 HH PPS proposed rule, one commenter expressed support for IV Medications data elements.

Subsequent to receiving comments on the CY 2018 HH PPS proposed rule, the IV Medications data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the IV Medications data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the IV Medications data element in the National Beta Test can be found in the document titled, "Proposed Specifications for HH QRP Quality Measures and SPADEs", 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. Although the TEP did not specifically discuss the IV Medications data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled "SPADE Technical Expert Panel Summary (Third Convening)" is available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.

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

ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled "Input on 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 IV medications, stakeholder input, and strong test results, we are proposing that the IV Medications (Antibiotics, Anticoagulation, 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 HH QRP.

i. Transfusions

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

As described in the CY 2018 HH PPS proposed rule (82 FR 35365), transfusion refers to introducing blood, blood products, or other fluid 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 a single Transfusions data element. A data element on transfusion is currently in use in the MDS in SNFs ("Transfusions") and a data element tested in the PAC PRD ("Blood Transfusions") was found feasible for use in each of the four PAC settings. For more information on the Transfusions data element, we refer readers to the document titled, "Proposed Specifications for HH QRP Quality Measures and SPADEs, 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 Transfusions data element was first proposed as a standardized patient assessment data element in the CY 2018 HH PPS proposed rule (82 FR 35365).

In response to our proposal in the CY 2018 HH PPS proposed rule, we received public comments in support of the special services, treatments, and interventions data elements in general; no additional comments were received that were specific to the Transfusions data element.

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

residents. More information about the performance of the Transfusions data element in the National Beta Test can be found in the document titled, "Proposed Specifications for HH QRP Quality Measures and SPADEs, 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. Although the TEP did not specifically discuss the Transfusions data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled "SPADE Technical Expert Panel Summary (Third Convening)" is available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.

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

j. Dialysis (Hemodialysis, Peritoneal Dialysis)

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

As described in the CY 2018 HH PPS proposed rule (82 FR 35365 through 35366), 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. 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 patient is receiving dialysis on the principal Dialysis data element, the assessor would then indicate which type (Hemodialysis, Peritoneal Dialysis). The principal Dialysis data element is currently included on the MDS in SNFs and the LCDS for LTCHs and assesses the overall use of dialysis. As the result of public feedback described, in this proposed rule, we are proposing data elements that include the principal Dialysis data element and two sub-elements (Hemodialysis and Peritoneal Dialysis). For more information on the Dialysis data element, we refer readers to the document titled, "Proposed Specifications for HH QRP Quality Measures and SPADEs", 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 elements in the CY 2018 HH PPS proposed rule (82 FR 35365 through 35366). 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 on a singular Hemodialysis data element from August 12 to September 12, 2016 supported the assessment of hemodialysis and recommended that the data element be expanded to include peritoneal dialysis. We also stated that those commenters had supported the singular Hemodialysis data element, noting the relevance of this information for sharing across the care continuum to facilitate care coordination and care transitions, the potential for this data element to be used to improve quality, and the feasibility for use in PAC. In addition, we received comment that the item would be useful in improving patient and resident transitions of care. We

also noted that several commenters had stated that peritoneal dialysis should be included in a standardized data element on dialysis and recommended collecting information on peritoneal dialysis in addition to hemodialysis. The rationale for including peritoneal dialysis from commenters included the fact that patients and residents receiving peritoneal dialysis will have different needs at post-acute discharge compared to those receiving hemodialysis or not having any dialysis. Based on these comments, the Hemodialysis data element was expanded to include a principal Dialysis data element and two sub-elements, Hemodialysis and Peritoneal Dialysis. We are proposing the expanded version of the Dialysis data 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 CY 2018 HH PPS proposed rule, we received public comments in support of the special services, treatments, and interventions data elements in general; no additional comments were received that were specific to the Dialysis data element.

Subsequent to receiving comments on the CY 2018 HH PPS proposed rule, the Dialysis data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Dialysis data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Dialysis data element in the National Beta Test can be found in the document titled, "Proposed Specifications for HH QRP Quality Measures and SPADEs", 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. 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 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 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 dialysis, stakeholder input, and strong test results, we are proposing that the Dialysis (Hemodialysis, Peritoneal Dialysis) data element with a principal data element and two sub-elements meets the definition of standardized patient

assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Dialysis (Hemodialysis, Peritoneal Dialysis) data element as standardized patient assessment data for use in the HH QRP.

k. Intravenous (IV) Access (Peripheral IV, Midline, Central Line)

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

As described in the CY 2018 HH PPS proposed rule (82 FR 35366), 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 element 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, although there is a related response option in the M1030 data element in the OASIS. We are proposing to replace the existing "Intravenous or Infusion Therapy" response option of the M1030 data element in the OASIS with the IV Access

(Peripheral IV, Midline, Central Line) data element. For more information on the IV Access data element, we refer readers to the document titled, "Proposed Specifications for HH QRP Quality Measures and SPADEs, 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 elements in the CY 2018 HH PPS proposed rule (82 FR 35366). 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 was submitted on one of the PAC PRD data elements, Central Line Management, from August 12 to September 12, 2016. A central line is one type of IV access. We stated that those commenters had 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 elsewhere in this proposed rule, 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 CY 2018 HH PPS proposed rule, one commenter expressed support for the IV Access data element.

Subsequent to receiving comments on the CY 2018 HH PPS proposed rule, the IV Access data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the IV Access data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the IV Access data element in the National Beta Test can be found in the document titled, "Proposed Specifications for HH QRP Quality Measures and SPADEs, 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. 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 ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present results of the National Beta Test and solicit additional comments. General input on the testing and item development process and

concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled "Input on 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 IV access, stakeholder input, and strong test results, we are proposing that the IV access (Peripheral IV, Midline, Central Line) data element with a principal data element and three sub-elements meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the IV Access (Peripheral IV, Midline, Central Line) data element as standardized patient assessment data for use in the HH QRP.

l. Nutritional Approach: Parenteral/IV Feeding

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

As described in the CY 2018 HH PPS proposed rule (82 FR 35366 through 35367), 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 parenteral nutrition/IV feeding indicates a clinical complexity that prevents the patient or resident from meeting his or her nutritional needs internally, and is more resource intensive than other forms of nutrition, as it often requires monitoring of blood chemistries and 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 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 for SNFs, and equivalent or related data elements are in use in the LCDS, IRF-PAI, and OASIS. We are proposing to replace the existing ''Parenteral nutrition (TPN or lipids)'' response option of the M1030 data element in the OASIS with the proposed Parenteral/IV Feeding data element. For more information on the Parenteral/IV Feeding data element, we refer readers to the document titled, "Proposed Specifications for HH QRP Quality Measures and SPADEs," 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 standardized patient assessment data element in the CY 2018 HH PPS proposed rule (82 FR 35366 through 35367). 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 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), which was included in a call for public input from August 12 to September 12, 2016. We stated that commenters had 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 CY 2018 HH PPS proposed rule, two commenters expressed support for the Parenteral/IV Feeding data element.

Subsequent to receiving comments on the CY 2018 HH PPS proposed rule, the Parenteral/IV Feeding data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Parenteral/IV Feeding data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Parenteral/IV Feeding data element in the National Beta Test can be found in the document titled, "Proposed Specifications for HH QRP Quality Measures and SPADEs, 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. Although the TEP did not specifically discuss the Parenteral/IV Feeding data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled "SPADE Technical Expert Panel Summary (Third Convening)" is available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled "Input on 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 parenteral/IV feeding, stakeholder input, and strong test results, we are proposing that the Parenteral/IV Feeding data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Parenteral/IV Feeding data element as standardized patient assessment data for use in the HH QRP.

m. Nutritional Approach: Feeding Tube

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

As described in the CY 2018 HH PPS proposed rule (82 FR 35367 through 35368), 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.[104] 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 (nasogastric, gastrostomy, jejunostomy, or any other artificial entry into the alimentary canal)". A related data element, collected in the IRF-PAI for IRFs (Tube/Parenteral Feeding), assesses use of both feeding tubes and parenteral nutrition. We are proposing to rename ''Enteral nutrition (nasogastric, gastrostomy, jejunostomy, or any other artificial entry into the alimentary canal)'' data element to "Feeding Tube," and adopt it as a SPADE for the HH QRP. For more information on the Feeding Tube data element, we refer readers to the document titled, "Proposed Specifications for HH QRP Quality Measures and SPADEs," 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 standardized patient assessment data element in the CY 2018 HH PPS proposed rule (82 FR 35367 through 35368). 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

104 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.

on an Enteral Nutrition data element (which is the same as the data element we are proposing in this proposed rule, but is used in the OASIS under a different name) from August 12 to September 12, 2016 supported the data element, noting the importance of assessing enteral nutrition status for facilitating care coordination and care transitions. After the public comment period, the Enteral Nutrition data element used in public comment was renamed Feeding Tube, indicating the presence of an assistive device. A summary report for the August 12 to September 12, 2016 public comment period titled "SPADE August 2016 Public Comment Summary Report" is available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.

In response to our proposal in the CY 2018 HH PPS proposed rule, a few commenters expressed support for the Feeding Tube data element. A commenter also recommended that the term "enteral feeding" be used instead of "feeding tube."

Subsequent to receiving comments on the CY 2018 HH PPS proposed rule, the Feeding Tube data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Feeding Tube data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Feeding Tube data element in the National Beta Test can be found in the document titled, "Proposed Specifications for HH QRP Quality Measures and SPADEs," 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. Although the TEP did not specifically discuss the Feeding Tube data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled "SPADE Technical Expert Panel Summary (Third Convening)" is available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled "Input on 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 feeding tubes, stakeholder input, and strong test results, we are proposing that the Feeding Tube data element meets the definition of standardized patient assessment data with respect to special services, treatments, and

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

n. Nutritional Approach: Mechanically Altered Diet

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

As described in the CY 2018 HH PPS proposed rule (82 FR 35368), 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.[105]

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.

105 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.

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

The Mechanically Altered Diet data element was first proposed as a standardized patient assessment data element in the CY 2018 HH PPS proposed rule (82 FR 35368).

In response to our proposal in the CY 2018 HH PPS proposed rule, one commenter expressed support for the Mechanically Altered Diet data element.

Subsequent to receiving comments on the CY 2018 HH PPS proposed rule, the Mechanically Altered Diet data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Mechanically Altered Diet data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Mechanically Altered Diet data element in the National Beta Test can be found in the document titled, "Proposed Specifications for HH QRP Quality Measures and SPADEs, 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. 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 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 mechanically altered diet, stakeholder input, and strong test results, we are proposing that the Mechanically Altered Diet data element meets the definition of standardized patient assessment data with respect to special services, treatments,

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

o. Nutritional Approach: Therapeutic Diet

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

As described in the CY 2018 HH PPS proposed rule (82 FR 35368 through 35369), 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. The Therapeutic Diet data element is currently in use in the MDS for SNFs. For more information on the Therapeutic Diet data element, we refer readers to the document titled, "Proposed Specifications for HH QRP Quality Measures and SPADEs," 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 a standardized patient assessment data element in the CY 2018 HH PPS proposed rule (82 FR 35368 through 35369).

In response to our proposal in the CY 2018 HH PPS proposed rule, one commenter expressed support for the Therapeutic Diet data element and encouraged CMS to align with the Academy of Nutrition and Dietetics definition of "therapeutic diet."

Subsequent to receiving comments on the CY 2018 HH PPS proposed rule, the Therapeutic Diet data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Therapeutic Diet data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Therapeutic Diet data element in the National Beta Test can be found in the document titled, "Proposed Specifications for HH QRP Quality Measures and SPADEs," 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. 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 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 therapeutic diet, stakeholder input, and strong test results, we are proposing that the Therapeutic Diet data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Therapeutic data element as standardized patient assessment data for use in the HH QRP.

p. High-Risk Drug Classes: Use and Indication

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

Most patients and residents receiving PAC services depend on short- and long-term medications to manage their medical conditions. However, as a treatment, medications are not without risk; medications are in fact a leading cause of adverse events. A study by the U.S. Department of Health and Human Services found that 31 percent of adverse events that occurred in 2008 among hospitalized Medicare beneficiaries were related to medication.[106] Moreover,

106 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.

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.[107]

ADEs are known to occur across different types of healthcare. For example, the incidence of ADEs in the outpatient setting has been estimated at 1.15 ADEs per 100 person-months,[108] while the rate of ADEs in the long-term care setting is approximately 9.80 ADEs per 100 resident-months.[109] In the hospital setting, the incidence has been estimated at 15 ADEs per 100 admissions.[110] 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.[111,112,113] ADEs are more common among older adults, who make up most patients and residents 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.[114]

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

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107 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.

108 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

109 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.

110 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]

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

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

113Gleason 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

114 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.

associated with more risk than others.[115] We are proposing one High-Risk Drug Class data element with six sub-elements. The six medication classes response options are: anticoagulants; antiplatelets; hypoglycemics (including insulin); opioids; antipsychotics; and antibiotics. These drug classes are high-risk due to the adverse effects that may result from use. In particular, bleeding risk is associated with anticoagulants and antiplatelets;[116,117] fluid retention, heart failure, and lactic acidosis are associated with hypoglycemics;[118] misuse is associated with opioids;[119] fractures and strokes are associated with antipsychotics;[120,121] and various adverse events such as central nervous systems effects and gastrointestinal intolerance are associated with antimicrobials,[122] the larger category of medications that include antibiotics. Moreover, some medications in five of the six drug classes included as response options in this data element are included in the 2019 Updated Beers Criteria® list as potentially inappropriate medications for use in older adults.[123] Finally, although a complete medication list should record several important attributes of each medication (for example, dosage, route, stop date), recording an indication for the drug is of crucial importance.[124]

The High-Risk Drug Classes: Use and Indication data element requires an assessor to

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115 Ibid.
116 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.
117 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.
118 Hamnvik OP, McMahon GT. Balancing Risk and Benefit with Oral Hypoglycemic Drugs. *The Mount Sinai journal of medicine*, New York. 2009; 76:234–243.
119 Naples JG, Gellad WF, Hanlon JT. The Role of Opioid Analgesics in Geriatric Pain Management. *Clin Geriatr Med*. 2016;32(4):725-735.
120 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]
121 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
122 Faulkner CM, Cox HL, Williamson JC. Unique aspects of antimicrobial use in older adults. *Clin Infect Dis*. 2005;40(7):997–1004.
123 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
124 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.

record whether or not a patient is taking any medications within 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 data response options are Anticoagulants, Antiplatelets, Hypoglycemics, Opioids, Antipsychotics, and Antibiotics. For each drug class, the assessor is asked to indicate if the patient 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 patient 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. For more information on the High-Risk Drug Classes: Use and Indication data element, we refer readers to the document titled, "Proposed Specifications for HH QRP Quality Measures and SPADEs," 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,[125] although they were supportive of the other six drug classes named in the draft version of the data element, which are the six drug classes being proposed as response options in the proposed High-Risk Drug Classes: Use and Indications SPADE. 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 received public input on data elements related to medication reconciliation through a call for input published on the CMS Measures Management System Blueprint website. In input received 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 stating that the items seemed

125 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.

feasible and clinically useful. A few commenters were critical of the choice of ten drug classes posted during that comment period – the six drug classes in the proposed SPADE, along with antidepressants, diuretics, antianxiety, and hypnotics -- 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, "Proposed Specifications for HH QRP Quality Measures and SPADEs," 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. The TEP acknowledged the challenges of assessing medication safety, and 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 – which they identified from among other options during the second convening of the TEP, described

previously -- and of using these classes to assess whether the indication for a drug is recorded. A summary of the September 17, 2018 TEP meeting titled "SPADE Technical Expert Panel Summary (Third Convening)" is available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. These activities provided updates on the field-testing work and solicited feedback on data elements considered for standardization, including the High-Risk Drug Classes: Use and Indication data element. One stakeholder group was critical of the six drug classes included as response options in the High-Risk Drug Classes: Use and Indication data element, noting that potentially risky medications (for example, muscle relaxants) are not included in this list; that there may be important differences between drugs within classes (for example, more recent versus older style antidepressants); and that drug allergy information is not captured. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. Additionally, one commenter questioned whether the time to complete the High-Risk Drug Classes: Use and Indication data element would differ across settings. A summary of the public input received from the November 27, 2018 stakeholder meeting titled "Input on SPADEs Received After November 27, 2018 Stakeholder Meeting" is available at:

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

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

3. 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.

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.[126] 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.[127] [128] [129]

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; promoting effective prevention and treatment of chronic disease; strengthening person and family engagement as partners in their care; and promoting effective communication and coordination of care. The proposed 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.

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126 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

127. 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

128 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.

129 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

We are inviting comment on our proposals to collect as standardized patient assessment data the following data with respect to medical conditions and comorbidities.

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 are seeking comment on whether or not we should add these pain items in light of those concerns. Commenters should address to what extent collection of the data through patient queries might encourage providers to prescribe opioids.

We are proposing that a set of three data elements on the topic of Pain Interference (Pain Effect on Sleep, Pain Interference with Therapy Activities, and Pain Interference with Day-to-Day Activities) meet the definition of standardized patient assessment data with respect to medical conditions and comorbidities 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.[130] 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.[131] Quality pain management, based on current guidelines and evidence-based practices, can minimize unnecessary opioid prescribing both by offering alternatives or supplemental treatment to opioids

130 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/.

131 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

and by clearly stating when they may be appropriate, and how to utilize risk-benefit analysis for opioid and non-opioid treatment modalities.[132]

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 toward 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.[133] 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 this proposed rule we have also proposed a SPADE that assess for the use of, as well as importantly the indication for that use of, high risk drugs, including opioids. Further, in the CY 2017 HH PPS final rule (81 FR 76780) we adopted the Drug Regimen Review Conducted With Follow-Up for Identified Issues—Post Acute Care (PAC) HH QRP measure, which assesses whether PAC providers were responsive to potential or

132 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.
133 National Pain Strategy: A Comprehensive Population-Health Level Strategy for Pain. https://iprcc.nih.gov/sites/default/files/HHSNational_Pain_Strategy_508C.pdf

actual clinically significant medication issue(s) including issues associated with use and misuse of opioids for pain management, when such issues were identified.

We also note that the proposed SPADEs 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, an array of successful non-pharmacologic and non-opioid approaches to pain management may be considered.[134] [135] [136] 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 implemented for pain management include, but are not limited to, biofeedback, application of heat/cold, massage, physical therapy, nerve block, stretching and strengthening exercises, chiropractic, electrical stimulation, radiotherapy, and ultrasound.[137] [138] [139]

We believe that standardized assessment of pain interference will support PAC clinicians in applying best-practices in pain management for chronic and acute pain, consistent with current clinical guidelines. For example, the standardized assessment of both opioids and pain interference would support providers in successfully tapering patients/residents who arrive in the PAC setting with long-term use of opioids onto non-pharmacologic treatments and non-opioid

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134 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.

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

136 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.

137 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.

138 Kligler, B., Bair, M.J., Banerjea, 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

139 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. An*nals of Internal Medicine, 166*(7):493-505.

medications, as recommended by the Society for Post-Acute and Long-Term Care Medicine,[140] and consistent with HHS's 5-Point Strategy To Combat the Opioid Crisis[141] which includes "Better Pain Management."

The Pain Interference data element set consists 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 patient's sleep. Pain Interference with Therapy Activities assesses the frequency with which pain interferes with a patient's ability to participate in therapies. The Pain Interference with Day-to-Day Activities assesses the extent to which pain interferes with a patient'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 in SNFs. We are proposing to add the Pain Interference data element set (Pain Effect on Sleep, Pain Interference with Therapy Activities, and Pain Interference with Day-to-Day Activities) to the OASIS and to remove M1242, Frequency of Pain Interfering with Patient's Activity or Movement. For more information on the Pain Interference data elements, we refer readers to the document titled, "Proposed Specifications for HH QRP Quality Measures and SPADEs," available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.

We sought public input on the relevance of conducting assessments on pain and specifically on the larger set of Pain Interview data elements included in the National Beta Test.

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

141 https://www.hhs.gov/opioids/about-the-epidemic/hhs-response/index.html

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 comment period in 2016 to solicit feedback on the standardization of pain and several other items that were under development in prior efforts, through a call for input published on the CMS Measures Management System Blueprint website. 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 comment, also published on the CMS Measures Management System Blueprint website, open from April 26 to June 26, 2017. The items we sought comment on were modified from all stakeholder and test efforts. Commenters provided general comments about pain assessment in general in addition to feedback on the specific pain items. A few commenters shared their support for assessing pain, the potential for pain assessment to improve the quality of care, and

for the validity and reliability of the data elements. Commenters affirmed that the item of pain and the effect on sleep would be suitable for PAC settings. Commenters' main concerns included redundancy with existing data elements, feasibility and utility for cross-setting use, and the applicability of interview-based items to patients and residents with cognitive or communication impairments, and deficits. A summary report for the April 26 to June 26, 2017 public comment period titled "SPADE May-June 2017 Public Comment Summary Report" is available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.

The Pain Interference data elements were included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Pain Interference data elements to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Pain Interference data elements in the National Beta Test can be found in the document titled, "Proposed Specifications for HH QRP Quality Measures and SPADEs," 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 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 ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. Additionally, one commenter expressed strong support for the proposed pain SPADEs and was encouraged by the fact that this portion of the assessment surpasses pain presence. A summary of the public input received from the November 27, 2018 stakeholder meeting titled "Input on 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 the effect of pain on function, stakeholder input, and strong test results, we are proposing that the set of Pain Interference data elements (Pain Effect on Sleep, Pain Interference with Therapy Activities, and Pain Interference with Day--to-Day Activities) meet the definition of standardized patient assessment data with respect to medical conditions and comorbidities under section 1899B(b)(1)(B)(iv) of the Act and to adopt the Pain Interference data elements (Pain Effect on Sleep, Pain Interference with Therapy

Activities, and Pain Interference with Day-to-Day Activities) as standardized patient assessment data for use in the HH QRP.

4. 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 addition, entities that receive Federal financial assistance, such as through Medicare Parts A, C,

and D, must take appropriate steps to ensure effective communication for individuals with disabilities, including provision of appropriate auxiliary aids and services.[142]

In alignment with our Meaningful Measures Initiative, we expect accurate 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; promoting effective prevention and treatment of chronic disease; strengthening person and family engagement as partners in their care; and promoting 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 CY 2018 HH PPS proposed rule (82 FR 35369 through 35371) public comment period. We received public comments regarding the Hearing and Vision data elements; no additional comments were received about impairments in general.

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

142 Section 504 of the Rehabilitation Act of 1973, section1557 of the Affordable Care Act, and their respective implementing regulations. More information is available at: https://www.hhs.gov/civil-rights/for-individuals/disability/index.html, and https://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html.

a. Hearing

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

As described in the CY 2018 HH PPS proposed rule (82 FR 35369 through 35370), 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, and social functioning, and emotional health. [143,144] Treatment and accommodation of hearing impairment led to improved health outcomes, including but not limited to quality of life. [145] For example, hearing loss in elderly individuals has been associated with depression and cognitive impairment,[146,147,148] higher rates of incident cognitive impairment and cognitive decline,[149] and less time in occupational therapy.[150] 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, "Proposed Specifications for HH QRP Quality Measures and SPADEs", available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-

143 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.
144 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.
145 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.
146 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.
147 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.
148 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.
149 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.
150 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.

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 standardized patient assessment data element in the CY 2018 HH PPS proposed rule (82 FR 35369 through 35370). 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 on the PAC PRD form of the data element ("Ability to Hear") 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 CY 2018 HH PPS proposed rule, one commenter noted that resources would be needed for a change in the OASIS to account for the Hearing data element.

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

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

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

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

Due to the relatively stable nature of hearing impairment, we are proposing that HHAs that submit the Hearing data element with respect to SOC will be deemed to have submitted with respect to discharge. Taking together the importance of assessing hearing, stakeholder input, and strong test results, we are proposing that the Hearing data element meets the definition of standardized patient assessment data with respect to impairments under section 1899B(b)(1)(B)(v) of the Act and to adopt the Hearing data element as standardized patient assessment data for use in the HH QRP.

b. Vision

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

As described in the CY 2018 HH PPS proposed rule (82 FR 35370 through 35371), evaluation of an individual's ability to see is important for assessing 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.[151, 152, 153, 154, 155, 156, 157] Individualized initial screening can lead to life-improving

151 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.
152 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.
153 Keepnews D, Capitman JA, Rosati RJ. Measuring patient-level clinical outcomes of home health care. *J Nurs Scholarsh.* 2004;36(1):79-85.
154 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.
155 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.
156 Rovner BW, Ganguli M. Depression and disability associated with impaired vision: the MoVies Project. *J Am Geriatr Soc.* 1998;46(5):617-619.

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 HH setting for care planning and defining resource use.

The proposed data element consists of the single Vision (Ability to See in Adequate Light) data element that consists of one question with five response categories. The Vision data element that we are proposing for standardization was tested as part of the development of the MDS for SNFs and is currently in use in that assessment. A similar data element, but with different wording and fewer response option categories, is in use in the OASIS. We are proposing to add the Vision (Ability to See in Adequate Light) data element to the OASIS to replace M1200, Vision. For more information on the Vision data element, we refer readers to the document titled, "Proposed Specifications for HH QRP Quality Measures and SPADEs," 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 Vision data element was first proposed as a standardized patient assessment data element in the CY 2018 HH PPS proposed rule (82 FR 35370 through 35371). In that proposed rule, we stated that the proposal was informed by input we received from August 12 to September 12, 2016, 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. The data element on which we solicited input

157 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.

differed from the proposed data element, but input submitted from August 12 to September 12, 2016 supported the assessment of 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 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 CY 2018 HH PPS proposed rule, one commenter noted that resources would be needed for a change in the OASIS to account for the Vision data element.

Subsequent to receiving comments on the CY 2018 HH PPS proposed rule, the Vision data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Vision data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Vision data element in the National Beta Test can be

found in the document titled, "Proposed Specifications for HH QRP Quality Measures and SPADEs," available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.

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

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

Due to the relatively stable nature of vision impairment, we are proposing that HHAs that submit the Vision data element with respect to SOC will be deemed to have submitted with respect to discharge. Taking together the importance of assessing vision, stakeholder input, and strong test results, we are proposing that the Vision data element meets the definition of standardized patient assessment data with respect to impairments under section 1899B(b)(1)(B)(v) of the Act and to adopt the Vision data element as standardized patient assessment data for use in the HH QRP.

5. Proposed New Category: Social Determinants of Health

a. Proposed Social Determinants of Health Data Collection to Inform Measures and Other Purposes

Subparagraph (A) of section 2(d)(2) of the IMPACT Act requires CMS to assess appropriate adjustments to quality measures, resource measures, and other measures, and to assess and implement appropriate adjustments to payment under Medicare based on those measures, after taking into account studies conducted by ASPE on social risk factors (described elsewhere in this proposed rule) 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 previously in such subparagraph (A) and for periodic analyses in such subparagraph (C)).

Accordingly we are proposing to use our authority under subparagraph (B) of section 2(d)(2) of the IMPACT Act to establish a new data source for information to meet the requirements of subparagraphs (A) and (C) of section 2(d)(2). In this rule, we are proposing 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 elsewhere in this proposed rule. Social determinants of health, also known as social risk factors, or health-related social needs, are the socioeconomic, cultural and environmental circumstances in which individuals live that impact their health. We are proposing to collect information on seven proposed SDOH SPADE data elements relating to race, ethnicity, preferred language, interpreter services, health literacy, transportation, and social isolation; a detailed discussion of each of the proposed SDOH data elements is found in section IV.A.7.f.(ii). of this proposed rule.

We are also proposing to use the OASIS, the current version being OASIS-D, described as the PAC assessment instrument for home health agencies under section 1899B(a)(2)(B)(i) 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 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 IV.A.7.f.(2). of this proposed rule. Subparagraphs (A) and (B) of section 2(d)(1) of the IMPACT Act require the Secretary, acting through the Office of the Assistant Secretary for Planning and Evaluation (ASPE), to conduct two studies that examine the effect of risk factors,

including individuals' socioeconomic status, on quality, resource use and other measures under the Medicare program. The first ASPE study was completed in December 2016 and is discussed in this proposed rule, 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, entitled "Social Risk Factors."[158] Consequently NASEM framed the results of its report in terms of "social risk

[158] 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.

factors" rather than "socioeconomic status" or "sociodemographic status." The full text of the "Social Risk Factors" NASEM report is available for reading on the website at https://www.nap.edu/read/21858/chapter/1.

Each of the data elements we are proposing to collect and access pursuant to our authority under section 2(d)(2)(B) of the IMPACT Act is identified in the 2016 NASEM report as a social risk factor that has been shown to impact care use, cost and outcomes for Medicare beneficiaries. CMS uses the term social determinants of health (SDOH) to denote social risk factors, which is consistent with the objectives of Healthy People 2020.[159]

ASPE issued its first Report to Congress, entitled "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.[160] 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,

[159] Social Determinants of Health. Healthy People 2020. https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-of-health. (February 2019).
[160] 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.

including the full report, is available on the website at https://aspe.hhs.gov/social-risk-factors-and-medicares-value-based-purchasing-programs-reports.

Section 2(d)(2) of the IMPACT Act relates to CMS activities and imposes several responsibilities on the Secretary relating to quality, resource use, and other measures under Medicare. As mentioned previously, under of subparagraph (A) of section 2(d)(2) of the IMPACT Act, the Secretary is required, on an ongoing basis, taking into account the ASPE studies and other information, and based on an individual's health status and other factors, to assess appropriate adjustments to quality, resource use, and other measures, and to assess and implement appropriate adjustments to Medicare payments based on those measures. Section 2(d)(2)(A)(i) of the IMPACT Act applies to measures adopted under subsections (c) and (d) of section 1899B of the Act and to other measures under Medicare. However, our 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 related 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)(2) of the IMPACT Act through both new and existing data sources. Taking into consideration NASEM's conceptual framework for social risk factors discussed previously, 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 are proposing to collect and access data about SDOH under section 2(d)(2) of the IMPACT Act. Our collection and use of the SDOH data described in section IV.A.7.f.(i). of this proposed rule, under section 2(d)(2) of the IMPACT Act, would be independent of our proposal (in section IV.A.7.f.(2). of this proposed rule) and our authority to require submission of that data for use as SPADE under section 1899B(a)(1)(B) of the Act.

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

quality measures, resource use measures, and other measures, and to assess and implement appropriate adjustments to Medicare payments based on those measures. We agree with ASPE's observations, in the value-based purchasing context, that the ability to measure and track quality, outcomes, and costs for beneficiaries with social risk factors over time is critical as policymakers and providers seek to reduce disparities and improve care for these groups. Collecting the data as proposed will provide the basis for our periodic analyses of the relationship between an individual's health status and other factors and quality, resource, and other measures, as required by section 2(d)(2) of the IMPACT Act, and to assess appropriate adjustments. These data would 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 previously, we are proposing under section 2(d)(2) of the IMPACT Act, to collect the data on the following SDOH: (1) Race, as described in section V.G.5.b.(1). of this proposed rule; (2) Ethnicity, described in section V.G.5.b.(1). of this proposed rule; (3) Preferred Language, as described in section V.G.5.(ii).(2). of this proposed rule; (4) Interpreter Services, as described in section V.G.5.b.(2). of this proposed rule; (5) Health Literacy, as described in section V.G.5.b.(3). of this proposed rule; (6) Transportation, as described in section V.G.5.(ii).(4). of this proposed rule; and (7) Social Isolation, as described in section V.G.5.b.(5). of this proposed rule. These data elements are discussed in more detail in section V.G.5. of this proposed rule.

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

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

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

We also considered feedback received during a listening session that we held on December 13, 2018. The purpose of the listening session was to solicit feedback from health systems, research organizations, advocacy organizations, 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.

(1) Race and Ethnicity

The persistence of racial and ethnic disparities in health and health care is widely documented, including in PAC settings.[161,162,163,164,165] Despite the trend toward overall improvements in quality of care and health outcomes, the Agency for Healthcare Research and Quality, in its National Healthcare Quality and Disparities Reports, consistently indicates that racial and ethnic disparities persist, even after controlling for factors such as income, geography, and insurance.[166] 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.[167] Studies have also shown that African Americans are significantly more likely than white Americans to die prematurely from heart disease and stroke.[168] 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.[169]

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[161] 2017 National Healthcare Quality and Disparities Report. Rockville, MD: Agency for Healthcare Research and Quality; September 2018. AHRQ Pub. No. 18-0033-EF.
[162] 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.
[163] 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.
[164] 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.
[165] 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.
[166] National Healthcare Quality and Disparities Reports. (December 2018). Agency for Healthcare Research and Quality, Rockville, MD. http://www.ahrq.gov/research/findings/nhqrdr/index.html
[167] National Center for Health Statistics. Health, United States, 2017: With special feature on mortality. Hyattsville, Maryland. 2018.
[168] HHS. Heart disease and African Americans. 2016b. (October 24, 2016). http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=19.
[169] National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Population Health and Public Health Practice; Committee on Community-Based Solutions to Promote Health Equity in the United States; Baciu A, Negussie Y, Geller A, et al., editors. Communities in Action: Pathways to Health Equity. Washington (DC): National Academies Press (US); 2017 Jan 11. 2, The State of Health Disparities in the United States. Available from: https://www.ncbi.nlm.nih.gov/books/NBK425844/.

The ability to improve understanding of and address racial and ethnic disparities in PAC outcomes requires the availability of better data. There is currently a Race and Ethnicity data element, collected in the MDS, LCDS, IRF-PAI, and OASIS, that consists of a single question, which aligns with the 1997 Office of Management and Budget (OMB) minimum data standards for federal data collection efforts.[170] The 1997 OMB Standard lists five minimum categories of race: (1) American Indian or Alaska Native; (2) Asian; (3) Black or African American; (4) Native Hawaiian or Other Pacific Islander; (5) and White. The 1997 OMB Standard also lists two minimum categories of ethnicity: (1) Hispanic or Latino; and (2) Not Hispanic or Latino. The 2011 HHS Data Standards requires a two-question format when self-identification is used to collect data on race and ethnicity. Large federal surveys such as the National Health Interview Survey, Behavioral Risk Factor Surveillance System, and the National Survey on Drug Use and Health, have implemented the 2011 HHS race and ethnicity data standards. CMS has similarly updated the Medicare Current Beneficiary Survey, Medicare Health Outcomes Survey, and the Health Insurance Marketplace Application for Health Coverage with the 2011 HHS data standards. More information about the HHS Race and Ethnicity Data Standards are available on the website at https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=3&lvlid=54.

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

[170] "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.

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

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

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

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

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

We believe that the proposed modified race and ethnicity data elements more accurately reflect the diversity of the U.S. population than the current race/ethnicity data element included in MDS, LCDS, IRF-PAI, and OASIS.[171,172,173,174] We believe, and research consistently shows, that improving how race and ethnicity data are collected is an important first step in improving quality of care and health outcomes. Addressing disparities in access to care, quality of care, and health outcomes for Medicare beneficiaries begins with identifying and analyzing how SDOH, such as race and ethnicity, align with disparities in these areas.[175] Standardizing self-reported data collection for race and ethnicity allows for the equal comparison of data across multiple healthcare entities.[176] 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 U.S. 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 HH QRP Measures and Standardized Patient Assessment Data Elements," available at

[171] 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.
[172] 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.
[173] IOM (Institute of Medicine). 2009. Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement. Washington, DC: The National Academies Press.
[174] "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.
[175] 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/.
[176] IOM (Institute of Medicine). 2009. Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement. Washington, DC: The National Academies Press.

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

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

Specifically, we are proposing to replace the current Race/Ethnicity data element, M0140, with the proposed Race and Ethnicity data elements. Due to the stable nature of Race/Ethnicity, we are proposing that HHAs that submit the Race and Ethnicity SPADEs with respect to SOC only will be deemed to have submitted those SPADEs with respect to SOC, ROC, and discharge, because it is unlikely that the assessment of those SPADEs with respect to SOC will differ from the assessment of the same SPADES with respect to ROC and discharge.

(2) 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).[177] Individuals with LEP have been shown to receive worse care and have poorer health outcomes, including higher readmission rates.[178,179,180] 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

[177] U.S. Census Bureau, 2013-2017 American Community Survey 5-Year Estimates
[178] 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.
[179] 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.
[180] 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.

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 patients with LEP, including individuals who are Deaf or hard of hearing, is critical for ensuring good outcomes.

Presently, the preferred language of patients and need for interpreter services are assessed in two PAC assessment tools. The LCDS and the MDS use the same two data elements to assess preferred language and whether a patient or resident needs or wants an interpreter to communicate with health care staff. The MDS initially implemented preferred language and interpreter services data elements to assess the needs of SNF residents and patients and inform care planning. For alignment purposes, the LCDS later adopted the same data elements for LTCHs. The 2009 NASEM (formerly Institute of Medicine) report on standardizing data for health care quality improvement emphasizes that language and communication needs should be assessed as a standard part of health care delivery and quality improvement strategies.[181]

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 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

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

Improvement." In it, the committee recommended that organizations evaluating a patient's language and communication needs for health care purposes, should collect data on the preferred spoken language and on an individual's assessment of his/her level of English proficiency.

A second language data element in LCDS and MDS asks, "Do you want or need an interpreter to communicate with a doctor or health care staff?" and includes yes or no response options. In contrast, the 2011 HHS Primary Language Data Standard recommends either a single question to assess how well someone speaks English or, if more granular information is needed, a two-part question to assess whether a language other than English is spoken at home and if so, identify that language. However, neither option allows for a direct assessment of a patient's 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 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.[182] 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. Therefore

[182] 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.

we are proposing to use the Preferred Language and Interpreter Services data elements currently in use on the MDS and LCDS, on the OASIS.

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

Improving how preferred language and need for interpreter services data are collected is an important component of improving quality by helping PAC providers and other providers 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 HH QRP Measures and Standardized Patient Assessment Data Elements," available on the website at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.

In an effort to standardize the submission of language data among IRFs, HHAs, SNFs and LTCHs, for the purposes outlined in section 1899B(a)(1)(B) of the Act, while minimizing

the reporting burden, we are proposing to adopt the Preferred Language and Interpreter Services data elements currently used on the LCDS and MDS, and described previously, as SPADES with respect to the Social Determinants of Health category.

(3) 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."[183] Similar to language barriers, 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. 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.[184]

Health literacy is prioritized by Healthy People 2020 as an SDOH.[185] 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 report 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.[186] Assessing for health literacy across PAC settings would facilitate

[183] 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.
[184] 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.
[185] Social Determinants of Health. Healthy People 2020. https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-of-health. (February 2019).
[186] 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-medicares-value-based-purchasing-programs. Washington, DC: 2016.

better care coordination and discharge planning. A significant challenge in assessing the health literacy of individuals is avoiding excessive burden on patients and health care providers. The majority of existing, validated health literacy assessment tools use multiple screening items, generally with no fewer than four, which would make them burdensome if adopted in MDS, LCDS, IRF-PAI, and OASIS.

The Single Item Literacy Screener (SILS) question asks, "How often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor or pharmacy?" Possible response options are: (1) Never; (2) Rarely; (3) Sometimes; (4) Often; and (5) Always. The SILS question, which assesses reading ability (a primary component of health literacy), tested reasonably well against the 36 item Short Test of Functional Health Literacy in Adults (S-TOFHLA), a thoroughly vetted and widely adopted health literacy test, in assessing the likelihood of low health literacy in an adult sample from primary care practices participating in the Vermont Diabetes Information System.[187,188] 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.[189] Furthermore, the S-TOFHLA instrument is proprietary and subject to purchase for individual entities or users.[190] Given that SILS is publicly available, shorter and easier to administer than the full health literacy screen, and research found that a positive result on the SILS demonstrates an increased likelihood that an individual has low health literacy, we are proposing to use the single-item reading question for health literacy in the

[187] 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.

188 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.

[189] 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 from: https://elcentro.sonhs.miami.edu/research/measures-library/tofhla/index.html

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

standardized data collection across PAC settings. We believe that use of this data element will provide sufficient information about the health literacy of HH patients to facilitate appropriate care planning, care coordination, and interoperable data exchange across PAC settings.

In addition, we received feedback during the December 13, 2018 SDOH listening session on the importance of recognizing health literacy as more than understanding written materials and filling out forms, as it is also important to evaluate whether patients 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.[191] 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.[192] For more information on the proposed Health Literacy data element, we refer readers to the document titled "Proposed Specifications for HH QRP Measures and Standardized Patient Assessment Data Elements," available on the website at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.

In an effort to standardize the submission of health literacy data among IRFs, HHAs, SNFs and LTCHs, for the purposes outlined in section 1899B(a)(1)(B) of the Act, while minimizing the reporting burden, we are proposing to adopt the SILS question, described

[191] 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.
[192] 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.

previously for the Health Literacy data element, as SPADE under the Social Determinants of Health category. We are proposing to add the Health Literacy data element to the OASIS.

(4) 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.[193] 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 a 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 would be given the option to select all responses that apply. We are proposing to use the transportation data element from the PRAPARE Tool, with permission from National Association of

[193] 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.

Community Health Centers (NACHC), after considering research on the importance of addressing transportation needs as a critical SDOH.[194]

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.[195] 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.[196] We believe that use of this data element will provide sufficient information about transportation barriers to medical and non-medical care for HH patients to facilitate appropriate discharge planning and care coordination across PAC settings. As such, we are proposing to adopt the Transportation data element from PRAPARE. More information

[194] 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.
[195] 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.
[196] Northwestern University. (2017). PROMIS Item Bank v. 1.0 – Emotional Distress – Anger - Short Form 1.

about development of the PRAPARE tool is available on the website at https://protect2.fireeye.com/url?k=7cb6eb44-20e2f238-7cb6da7b-0cc47adc5fa2-1751cb986c8c2f8c&u=http://www.nachc.org/prapare.

In addition, we received stakeholder feedback during the December 13, 2018 SDOH listening session on the impact of transportation barriers on unmet care needs. While recognizing that there is no consensus in the field about whether providers should have 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 HH QRP Measures and Standardized Patient Assessment Data Elements," available on the website at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.

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

(5) 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.[197, 198] Social isolation tends to increase with age, is a risk factor for physical and mental illness, and a predictor of mortality.[199,200,201] Post-acute care providers are well-suited to design and implement programs to increase social engagement of patients, while also taking into account individual needs and preferences. Adopting a data element to collect and analyze information about social isolation for patients receiving HH services and across PAC settings would facilitate the identification of patients who are socially isolated and who may benefit from engagement efforts.

We are proposing to adopt as SPADE a single social isolation data element that is currently part of the AHC Screening Tool. The AHC item was selected from the Patient-Reported Outcomes Measurement Information System (PROMIS®) Item Bank on Emotional Distress, and asks, "How often do you feel lonely or isolated from those around you?" The five response options are: (1) Never; (2) Rarely; (3) Sometimes; (4) Often; and (5) Always.[202] 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.

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[197] 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.
[198] 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
[199] 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.
[200] 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.
[201] Leigh-Hunt, N., Bagguley, D., Bash, K., Turner, V., Turnbull, S., Valtorta, N., and Caan, W. (2017). An overview of systematic reviews on the public health consequences of social isolation and loneliness. Public Health. 152:157-171.
[202] Northwestern University. (2017). PROMIS Item Bank v. 1.0 – Emotional Distress – Anger - Short Form 1.

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 patient complexity and the care goals of patients, thereby facilitating care coordination and continuity in care planning across PAC settings. For more information on the Social Isolation data element, we refer readers to the document titled "Proposed Specifications for HH 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 data about social isolation among IRFs, HHAs, SNFs and LTCHs, for the purposes outlined in section 1899B(a)(1)(B) of the Act, while minimizing the reporting burden, we are proposing to adopt the Social Isolation data element described previously as SPADE with respect to the proposed Social Determinants of Health category. We are proposing to add the Social Isolation data element to the OASIS.

J. Proposed Codification of the Home Health Quality Reporting Program Requirements

To promote alignment of the HH QRP and the SNF QRP, IRF QRP, and LTCH QRP regulatory text, we believe that with the exception of the provision governing the 2 percentage point reduction to the update of the unadjusted national standardized prospective payment rate, it is appropriate to codify the requirements that apply to the HH QRP in a single section of our regulations. Accordingly, we are proposing to amend 42 CFR chapter IV, subchapter G by creating a new § 484.245, titled "Home Health Quality Reporting Program".

The provisions we are proposing to codify are as follows:

- The HH QRP participation requirements at § 484.245(a) (72 FR 49863).
- The HH QRP data submission requirements at § 484.245(b)(1), including--

++ Data on measures specified under section 1899B(c)(1) and 1899B(d)(1) of the Act;

++ Standardized patient assessment data required under section 1899B(b)(1) of the Act (82 FR 51735 through 51736); and

++ Quality data specified under section 1895(b)(3)(B)(v)(II) of the Act including the HHCAHPS survey data submission requirements at § 484.245(b)(1)(iii)(A) through (E) (redesignated from § 484.250(b) through (c)(3) and striking § 484.250(a)(2)).

- The HH QRP data submission form, manner, and timing requirements at § 484.245(b)(2).
- The HH QRP exceptions and extension requirements at § 484.245(c) (redesignated from § 484.250(d)(1) through (d)(4)(ii)).
- The HH QRP's reconsideration policy at § 484.245(d) (redesignated from § 484.250(e)(1) through (4)).
- The HH QRP appeals policy at § 484.245(e) (redesignated from § 484.250(f)).

We also note the following codification proposals:

- The addition of the HHCAHPS and HH QRP acronyms to the definitions at §484.205.
- The removal of the regulatory provision in §484.225(b) regarding the unadjusted national prospective 60-day episode rate for HHAs that submit their quality data as specified by the Secretary.
- The redesignation of the regulatory provision in §484.225(c) to §484.225(b) regarding the unadjusted national prospective 60-day episode rate for HHAs that do not submit their quality data as specified by the Secretary.
- The redesignation of the regulatory provision in §484.225(d) to §484.225(c) regarding the national, standardized prospective 30-day payment amount. The cross-reference in newly redesignated paragraph (c) would also be revised.

K. Home Health Care Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Survey (HHCAHPS)

We are proposing to remove Question 10 from all HHCAHPS Surveys (both mail surveys and telephone surveys) which says, "In the last 2 months of care, did you and a home health provider from this agency talk about pain?" which is one of seven questions (they are questions 3, 4, 5, 10, 12, 13 and 14) in the "Special Care Issues" composite measure, beginning July 1, 2020. The "Special Care Issues" composite measure also focuses on home health agency staff discussing home safety, the purpose of the medications that are being taken, side effects of medications, and when to take medications. In the initial development of the HHCAHPS Survey, this question was included in the survey since home health agency staff talk about pain to identify any emerging issues (for example, wounds that are getting worse) every time they see their home health patients.

We are proposing to remove pain questions from the HHCAHPS Survey and pain items from the OASIS data sets to avoid potential unintended consequences that may arise from their inclusion in CMS surveys and datasets. The reason that CMS is proposing removing this particular pain question is consistent with the proposed removal of pain items from OASIS in section IV.D.1. of this proposed rule and also consistent with the removal of pain items from the Hospital CAHPS Survey. The removal of pain questions from CMS surveys and removal of pain items from CMS data sets is to avoid potential unintended consequences that arise from their inclusion in CMS surveys and datasets. We welcome comments about the proposed removal of Q10 from the HHCAHPS Survey. In the initial development of the HHCAHPS Survey, this question was included in the survey, and, consequently, from the "Special Care Issues" measure.

The HHCAHPS Survey is available on the official website for HHCAHPS, at https://homehealthcahps.org.

I. Form, Manner, and Timing of Data Submission Under the HH QRP

1. Background

Section 484.250(a), requires HHAs to submit OASIS data and Home Health Care Consumer Assessment of Healthcare Providers and Systems Survey (HHCAHPS) data to meet the quality reporting requirements of section 1895(b)(3)(B)(v) of the Act. Not all OASIS data described in § 484.55(b) and (d) are necessary for purposes of complying with the quality reporting requirements of section 1895(b)(3)(B)(v) of the Act. OASIS data items may be used for other purposes unrelated to the HH QRP, including payment, survey and certification, the HH VBP Model, or care planning. Any OASIS data that are not submitted for the purposes of the HH QRP are not used for purposes of determining HH QRP compliance.

2. Proposed Schedule for Reporting the Transfer of Health Information Quality Measures Beginning With the CY 2022 HH QRP

As discussed in section V.E. of this proposed rule, we are proposing to adopt the Transfer of Health Information to Provider–Post-Acute Care (PAC) and Transfer of Health Information to Patient–Post-Acute Care (PAC) quality measures beginning with the CY 2022 HH QRP. We are also proposing that HHAs would report the data on those measures using the OASIS. We are proposing that HHAs would be required to collect data on both measures for patients beginning with patients discharged or transferred on or after January 1, 2021. HHAs would be required to report these data for the CY 2022 HH QRP at discharge and transfer between January 1, 2021 and June 30, 2021. Following the initial reporting period for the CY 2022 HH QRP, subsequent

years for the HH QRP would be based on 12 months of such data reporting beginning with July 1, 2021 through June 30, 2022 for the CY 2023 HH QRP.

3. Proposed Schedule for Reporting Standardized Patient Assessment Data Elements Beginning With the CY 2022 HH QRP

As discussed in section V.G. of this proposed rule, we are proposing to adopt additional SPADEs beginning with the CY 2022 HH QRP. We are proposing that HHAs would report the data using the OASIS. HHAs would be required to collect the SPADEs for episodes beginning or ending on or after January 1, 2021. We are also proposing that HHAs that submit the Hearing, Vision, Race, and Ethnicity SPADEs with respect to SOC will be deemed to have submitted those SPADEs with respect to SOC, ROC, and discharge, because it is unlikely that the assessment of those SPADEs with respect to SOC will differ from the assessment of the same SPADES with respect to ROC or discharge. HHAs would be required to report the remaining SPADES for the CY 2022 HH QRP at SOC, ROC, and discharge time points between January 1, 2021 and June 30, 2021. Following the initial reporting period for the CY 2022 HH QRP, subsequent years for the HH QRP would be based on 12 months of such data reporting beginning with July 1, 2021 through June 30, 2022 for the CY 2023 HH QRP.

4. Input Sought to Expand the Reporting of OASIS Data Used for the HH QRP to Include Data on All Patients Regardless of Their Payer

We continue to believe that the reporting of all-payer data under the HH QRP would add value to the program and provide a more accurate representation of the quality provided by HHA's. In the CY 2018 HH PPS final rule (82 FR 51736 through 51737), we received and responded to comments sought for data reporting related to assessment based measures, specifically on whether we should require quality data reporting on all HH patients, regardless of

payer, where feasible. Several commenters supported data collection of all patients regardless of payer but other commenters did express concerns about the burden imposed on the HHAs as a result of OASIS reporting for all patients, including healthcare professionals spending more time with documentation and less time providing patient care, and the need to increase staff hours or hire additional staff. A commenter requested CMS provide additional explanation of what the benefit would be to collecting OASIS data on all patients regardless of payer.

We are sensitive to the issue of burden associated with data collection and acknowledge concerns about the additional burden required to collect quality data on all patients. We are aware that while some providers use a separate assessment for private payers, many HHA's currently collect OASIS data on all patients regardless of payer to assist with clinical and work flow implications associated with maintaining two distinct assessments. We believe collecting OASIS data on all patients regardless of payer will allow us to ensure data that is representative of quality provided to all patients in the HHA setting and therefore, allow us to better determine whether HH Medicare beneficiaries receive the same quality of care that other patients receive. We also believe it is the overall goal of the IMPACT Act to standardize data and measures in the four PAC programs to permit longitudinal analysis of the data. The absence of all payer data limits CMS's ability to compare all patients receiving services in each PAC setting, as was intended by the Act.

We plan to propose to expand the reporting of OASIS data used for the HH QRP to include data on all patients, regardless of their payer, in future rulemaking. Collecting data on all HHA patients, regardless of their payer would align our data collection requirements under the HH QRP with the data collection requirements currently adopted for the Long-Term Care Hospital (LTCH) QRP and the Hospice QRP. Additionally, collection of data on all patients,

regardless of their payer is currently being proposed in the FY 2020 rules for the Skilled Nursing Facility (SNF) QRP (84 FR 17678 through 17679) and the Inpatient Rehabilitation Facilities (IRF) QRP (84 FR 17326 through 17327). To assist us regarding a future proposal, we are seeking input on the following questions related to requiring quality data reporting on all HH patients, regardless of payer:

- Do you agree there is a need to collect OASIS data for the HH QRP on all patients regardless of payer?
- What percentage of your HHA's patients are you not currently reporting OASIS data for the HH QRP?
- Are there burden issues that need to be considered specific to the reporting of OASIS data on all HH patients, regardless of their payer?
- What differences, if any, do you notice in patient mix or in outcomes between those patients that you currently report OASIS data, and those patients that you do not report data for the HH QRP?
- Are there other factors that should be considered prior to proposing to expand the reporting of OASIS data used for the HH QRP to include data on all patients, regardless of their payer?

As stated previously, there is no proposal in this rule to expand the reporting of OASIS data used for the HH QRP to include data on all HHA patients regardless of payer. However we look forward to receiving comments on this topic, including the questions noted previously, and will take all recommendations received into consideration.

VI. Medicare Coverage of Home Infusion Therapy Services

A. Background and Overview

1. Background

Section 5012 of the 21st Century Cures Act ("the Cures Act") (Pub. L. 114-255), which amended sections 1861(s)(2) and 1861(iii) of the Act, established a new Medicare home infusion therapy benefit. The Medicare home infusion therapy benefit covers the professional services, including nursing services, furnished in accordance with the plan of care, patient training and education (not otherwise covered under the durable medical equipment benefit), remote monitoring, and monitoring services for the provision of home infusion therapy and home infusion drugs furnished by a qualified home infusion therapy supplier. This benefit will ensure consistency in coverage for home infusion benefits for all Medicare beneficiaries.

Section 50401 of the BBA of 2018 amended section 1834(u) of the Act by adding a new paragraph (7) that establishes a home infusion therapy services temporary transitional payment for eligible home infusion suppliers for certain items and services furnished in coordination with the furnishing of transitional home infusion drugs beginning January 1, 2019. This temporary payment covers the cost of the same items and services, as defined in section 1861(iii)(2)(A) and (B) of the Act, related to the administration of home infusion drugs. The temporary transitional payment began on January 1, 2019 and will end the day before the full implementation of the home infusion therapy benefit on January 1, 2021, as required by section 5012 of the 21st Century Cures Act.

In the CY 2019 HH PPS final rule (83 FR 32340), we finalized the implementation of temporary transitional payments for home infusion therapy services to begin on January 1, 2019. In addition, we implemented the establishment of regulatory authority for the oversight of

national accrediting organizations (AOs) that accredit home infusion therapy suppliers, and their CMS-approved home infusion therapy accreditation programs.

2. Overview of Infusion Therapy

Infusion drugs can be administered in multiple health care settings, including inpatient hospitals, skilled nursing facilities (SNFs), hospital outpatient departments (HOPDs), physicians' offices, and in the home. Traditional fee-for-service (FFS) Medicare provides coverage for infusion drugs, equipment, supplies, and administration services. However, Medicare coverage requirements and payment vary for each of these settings. Infusion drugs, equipment, supplies, and administration are all covered by Medicare in the inpatient hospital, SNFs, HOPDs, and physicians' offices.

Generally, Medicare payment under Part A for the drugs, equipment, supplies, and services are bundled, meaning a single payment is made on the basis of expected costs for clinically-defined episodes of care. For example, if a beneficiary is receiving an infusion drug during an inpatient hospital stay, the Part A payment for the drug, supplies, equipment, and drug administration is included in the diagnosis-related group (DRG) payment to the hospital under the Medicare inpatient prospective payment system. Beneficiaries are liable for the Medicare inpatient hospital deductible and no coinsurance for the first 60 days. Similarly, if a beneficiary is receiving an infusion drug while in a SNF under a Part A stay, the payment for the drug, supplies, equipment, and drug administration are included in the SNF prospective payment system payment. After 20 days of SNF care, there is a daily beneficiary cost-sharing amount through day 100 when the beneficiary becomes responsible for all costs for each day after day 100 of the benefit period.

Under Medicare Part B, certain items and services are paid separately while other items and services may be packaged into a single payment together. For example, in an HOPD and in

a physician's office, the drug is paid separately, generally at the average sales price (ASP) plus 6 percent (77 FR 68210).[203] Medicare also makes a separate payment to the physician or hospital outpatient departments (HOPD) for administering the drug. The separate payment for infusion drug administration in an HOPD and in a physician's office generally includes a base payment amount for the first hour and a payment add-on that is a different amount for each additional hour of administration. The beneficiary is responsible for the 20 percent coinsurance under Medicare Part B.

Medicare FFS covers outpatient infusion drugs under Part B, "incident to" a physician's service, provided the drugs are not usually self-administered by the patient. Drugs that are "not usually self-administered," are defined in our manual according to how the Medicare population as a whole uses the drug, not how an individual patient or physician may choose to use a particular drug. For the purpose of this exclusion, the term "usually" means more than 50 percent of the time for all Medicare beneficiaries who use the drug. The term "by the patient" means Medicare beneficiaries as a collective whole. Therefore, if a drug is self-administered by more than 50 percent of Medicare beneficiaries, the drug is generally excluded from Part B coverage. This determination is made on a drug-by-drug basis, not on a beneficiary-by-beneficiary basis.[204] The MACs update Self-Administered Drug (SAD) exclusion lists on a quarterly basis.[205]

Home infusion therapy involves the intravenous or subcutaneous administration of drugs or biologicals to an individual at home. Certain drugs can be infused in the home, but the nature

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203 https://www.govinfo.gov/content/pkg/FR-2012-11-15/pdf/2012-26902.pdf

[204] Medicare Benefit Policy Manual, chapter 15, "Covered Medical and Other Health Services", section 50.2 - Determining Self-Administration of Drug or Biological found at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf

[205] www.cms.gov/medicare-coverage-database/reports/sad-exclusion-list-report.aspx?bc=AQAAAAAAAAAAAA%3D%3D

of the home setting presents different challenges than the settings previously described. Generally, the components needed to perform home infusion include the drug (for example, antivirals, immune globulin), equipment (for example, a pump), and supplies (for example, tubing and catheters). Likewise, nursing services are usually necessary to train and educate the patient and caregivers on the safe administration of infusion drugs in the home. Visiting nurses often play a large role in home infusion. These nurses typically train the patient or caregiver to self-administer the drug, educate on side effects and goals of therapy, and visit periodically to assess the infusion site and provide dressing changes. Depending on patient acuity or the complexity of the drug administration, certain infusions may require more training and education, especially those that require special handling or pre-or post-infusion protocols. The home infusion process typically requires coordination among multiple entities, including patients, physicians, hospital discharge planners, health plans, home infusion pharmacies, and, if applicable, home health agencies.

With regard to payment for home infusion therapy under traditional Medicare, drugs are generally covered under Part B or Part D. Certain infusion pumps, supplies (including home infusion drugs and the services required to furnish the drug, (that is, preparation and dispensing), and nursing are covered in some circumstances through the Part B durable medical equipment (DME) benefit, the Medicare home health benefit, or some combination of these benefits. In accordance with section 50401 of the Bipartisan Budget Act (BBA) of 2018, beginning on January 1, 2019, for CYs 2019 and 2020, Medicare implemented temporary transitional payments for home infusion therapy services furnished in coordination with the furnishing of transitional home infusion drugs. This payment, for home infusion therapy services, is only made if a beneficiary is furnished certain drugs and biologicals administered through an item of

covered DME, and payable only to suppliers enrolled in Medicare as pharmacies that provide external infusion pumps and external infusion pump supplies (including the drug). With regard to the coverage of the home infusion drugs, Medicare Part B covers a limited number of home infusion drugs through the DME benefit if: (1) the drug is necessary for the effective use of an external infusion pump classified as DME and determined to be reasonable and necessary for administration of the drug; and (2) the drug being used with the pump is itself reasonable and necessary for the treatment of an illness or injury. Additionally, in order for the infusion pump to be covered under the DME benefit, it must be appropriate for use in the home (§ 414.202).

Only certain types of infusion pumps are covered under the DME benefit. The Medicare *National Coverage Determinations Manual*, chapter 1, part 4, section 280.14 describes the types of infusion pumps that are covered under the DME benefit.[206] For DME external infusion pumps, Medicare Part B covers the infusion drugs and other supplies and services necessary for the effective use of the pump. Through the Local Coverage Determination (LCD) for External Infusion Pumps (L33794), the DME Medicare administrative contractors (MACs) specify the details of which infusion drugs are covered with these pumps. Examples of covered Part B DME infusion drugs include, among others, certain IV drugs for heart failure and pulmonary arterial hypertension, immune globulin for primary immune deficiency (PID), insulin, antifungals, antivirals, and chemotherapy, in limited circumstances.

3. Home Infusion Therapy Legislation

a. 21st Century Cures Act

Effective January 1, 2021, section 5012 of the 21st Century Cures Act (Pub. L. 114-255) (Cures Act) created a separate Medicare Part B benefit category under section 1861(s)(2)(GG) of

206 https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS014961.html

the Act for coverage of home infusion therapy services needed for the safe and effective administration of certain drugs and biologicals administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the home of an individual, through a pump that is an item of DME. The infusion pump and supplies (including home infusion drugs) will continue to be covered under the Part B DME benefit. Section 1861(iii)(2) of the Act defines home infusion therapy to include the following items and services: the professional services, including nursing services, furnished in accordance with the plan, training and education (not otherwise paid for as DME), remote monitoring, and other monitoring services for the provision of home infusion therapy and home infusion drugs furnished by a qualified home infusion therapy supplier, which are furnished in the individual's home. Section 1861(iii)(3)(B) of the Act defines the patient's home to mean a place of residence used as the home of an individual as defined for purposes of section 1861(n) of the Act. As outlined in section 1861(iii)(1) of the Act, to be eligible to receive home infusion therapy services under the home infusion therapy benefit, the patient must be under the care of an applicable provider (defined in section 1861(iii)(3)(A) of the Act as a physician, nurse practitioner, or physician's assistant), and the patient must be under a physician-established plan of care that prescribes the type, amount, and duration of infusion therapy services that are to be furnished. The plan of care must be periodically reviewed by the physician in coordination with the furnishing of home infusion drugs (as defined in section 1861(iii)(3)(C) of the Act). Section 1861(iii)(3)(C) of the Act defines a "home infusion drug" under the home infusion therapy benefit as a drug or biological administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the patient's home, through a pump that is an item of DME as defined under section 1861(n) of the Act. This

definition does not include insulin pump systems or any self-administered drug or biological on a self-administered drug exclusion list.

Section 1861(iii)(3)(D)(i) of the Act defines a "qualified home infusion therapy supplier" as a pharmacy, physician, or other provider of services or supplier licensed by the state in which supplies or services are furnished. The provision specifies qualified home infusion therapy suppliers must furnish infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs; ensure the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis; be accredited by an organization designated by the Secretary; and meet other such requirements as the Secretary deems appropriate, taking into account the standards of care for home infusion therapy established by Medicare Advantage (MA) plans under Part C and in the private sector. The supplier may subcontract with a pharmacy, physician, other qualified supplier or provider of medical services, in order to meet these requirements.

Section 1834(u)(1) of the Act requires the Secretary to implement a payment system under which, beginning January 1, 2021, a single payment is made to a qualified home infusion therapy supplier for the items and services (professional services, including nursing services; training and education; remote monitoring, and other monitoring services). The single payment must take into account, as appropriate, types of infusion therapy, including variations in utilization of services by therapy type. In addition, the single payment amount is required to be adjusted to reflect geographic wage index and other costs that may vary by region, patient acuity, and complexity of drug administration. The single payment may be adjusted to reflect outlier situations, and other factors as deemed appropriate by the Secretary, which are required to be done in a budget-neutral manner. Section 1834(u)(2) of the Act specifies certain items that "the

Secretary may consider" in developing the HIT payment system: "the costs of furnishing infusion therapy in the home, consult[ation] with home infusion therapy suppliers, . . . payment amounts for similar items and services under this part and part A, and . . . payment amounts established by Medicare Advantage plans under part C and in the private insurance market for home infusion therapy (including average per treatment day payment amounts by type of home infusion therapy)". Section 1834(u)(3) of the Act specifies that annual updates to the single payment are required to be made, beginning January 1, 2022, by increasing the single payment amount by the percent increase in the Consumer Price Index for all urban consumers (CPI-U) for the 12-month period ending with June of the preceding year, reduced by the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP). Under section 1834(u)(1)(A)(iii), the single payment amount for each infusion drug administration calendar day, including the required adjustments and the annual update, cannot exceed the amount determined under the fee schedule under section 1848 of the Act for infusion therapy services if furnished in a physician's office. This statutory provision limits the single payment amount so that it cannot reflect more than 5 hours of infusion for a particular therapy per calendar day. Section 1834(u)(4) of the Act also allows the Secretary discretion, as appropriate, to consider prior authorization requirements for home infusion therapy services. Finally, section 5012(c)(3) of the 21st Century Cures Act amended section 1861(m) of the Act to exclude home infusion therapy from the HH PPS beginning on January 1, 2021.

b. Bipartisan Budget Act of 2018

Section 50401 of the Bipartisan Budget Act of 2018 (Pub. L. 115-123) amended section 1834(u) of the Act by adding a new paragraph (7) that established a home infusion therapy services temporary transitional payment for eligible home infusion suppliers for certain items

and services furnished in coordination with the furnishing of transitional home infusion drugs, beginning January 1, 2019. This payment covers the same items and services as defined in section 1861(iii)(2)(A) and (B) of the Act, furnished in coordination with the furnishing of transitional home infusion drugs. Section 1834(u)(7)(A)(iii) of the Act defines the term "transitional home infusion drug" using the same definition as "home infusion drug" under section 1861(iii)(3)(C) of the Act, which is a parenteral drug or biological administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the home of an individual through a pump that is an item of DME as defined under section 1861(n) of the Act. The definition of "home infusion drug" excludes "a self-administered drug or biological on a self-administered drug exclusion list" but the definition of "transitional home infusion drug" notes that this exclusion shall not apply if a drug described in such clause is identified in clauses (i), (ii), (iii) or (iv) of 1834(u)(7)(C) of the Act. Section 1834(u)(7)(C) of the Act sets out the Healthcare Common Procedure Coding System (HCPCS) codes for the drugs and biologicals covered under the DME LCD for External Infusion Pumps (L33794), as the drugs covered during the temporary transitional period. In addition, section 1834(u)(7)(C) of the Act states that the Secretary shall assign to an appropriate payment category drugs which are covered under the DME LCD for External Infusion Pumps and billed under HCPCS codes J7799 (Not otherwise classified drugs, other than inhalation drugs, administered through DME) and J7999 (Compounded drug, not otherwise classified), or billed under any code that is implemented after the date of the enactment of this paragraph and included in such local coverage determination or included in sub-regulatory guidance as a home infusion drug.

Section 1834(u)(7)(E)(i) of the Act states that payment to an eligible home infusion supplier or qualified home infusion therapy supplier for an infusion drug administration calendar

day in the individual's home refers to payment only for the date on which professional services, as described in section 1861(iii)(2)(A) of the Act, were furnished to administer such drugs to such individual. This includes all such drugs administered to such individual on such day. Section 1842(u)(7)(F) of the Act defines "eligible home infusion supplier" as a supplier who is enrolled in Medicare as a pharmacy that provides external infusion pumps and external infusion pump supplies, and that maintains all pharmacy licensure requirements in the State in which the applicable infusion drugs are administered.

As set out at section 1834(u)(7)(C) of the Act, identified HCPCS codes for transitional home infusion drugs are assigned to three payment categories, as identified by their corresponding HCPCS codes, for which a single amount will be paid for home infusion therapy services furnished on each infusion drug administration calendar day. Payment category 1 includes certain intravenous infusion drugs for therapy, prophylaxis, or diagnosis, including antifungals and antivirals; inotropic and pulmonary hypertension drugs; pain management drugs; and chelation drugs. Payment category 2 includes subcutaneous infusions for therapy or prophylaxis, including certain subcutaneous immunotherapy infusions. Payment category 3 includes intravenous chemotherapy infusions, including certain chemotherapy drugs and biologicals. The payment category for subsequent transitional home infusion drug additions to the LCD and compounded infusion drugs not otherwise classified, as identified by HCPCS codes J7799 and J7999, will be determined by the DME MACs.

In accordance with section 1834(u)(7)(D) of the Act, each payment category is paid at amounts in accordance with the Physician Fee Schedule (PFS) for each infusion drug administration calendar day in the individual's home for drugs assigned to such category, without geographic adjustment. Section 1834(u)(7)(E)(ii) of the Act requires that in the case that

two (or more) home infusion drugs or biologicals from two different payment categories are administered to an individual concurrently on a single infusion drug administration calendar day, one payment for the highest payment category will be made.

4. Summary of CY 2019 Home Infusion Therapy Provisions

In the CY 2019 Home Health Prospective Payment System (HH PPS) final rule (83 FR 56579) we finalized the implementation of the home infusion therapy services temporary transitional payments under paragraph (7) of section 1834(u) of the Act. These services are furnished in the individual's home to an individual who is under the care of an applicable provider (defined in section 1861(iii)(3)(A) of the Act as a physician, nurse practitioner, or physician's assistant) and where there is a plan of care established and periodically reviewed by a physician prescribing the type, amount, and duration of infusion therapy services. Only eligible home infusion suppliers can bill for the temporary transitional payments. Therefore, in accordance with section 1834(u)(7)(F) of the Act, we clarified that this means that existing DME suppliers that are enrolled in Medicare as pharmacies that provide external infusion pumps and external infusion pump supplies, who comply with Medicare's DME Supplier and Quality Standards, and maintain all pharmacy licensure requirements in the State in which the applicable infusion drugs are administered, are considered eligible home infusion suppliers.

Section 1834(u)(7)(C) of the Act assigns transitional home infusion drugs, identified by the HCPCS codes for the drugs and biologicals covered under the DME LCD for External Infusion Pumps (L33794)[207], into three payment categories, for which we established a single payment amount in accordance with section 1834(u)(7)(D) of the Act. This section states that each single payment amount per category will be paid at amounts equal to the amounts

207 - https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33794&ver=83&Date=05%2f15%2f2019&DocID=L33794&bc=iAAAABAAAAAA&

determined under the PFS established under section 1848 of the Act for services furnished during the year for codes and units of such codes, without geographic adjustment. Therefore, we created a new HCPCS G-code for each of the three payment categories and finalized the billing procedure for the temporary transitional payment for eligible home infusion suppliers. We stated that the eligible home infusion supplier would submit, in line-item detail on the claim, a G-code for each infusion drug administration calendar day. The claim should include the length of time, in 15-minute increments, for which professional services were furnished. The G-codes can be billed separately from, or on the same claim as, the DME, supplies, or infusion drug, and are processed through the DME MACs. On August 10, 2018, we issued Change Request: R4112CP: Temporary Transitional Payment for Home Infusion Therapy Services for CYs 2019 and 2020 208 outlining the requirements for the claims processing changes needed to implement this payment.

And finally, we finalized the definition of "infusion drug administration calendar day" in regulation as the day on which home infusion therapy services are furnished by skilled professional(s) in the individual's home on the day of infusion drug administration. The skilled services provided on such day must be so inherently complex that they can only be safely and effectively performed by, or under the supervision of, professional or technical personnel (42 CFR 486.505). Section 1834(u)(7)(E)(i) of the Act clarifies that this definition is with respect to the furnishing of "transitional home infusion drugs" and "home infusion drugs" to an individual by an "eligible home infusion supplier" and a "qualified home infusion therapy supplier." The definition of "infusion drug administration calendar day" applies to both the temporary transitional payment in CYs 2019 and 2020 and the permanent home infusion therapy benefit to be implemented beginning in CY 2021. Although we finalized this definition in

208 https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R4112CP.pdf

regulation in the CY 2019 HH PPS final rule with comment (83 FR 56583), we stated that we would carefully monitor the effects of this definition on access to care and we stated that, if warranted and if within the limits of our statutory authority, we would engage in additional rulemaking our guidance regarding this definition. In that same rule, we also solicited additional comments on this interpretation and on its effects on access to care. We have been monitoring utilization of home infusion therapy services beginning on January 1, 2019; however, we do not have sufficient data on utilization yet to determine the effects on access to care. We will be addressing those comments received in response to the CY 2019 HH PPS final rule with comment as well as those received for this proposed rule in the CY 2020 HH PPS final rule.

B. CY 2020 Temporary Transitional Payment Rates for Home Infusion Therapy Services

As previously noted, section 50401 of the BBA of 2018 amended section 1834(u) of the Act by adding a new paragraph (7) that established a home infusion therapy services temporary transitional payment for eligible home infusion suppliers for certain items and services furnished to administer home infusion drugs beginning January 1, 2019. This temporary payment covers the cost of the same items and services including professional services, training and education, monitoring, and remote monitoring services, as defined in section 1861(iii)(2)(A) and (B) of the Act, related to the administration of home infusion drugs. The temporary transitional payment began on January 1, 2019 and will end the day before the full implementation of the home infusion therapy benefit on January 1, 2021, as required by section 5012 of the 21st Century Cures Act. The list of transitional home infusion drugs and the payment categories for the temporary transitional payment for home infusion therapy services can be found in Tables 55 and 56 in the CY 2019 HH PPS proposed rule (83 FR 32465 and 32466).[209]

209 https://www.govinfo.gov/content/pkg/FR-2018-07-12/pdf/2018-14443.pdf

Section 1834(u)(7)(D)(i) of the Act sets the payment amounts for each category equal to the amounts determined under the PFS established under section 1848 of the Act for services furnished during the year for codes and units for such codes specified without application of geographic wage adjustment under section 1848(e) of the Act. That is, the payment amounts are based on the PFS rates for the Current Procedural Terminology (CPT) codes corresponding to each payment category. For eligible home infusion suppliers to bill the temporary transitional payments for home infusion therapy services for an infusion drug administration calendar day, we created a G-code associated with each of the three payment categories. The J-codes for eligible home infusion drugs, the G-codes associated with each of the three payment categories, and instructions for billing for the temporary transitional home infusion therapy payment are found in Change Request 10836, "Temporary Transitional Payment for Home Infusion Therapy Services for CYs 2019 and 2020." [210]

Therefore, in this proposed rule, we are updating the temporary transitional payments based on the CPT code payment amounts in the CY 2020 PFS. At the time of publication of this proposed rule, we do not yet have the CY 2020 PFS rates. However, actual payments starting on January 1, 2020 will be based on the PFS amounts as specified in section 1834(u)(7)(D) of the Act as discussed earlier. We will publish these updated rates in the CY 2020 physician fee schedule final rule.211.

C. Proposed Home Infusion Therapy Services for CY 2021 and Subsequent Years

As previously described in this proposed rule, upon completion of the temporary transitional payments for home infusion therapy services at the end of CY 2020, payment for home infusion therapy services under Section 5012 of the 21st Century Cures Act (Pub. L. 114-

210 https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R4112CP.pdf
211 https://www.cms.gov/apps/physician-fee-schedule/

255) would be implemented beginning January 1, 2021. However, we are making proposals regarding home infusion therapy services for CY 2021 and beyond in the CY 2020 HH PPS proposed rule to allow adequate time for eligible home infusion therapy suppliers to make any necessary software and business process changes for implementation on January 1, 2021.

1. Scope of Benefit and Conditions for Payment

Section 1861(iii) of the Act establishes certain provisions related to home infusion therapy with respect to the requirements that must be met for Medicare payment to be made to qualified home infusion therapy suppliers. These provisions serve as the basis for determining the scope of the home infusion drugs eligible for coverage of home infusion therapy services, outlining beneficiary qualifications and plan of care requirements, and establishing who can bill for payment under the benefit.

a. Home Infusion Drugs

In the 2019 Home Health Prospective Payment System (HH PPS) proposed rule (83 FR 32466) we discussed the relationship between the home infusion therapy benefit and the DME benefit. We stated that, as there is no separate Medicare Part B DME payment for the professional services associated with the administration of certain home infusion drugs covered as supplies necessary for the effective use of external infusion pumps, we consider the home infusion therapy benefit to be a separate payment in addition to the existing payment for the DME equipment, accessories, and supplies (including the home infusion drug) made under the DME benefit. Consistent with the definition of "home infusion therapy," the home infusion therapy payment explicitly and separately pays for the professional services related to the administration of the drugs identified on the DME LCD for external infusion pumps, which are furnished in the individual's home. For purposes of the temporary transitional payments for

home infusion therapy services in CYs 2019 and 2020, the term "transitional home infusion drug" includes the HCPCS codes for the drugs and biologicals covered under the DME LCD for External Infusion Pumps (L33794). However, while section 1834(u)(7)(A)(iii) of the Act defines the term "transitional home infusion drug," section 1834(u)(7)(A)(iii) of the Act does not specify the HCPCS codes for home infusion drugs for which home infusion therapy services would be covered beginning in CY 2021. We received comments on the CY 2019 HH PPS proposed rule requesting clarification of the drugs and biologicals identified as "home infusion drugs" and whether, under the permanent benefit to be implemented in 2021, the scope of drugs would expand beyond the drugs identified for coverage under the temporary transitional payment. Consequently, we stated in the CY 2019 HH PPS final rule (83 FR 56584) that we would continue to examine the criteria for "home infusion drugs" for coverage of home infusion therapy services beginning in 2021.

Section 1861(iii)(3)(C) of the Act defines "home infusion drug" as a parenteral drug or biological administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the home of an individual through a pump that is an item of durable medical equipment (as defined in section 1861(n) of the Act). Such term does not include insulin pump systems or self-administered drugs or biologicals on a self-administered drug exclusion list. This definition not only specifies that the drug or biological must be administered through a pump that is an item of DME, but references the statutory definition of DME at 1861(n) of the Act. This means that "home infusion drugs" are drugs and biologicals administered through a pump that is covered under the Medicare Part B DME benefit. Therefore, we interpret this statutory reference in section 1861(iii)(3)(C) of the Act to mean that Medicare payment for home infusion therapy is

for services furnished in coordination with the furnishing of the infusion drugs and biologicals specified on the DME LCD for External Infusion Pumps. 212

In order to be covered under the Part B DME benefit, the external infusion pump must be classified as an item of DME, the related drug must be reasonable and necessary for the treatment of illness or injury or to improve the functioning of a malformed body member, an infusion pump is necessary to safely administer the drug, and it has to meet all other applicable Medicare statutory and regulatory requirements.213 The DME LCD for External Infusion Pumps (L33794) specifies the "reasonable and necessary" coverage criteria in order to support coverage of external infusion pumps for the indications identified on the National Coverage Determination (NCD) for Infusion Pumps.[214] The DME Medicare Administrative Contractors (MACs) make the determinations for which drugs meet this coverage criteria, and in general, update the LCDs quarterly or as needed. There are four MACs, covering various jurisdictions, that work together to issue the same LCD under their contracts. Therefore, we believe that the term "home infusion drugs" for coverage of home infusion therapy services, refers to the drugs and biologicals identified on the DME LCD for External Infusion Pumps (L33794). Therefore, we are proposing to carry forward the definition of "home infusion drugs" as defined for the temporary, transitional payment for home infusion therapy services (83 FR 56579). That is, for home infusion therapy services furnished on and after January 1, 2021, we are proposing that "home infusion drugs" are parenteral drugs and biologicals administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the home of an individual through a pump that is an item of DME covered under the Medicare Part B DME benefit.

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212 https://med.noridianmedicare.com/documents/2230703/7218263/External+Infusion+Pumps+LCD
213 Local Coverage Determination (LCD): External Infusion Pumps (L33794)
https://med.noridianmedicare.com/documents/2230703/7218263/External+Infusion+Pumps+LCD
214 https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=223&ncdver=2&DocID=280.14&SearchType=Advanced&bc=IAAAABAAAAAA&

For external infusion pumps, the supplier must instruct beneficiaries on the use of Medicare covered items, and maintain proof of delivery and beneficiary instruction in accordance with 42 CFR 424.57(c)(12). The teaching and training for the safe and effective use of the external infusion pump is covered and paid for under the DME benefit. By contrast, the services covered under the home infusion therapy benefit are intended to provide teaching and training on the provision of home infusion drugs besides the teaching and training covered under the DME benefit, as we described in the CY2019 HH PPS proposed rule (83 FR 32467). The teaching and training provided under the home infusion therapy benefit is not intended to duplicate teaching and training that is already covered under the DME benefit. We are soliciting comments on carrying forward the definition of "home infusion drugs" as described previously to the permanent home infusion therapy services benefit beginning on January 1, 2021.

b. Patient Eligibility and Plan of Care Requirements

Subparagraphs (A) and (B) of section 1861(iii)(1) of the Act set forth beneficiary eligibility and plan of care requirements for "home infusion therapy." In accordance with section 1861(iii)(1)(A) of the Act, the beneficiary must be under the care of an applicable provider, defined in section 1861(iii)(3)(A) of the Act as a physician, nurse practitioner, or physician assistant. In accordance with section 1861(iii)(1)(B) of the Act, the beneficiary must also be under a plan of care, established by a physician (defined at section 1861(r)(1) of the Act), prescribing the type, amount, and duration of infusion therapy services that are to be furnished, and periodically reviewed, in coordination with the furnishing of home infusion drugs under Part B based on these statutory requirements. Section 486.520 sets out the standards of care that qualified home infusion therapy suppliers must meet in order to participate in Medicare. Section 486.520(a) requires that all patients be under the care of an applicable provider, as defined at

§ 486.505. Section 486.520(b) requires that the qualified home infusion therapy supplier must ensure that all patients have a plan of care established by a physician that prescribes the type, amount, and duration of home infusion therapy services that are to be furnished. The plan of care must include the specific medication, the prescribed dosage and frequency, as well as the professional services to be utilized for treatment. In addition, the plan of care would specify the individualized care and services necessary to meet the patient-specific needs. Section 486.520(c) requires that the qualified home infusion therapy supplier must ensure that the patient plan of care is periodically reviewed by a physician.

We are proposing to make a number of revisions to the regulations to implement the home infusion therapy services payment system beginning with January 1, 2021, as outlined in section VI.D of this proposed rule. We propose to add a new 42 CFR part 414, subpart P, to implement the home infusion therapy services conditions for payment. In accordance with the standards at § 486.520, we are proposing conforming regulations text, at § 414.1505, requiring that home infusion therapy services be furnished to an eligible beneficiary by, or under arrangement with, a qualified home infusion therapy supplier that meets the health and safety standards for qualified home infusion therapy suppliers at § 486.520(a) through (c). We also propose at § 414.1510 that, as a condition for payment, qualified home infusion therapy suppliers ensure that a beneficiary meets certain eligibility criteria for coverage of services, as well as ensure that certain plan of care requirements are met. We propose at § 414.1510 to require that a beneficiary must be under the care of an applicable provider, defined in section 1861(iii)(3)(A) of the Act as a physician, nurse practitioner, or physician assistant. Additionally, we propose at § 414.1510, to require that a beneficiary must be under a plan of care, established by a physician. In accordance with section 1861(iii)(1)(B) of the Act, a physician is defined at section 1861(r)(1)

of the Act, as a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he performs such function or action. We propose to require at § 414.1515, that the plan of care must contain those items listed in § 486.520(b). In addition to the type of home infusion therapy services to be furnished, the physician's orders for services in the plan of care must also specify at what frequency the services will be furnished, as well as the healthcare professional that will furnish each of the ordered services. We are soliciting comments on the proposed conditions for payment, which include patient eligibility and plan of care requirements.

c. Qualified Home Infusion Therapy Suppliers and Professional Services

Section 1861(iii)(3)(D)(i) of the Act defines a "qualified home infusion therapy supplier" as a pharmacy, physician, or other provider of services or supplier licensed by the State in which the pharmacy, physician, or provider of services or supplier furnishes items or services. The qualified home infusion therapy supplier must: furnish infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs; ensure the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour a-day basis; be accredited by an organization designated by the Secretary; and meet such other requirements as the Secretary determines appropriate. In accordance with this section of the Act, 42 CFR part 486, subpart I, establishes the requirements that a qualified home infusion therapy supplier must meet in order to participate in the Medicare program. These requirements provide a framework for CMS to approve home infusion therapy accreditation organizations in order for them to approve Medicare certification of qualified home infusion therapy suppliers. Section 488.1010 sets forth the requirements that accrediting organizations must meet in order to demonstrate that their substantive accreditation requirements are sufficient for certification of a

Medicare qualified home infusion therapy supplier. And finally, § 486.525 sets out the services furnished by a qualified home infusion therapy supplier which are: professional services, including nursing services; training and education; and remote monitoring and monitoring services. Importantly, neither the statute, nor the health and safety standards and accreditation requirements require the qualified home infusion therapy supplier to furnish the pump, home infusion drug, or related pharmacy services. The infusion pump, drug, and other supplies, including the services required to furnish these items (that is, the compounding and dispensing of the drug) remain covered under the DME benefit.

In accordance with section 1861(iii)(1) of the Act, the CY 2019 HH PPS proposed rule described the professional and nursing services, as well as the training, education, and monitoring services included in the payment to a qualified home infusion therapy supplier for the provision of home infusion drugs (83 FR 32467). We did not specifically enumerate a list of "professional services" in order to avoid limiting services or the involvement of providers of services or suppliers that may be necessary in the care of an individual patient. However, it is important to note that, under section 1862(a)(1)(A) of the Act, no payment can be made for Medicare services under Part B that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, unless explicitly authorized by statutes (such as vaccines).

Payment to a qualified home infusion therapy supplier is for an infusion drug administration calendar day in the individual's home, which, in accordance with section 1834(u)(7)(E) of the Act, refers to payment only for the date on which professional services were furnished to administer such drugs to such individual. Ultimately, the qualified home infusion therapy supplier is the entity responsible for furnishing the necessary services to administer the

drug in the home and, as we noted in the CY 2019 HH PPS final rule (83 FR 56581), "administration" refers to the process by which the drug is entering the patient's body. Therefore, it is necessary for the qualified home infusion therapy supplier to be in the patient's home, on occasions when the drug is being administered in order to provide an accurate assessment to the physician responsible for ordering the home infusion drug and services. The services provided would include patient evaluation and assessment; training and education of patients and their caretakers, assessment of vascular access sites and obtaining any necessary bloodwork; and evaluation of medication administration. However, visits made solely for the purposes of venipuncture on days where there is no administration of the infusion drug would not be separately paid because the single payment includes all services for administration of the drug. Payment for an infusion drug administration calendar day is a bundled payment, which reflects not only the visit itself, but any necessary follow-up work (which could include visits for venipuncture), or care coordination provided by the qualified home infusion therapy supplier. Any care coordination, or visits made for venipuncture, provided by the qualified home infusion therapy supplier that occurs outside of an infusion drug administration calendar day would be included in the payment for the visit (83 FR 56581).

Additionally, section 1861(iii)(1)(B) of the Act requires that the patient be under a plan of care established and periodically reviewed by a physician, in coordination with the furnishing of home infusion drugs. The physician is responsible for ordering the reasonable and necessary services for the safe and effective administration of the home infusion drug, as indicated in the patient plan of care. In accordance with this section, the physician is responsible for coordinating the patient's care in consultation with the DME supplier furnishing the home infusion drug. We recognize that collaboration between the ordering physician and the DME

supplier furnishing the home infusion drug is imperative in providing safe and effective home infusion. Payment for physician services, including any home infusion care coordination services, are separately paid to the physician under the PFS and are not covered under the home infusion therapy benefit. However, payment under the home infusion therapy benefit to eligible home infusion therapy suppliers is for the professional services that inform collaboration between physicians and home infusion therapy suppliers. Care coordination between the physician and DME supplier, although likely to include review of the services indicated in the home infusion therapy supplier plan of care, is paid separately from the payment under the home infusion therapy benefit.

The DME Quality Standards require the supplier to review the patient's record and consult with the prescribing physician as needed to confirm the order and to recommend any necessary changes, refinements, or additional evaluations to the prescribed equipment, item(s), and/or service(s). Follow-up services to the beneficiary and/or caregiver(s), must be consistent with the type(s) of equipment, item(s) and service(s) provided, and include recommendations from the prescribing physician or healthcare team member(s).[215] Additionally, DME suppliers are required to communicate directly with patients regarding their medications. As described in Chapter 5 of the Medicare Program Integrity Manual: Items and Services Having Special DME Review Considerations, section 5.2.8, DME suppliers are required to contact the beneficiary prior to dispensing a refill to the original order. This is done to ensure that the refilled item remains reasonable and necessary, existing supplies are approaching exhaustion, and to confirm any changes/modifications to the order.[216]

215 https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Downloads/Final-DMEPOS-Quality-Standards-Eff-01-09-2018.pdf
216 https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c05.pdf

Additionally, the ordering physician can bill separately for physicians' services such as Chronic Care Management (CCM) and Remote Patient Monitoring codes under the PFS for care planning and coordination of home infusion therapy services. CCM services are typically provided outside of face-to-face patient visits, and focus on characteristics of advanced primary care such as a continuous relationship with a designated member of the care team; patient support for chronic diseases to achieve health goals; 24/7 patient access to care and health information; receipt of preventive care; patient and caregiver engagement; and timely sharing and use of health information[217]. Remote patient monitoring services, including telephone evaluation and management services by a physician, or brief virtual check-ins, can also be billed under the PFS. In general, when communication technology-based services originate from a related evaluation and management (E/M) visit provided within the previous 7 days by the same physician or other qualified health care professional, this service is considered bundled into that previous E/M visit and would not be separately billable. However, physicians can bill separately for remote monitoring services after an initial face-to-face visit. Billing for this service requires at least 30 minutes of physician time and includes the collection and interpretation of data. Beginning January 1, 2019, Medicare now also pays separately for set-up, interpretation, and transmission of data collected remotely. Additionally, virtual check-in services are billable when a physician or other qualified health care professional has a brief non-face-to-face check-in with a patient via communication technology to assess whether the patient's condition necessitates an office visit, and can be billed in cases where the check-in service does not lead to an office visit, as there is no office visit with which the check-in service can be bundled.[218]

217 https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnproducts/downloads/chroniccaremanagement.pdf
218 https://www.govinfo.gov/content/pkg/FR-2018-11-23/pdf/2018-24170.pdf

In summary, the qualified home infusion therapy supplier is responsible for the reasonable and necessary services related to the administration of the home infusion drug in the individual's home. These services may require some degree of care coordination or monitoring outside of an infusion drug administration calendar day; however, these services are built into the bundled payment. Care coordination furnished by the DME supplier, who is responsible for furnishing the equipment and supplies, including the home infusion drug, is required and paid for under the DME benefit. Care coordination furnished by the physician who establishes the plan of care is separately billable under the PFS.

d. Home Infusion Therapy and the Interaction with Home Health

Because a qualified home infusion therapy supplier is not required to become accredited as a Part B DME supplier or to furnish the home infusion drug, and because payment is determined by the provision of services furnished in the patient's home, we acknowledged in the CY 2019 HH PPS proposed rule the potential for overlap between the new home infusion therapy benefit and the home health benefit (83 FR 32469). We stated that a beneficiary is not required to be considered homebound in order to be eligible for the home infusion therapy benefit; however, there may be instances where a beneficiary under a home health plan of care also requires home infusion therapy services. Additionally, because section 5012 of the 21st Century Cures Act amends section 1861(m) of the Act to exclude home infusion therapy from home health services effective on January 1, 2021, we stated that a beneficiary may utilize both benefits concurrently. We solicited feedback on the relationship between the Medicare home health benefit and the home infusion therapy benefit, particularly in instances when a beneficiary meets eligibility requirements for both.

In general, commenters stated concern with the ability of qualified home infusion therapy suppliers to furnish the professional services required under both benefits when care needs overlap. One commenter stated that the benefits effectively do not overlap, as "each benefit stands independent from the other and covers different treatment and different care." Specifically, this commenter stated that home health agencies do not own or operate pharmacies, prepare home infusion drugs, or provide the care coordination necessary to manage drug infusion. Similarly, the commenter stated that home infusion providers are neither certified nor authorized to offer the full array of care services required of a home health agency.

We agree that there are unique services and providers involved in the delivery of care under both the home health benefit and the home infusion therapy benefit. We also recognize that home health agencies and DME suppliers have separate requirements for accreditation and conditions for payment. Likewise, the requirements for home infusion therapy accreditation, set out at 42 CFR part 486, subpart I, are unique to qualified home infusion therapy suppliers. For instance, in order to furnish the services related to the administration of home infusion drugs, a qualified home infusion therapy supplier is not required to meet the Medicare Home Health Conditions of Participation (CoPs) at 42 CFR part 484, unless such supplier is also a Medicare-certified home health agency. Additionally, a qualified home infusion therapy supplier is not required to meet the requirements under the DME Quality and Supplier Standards, unless such supplier is also a Medicare-enrolled DME supplier. Therefore, we would not expect a home health agency that becomes accredited as a qualified home infusion therapy supplier to furnish (or arrange for the furnishing of) the DME, supplies (including the home infusion drug), and related services when a patient is not under a home health plan of care, nor would it be permissible for a DME supplier that becomes accredited as a qualified home infusion therapy supplier to furnish home health services under the Medicare home health benefit. The home health benefit requires that home health agencies arrange for the necessary DME and coordinate home infusion services when a patient is under a home health plan of care. In accordance with the Home Health CoPs at 42 CFR 484.60, the home health agency must assure communication with all physicians involved in the plan of care, as well as integrate all orders and services provided by all physicians and other healthcare disciplines, such as nursing, rehabilitative, and social services.

Furthermore, because both the home health agency and the qualified home infusion therapy supplier furnish services in the individual's home, and may potentially be the same entity, it is necessary to outline the payment process in instances when a beneficiary is utilizing both benefits. We continue to believe that the best process for payment for furnishing home infusion therapy services to beneficiaries who qualify for both benefits is as outlined in the CY 2019 HH PPS proposed rule (83 FR 32469). If a patient receiving home infusion therapy is also under a home health plan of care, and receives a visit that is unrelated to home infusion therapy, then payment for the home health visit would be covered by the HH PPS and billed on the home health claim. When the home health agency furnishing home health services is also the qualified home infusion therapy supplier furnishing home infusion services, and a home visit is exclusively for the purpose of furnishing items and services related to the administration of the home infusion drug, the home health agency would submit a home infusion therapy services claim under the home infusion therapy benefit. If the home visit includes the provision of other home health services in addition to, and separate from, home infusion therapy services, the home health agency would submit both a home health claim under the HH PPS and a home infusion therapy claim under the home infusion therapy benefit. However, the agency must separate the time spent furnishing services covered under the HH PPS from the time spent furnishing services covered under the home infusion therapy benefit. DME continues to be excluded from the consolidated billing requirements governing the HH PPS and therefore, the DME services, equipment, and supplies (including the drug and related services) will continue to be paid for outside of the HH PPS. If the qualified home infusion therapy supplier is not the same entity as the home health agency furnishing the home health services, the home health agency would continue to bill under the HH PPS on the home health claim, and the qualified home infusion

therapy supplier would bill for the services related to the administration of the home infusion drugs on the home infusion therapy services claim.

After publishing the CY 2019 HH PPS final rule with comment period, we received correspondence requesting clarification of the relationship between the home health benefit and the furnishing of home infusion therapy services in CYs 2019 and 2020. Specifically, we received questions as to whether an eligible home infusion supplier can furnish home infusion therapy services, and bill for the temporary transitional payment, to the same patient that is under a home health plan of care, where the home health agency is furnishing care unrelated to the home infusion therapy, such as wound care and physical therapy. In response, we posted a "Frequently Asked Questions" (FAQs) document to our home infusion therapy web page,[219] relying on the authority of section 1834(u)(7)(G) of the Act (as added by section 50401 of the BBA of 2018), which allows the Secretary to implement the transitional home infusion therapy benefit by program instruction or otherwise, notwithstanding any other provision of law. In this FAQ, we clarified that during the 2-year temporary transitional payment period (CYs 2019 and 2020), home health services covered under the Medicare home health benefit continue to include the in-home services covered under the new home infusion therapy benefit. Therefore, if a patient's home health plan of care includes home infusion therapy services, the costs of such services would be recognized as part of the payment made for the patient's specific Home Health Resource Group (HHRG). The clarification in the FAQs was not intended to, and does not, make any changes to our general policy that, as with any other plan of care service that the HHA cannot provide, if a patient under a home health plan of care requires in-home skilled services needed for the safe and effective administration of a transitional home infusion drug and the home health agency determines it does not have the staff available to furnish those services as

219 https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Home-Infusion-Therapy/Overview.html

home health services under the home health benefit (and cannot provide such services under arrangement), the home health agency should not accept the patient on service or continue to provide other home health services under an existing plan of care. In accordance with the Home Health CoPs at §484.60 home health agencies can only accept patients for treatment on the reasonable expectation that the home health agency can meet the patient's medical, nursing, rehabilitative, and social needs in his or her place of residence.

We believe the statutory provisions at section 1861(m) of the Act do not allow both home health providers and eligible home infusion suppliers to furnish and bill for home infusion therapy services to beneficiaries under a home health plan of care. Therefore we stated in the CY 2019 HH PPS final rule that home infusion therapy was excluded from home health services beginning in CY 2019. This was intended to convey that payment for the separate, transitional home infusion therapy services benefit under section 1834(u)(7) of the Act is excluded from home health services. Sections 5012(c)(3) and (d) of the Cures Act, read together, clearly indicate that home infusion therapy is not excluded from home health services until January 1, 2021. A home health agency may subcontract with an eligible home infusion supplier in CYs 2019 and 2020 to furnish home infusion therapy services to a beneficiary under a home health plan of care; however, such services would be considered home health services and should be billed by the home health agency under the Medicare home health benefit and not the home infusion therapy benefit. In addition, the eligible home infusion supplier cannot bill for such services under the home infusion therapy benefit as such services are covered as home health services under the Medicare home health benefit.

Therefore, for home infusion therapy services furnished in CYs 2019 and 2020, if a patient who is considered homebound and is under a Medicare home health plan of care, the

home health agency should continue to furnish the professional services related to the administration of transitional home infusion drugs, in accordance with the Home Health CoPs and other regulations, as home health services. Additionally, the home health agency shall bill for such services as home health services under the Medicare home health benefit. Further, if an eligible home infusion supplier is under contract with a home health agency to provide the necessary home infusion therapy services to a patient under a home health plan of care, such services would be considered home health services and billed by the home health agency under the Medicare home health benefit and not the home infusion therapy benefit. Additionally, the eligible home infusion supplier under contract with the home health agency cannot bill Medicare for the temporary transitional payment but would seek payment from the home health agency. This clarification regarding the relationship between the home health benefit and the home infusion benefit in CYs 2019 and 2020 is not intended to limit access to home infusion therapy services to those beneficiaries receiving home health services under the Medicare home health benefit. Neither the transitional nor the permanent home infusion therapy services benefit require that the beneficiary be under a home health plan of care. Rather, because transitional home infusion therapy services are separately payable beginning January 1, 2019, the receipt of home health services is not necessary in order for a beneficiary to be eligible to receive home infusion therapy services.

2. Solicitation of Public Comments Regarding Notification of Infusion Therapy Options Available Prior to Furnishing Home Infusion Therapy Services

Section 1834(u)(6) of the Act requires that prior to the furnishing of home infusion therapy to an individual, the physician who establishes the plan described in section 1861(iii)(1) of the Act for the individual shall provide notification (in a form, manner, and frequency

determined appropriate by the Secretary) of the options available (such as home, physician's office, hospital outpatient department) for the furnishing of infusion therapy under this part. We recognize there are several possible forms, manners, and frequencies that physicians may use to notify patients of their infusion therapy options. For example, a physician may verbally discuss the treatment options with the patient during the visit and annotate the treatment decision in the medical records before establishing the infusion therapy plan. Some physicians may also provide options in writing to the patient in the hospital discharge papers or office visit summaries, as well as retain a written patient attestation that all options were provided and considered. Additionally, the frequency of discussing these options could vary based on a routine scheduled visit or according the individual's clinical needs.

We are soliciting comments in the CY 2020 PFS proposed rule regarding the appropriate form, manner, and frequency that any physician must use to provide notification of the treatment options available to his/her patient for the furnishing of infusion therapy (home or otherwise) under Medicare Part B. We also invite comments in this rule on any additional interpretations of this notification requirement and whether this requirement is already being met under the temporary transitional payment.

D. Proposed Payment Categories and Amounts for Home Infusion Therapy Services for CY 2021

Section 1834(u)(1) of the Act provides the authority for the development of a payment system for Medicare-covered home infusion therapy services. In accordance with section 1834(u)(1)(A)(i) of the Act, the Secretary is required to implement a payment system under which a single payment is made to a qualified home infusion therapy supplier for items and services furnished by a qualified home infusion therapy supplier in coordination with the

furnishing of home infusion drugs. Section 1834(u)(1)(A)(ii) of the Act states that a unit of single payment under this payment system is for each infusion drug administration calendar day in the individual's home, and requires the Secretary, as appropriate, to establish single payment amounts for different types of infusion therapy, taking into account variation in utilization of nursing services by therapy type. Section 1834(u)(1)(A)(iii) of the Act provides a limitation to the single payment amount, requiring that it shall not exceed the amount determined under the PFS (under section 1848 of the Act) for infusion therapy services furnished in a calendar day if furnished in a physician office setting. Furthermore, such single payment shall not reflect more than 5 hours of infusion for a particular therapy in a calendar day. This permanent payment system would become effective for home infusion therapy items and services furnished on or after January 1, 2021.

In accordance with section 1834(u)(1)(A)(ii) of the Act, a unit of single payment for each infusion drug administration calendar day in the individual's home must be established for types of infusion therapy, taking into account variation in utilization of nursing services by therapy type. Furthermore, section 1834(u)(1)(B)(ii) of the Act requires that the payment amount reflect factors such as patient acuity and complexity of drug administration. We believe that the best way to establish a single payment amount that varies by utilization of nursing services and reflects patient acuity and complexity of drug administration, is to group home infusion drugs by J-code into payment categories reflecting similar therapy types. Therefore, each payment category would reflect variations in infusion drug administration services.

Section 1834(u)(7)(C) of the Act established three payment categories, with the associated J-code for each transitional home infusion drug (see Table 28), for the home infusion therapy services temporary transitional payment. Payment category 1 comprises certain

intravenous infusion drugs for therapy, prophylaxis, or diagnosis, including, but not limited to, antifungals and antivirals; inotropic and pulmonary hypertension drugs; pain management drugs; and chelation drugs. Payment category 2 comprises subcutaneous infusions for therapy or prophylaxis, including, but not limited to, certain subcutaneous immunotherapy infusions. Payment category 3 comprises intravenous chemotherapy infusions, including certain chemotherapy drugs and biologicals.

Maintaining the three current payment categories, with the associated J-codes as outlined in section 1834(u)(7)(C) of the Act, utilizes an already established framework for assigning a unit of single payment (per category), accounting for different therapy types, as required by section 1834(u)(1)(A)(ii) of the Act. The payment amount for each of these three categories is different, though each category has its associated single payment amount. The single payment amount (per category) would thereby reflect variations in nursing utilization, complexity of drug administration, and patient acuity, as determined by the different categories based on therapy type. Retaining the three current payment categories would maintain consistency with the already established payment methodology and ensure a smooth transition between the temporary transitional payments and the permanent payment system to be implemented beginning with 2021. Therefore, we propose to carry forward the three temporary transitional payment categories for the home infusion therapy services payment in CY 2021. Table 28 provides the list of J-codes associated with the infusion drugs that fall within each of the payment categories. There are several drugs that are paid for under the transitional benefit but would not be defined as a home infusion drug under the permanent benefit beginning with 2021. As noted previously in this proposed rule, section 1861(iii)(3)(C) of the Act defines a home infusion drug as a parenteral drug or biological administered intravenously or subcutaneously for an administration

period of 15 minutes or more, in the home of an individual through a pump that is an item of DME. Such term does not include the following: (1) insulin pump systems; and (2) a self-administered drug or biological on a self-administered drug exclusion list. Hizentra, a subcutaneous immunoglobulin, is not included in this definition of home infusion drugs because it is listed on a self-administered drug (SAD) exclusion list by the MACs. This drug was included as a transitional home infusion drug since the definition of such drug in section 1834(u)(7)(A)(iii) of the Act does not exclude self-administered drugs or biologicals on a SAD exclusion list under the temporary transitional payment. Therefore, although home infusion therapy services related to the administration of Hizentra are covered under the temporary transitional payment, because it is on a SAD exclusion list, services related to the administration of this biological are not covered under the benefit in 2021. Similarly, in accordance with the definition of "home infusion drug" as a parenteral drug or biological administered intravenously or subcutaneously, home infusion therapy services related to the administration of Ziconotide and Floxuridine are also excluded, as these drugs are given via intrathecal and intra-arterial routes respectively and therefore do not meet the definition of home infusion drug. Subsequent drugs added to the DME LCD for external infusion pumps, and compounded infusion drugs not otherwise classified, as identified by HCPCS codes J7799 and J7999, will be grouped into the appropriate payment category by the DME MACs. Payment category 1 would include any subsequent intravenous infusion drug additions, payment category 2 would include any subsequent subcutaneous infusion drug additions, and payment category 3 would include any subsequent intravenous chemotherapy infusion drug additions.

TABLE 28: INFUSION DRUG J-CODES ASSOCIATED WITH HOME INFUSION THERAPY SERVICE PAYMENT CATEGORIES FOR CY 2021

J-Code	Drug
Category 1	
J0133	Injection, acyclovir, 5 mg
J0285	Injection, amphotericin b, 50 mg
J0287	Injection, amphotericin b lipid complex, 10 mg
J0288	Injection, amphotericin b cholesteryl sulfate complex, 10 mg
J0289	Injection, amphotericin b liposome, 10 mg
J0895	Injection, deferoxamine mesylate, 500 mg
J1170	Injection, hydromorphone, up to 4 mg
J1250	Injection, dobutamine hydrochloride, per 250 mg
J1265	Injection, dopamine hcl, 40 mg
J1325	Injection, epoprostenol, 0.5 mg
J1455	Injection, foscarnet sodium, per 1000 mg
J1457	Injection, gallium nitrate, 1 mg
J1570	Injection, ganciclovir sodium, 500 mg
J2175	Injection, meperidine hydrochloride, per 100 mg
J2260	Injection, milrinone lactate, 5 mg
J2270	Injection, morphine sulfate, up to 10 mg
J2274	Injection, morphine sulfate, preservative-free for epidural or intrathecal use, 10 mg
J3010	Injection, fentanyl citrate, 0.1 mg
J3285	Injection, treprostinil, 1 mg
Category 2	
J1555 JB*	Injection, immune globulin (cuvitru), 100 mg
J1561 JB*	Injection, immune globulin, (gamunex-c/gammaked), non-lyophilized (e.g., liquid), 500 mg
J1562 JB*	Injection, immune globulin (vivaglobin), 100 mg
J1569 JB*	Injection, immune globulin, (gammagard liquid), non-lyophilized, (e.g., liquid), 500 mg
J1575 JB*	Injection, immune globulin/hyaluronidase, (hyqvia), 100 mg immune globulin
Category 3	
J9000	Injection, doxorubicin hydrochloride, 10 mg
J9039	Injection, blinatumomab, 1 microgram
J9040	Injection, bleomycin sulfate, 15 units
J9065	Injection, cladribine, per 1 mg
J9100	Injection, cytarabine, 100 mg
J9190	Injection, fluorouracil, 500 mg
J9360	Injection, vinblastine sulfate, 1 mg
J9370	Injection, vincristine sulfate, 1 mg

*The JB modifier indicates that the route of administration is subcutaneous.

We are soliciting comments on retaining the three payment categories, as identified in Table 28, in CY 2021.

1. Proposed Payment Amounts

As described previously, section 1834(u)(1)(A)(ii) of the Act requires that the payment amount take into account variation in utilization of nursing services by therapy type.

Additionally, section 1834(u)(1)(A)(iii) of the Act provides a limitation that the single payment shall not exceed the amount determined under the fee schedule under section 1848 of the Act for infusion therapy services furnished in a calendar day if furnished in a physician office setting, except such single payment shall not reflect more than 5 hours of infusion for a particular therapy in a calendar day. Finally, section 1834(u)(1)(B)(ii) of the Act requires the payment amount to reflect patient acuity and complexity of drug administration.

The language at section 1834(u)(1)(A)(ii) of the Act is consistent with section 1834(u)(7)(B)(iv) of the Act, which establishes a "single payment amount" for the temporary transitional payment for an infusion drug administration calendar day. Currently, as set out at section 1834(u)(7)(D) of the Act, each temporary transitional payment category is paid at amounts in accordance with six infusion CPT codes and units of such codes under the PFS. These payment category amounts are set equal to 4 hours of infusion therapy administration services in a physician's office for each infusion drug administration calendar day, regardless of the length of the visit. We stated in the CY 2019 final rule (83 FR 56581) that a "single payment amount" means that all home infusion therapy services, which include professional services, including nursing; training and education; remote monitoring; and monitoring, are built into the day on which the services are furnished in the home and the drug is being administered. In other words, payment for an infusion drug administration calendar day is a bundled payment amount per visit. As such, because payment for an infusion drug administration calendar day under the permanent benefit is also a "unit of single payment," we propose to carry forward the payment methodology as outlined in section 1834(u)(7)(A) of the Act for the temporary transitional payments. We propose to pay a single payment amount for each infusion drug administration calendar day in the individual's home for drugs assigned under each proposed payment category.

Each proposed payment category amount would be in accordance with the six infusion CPT codes identified in section 1834(u)(7)(D) of the Act and as shown in Table 29. However, because section 1834(u)(1)(A)(iii) of the Act states that the single payment shall not exceed more than 5 hours of infusion for a particular therapy in a calendar day, we propose that the single payment amount be set at an amount equal to 5 hours of infusion therapy administration services in a physician's office for each infusion drug administration calendar day.

We believe that proposing a single unit of payment equal to 5 hours of infusion therapy services in a physician's office is a reasonable approach to account for the bundled services included under the home infusion therapy benefit, as described previously. We also understand that some patients may require more care coordination or longer visits than other patients, and while the physician payments would account for varying time spent furnishing care for individual patients (both during a visit and outside of a visit) in accordance with the specific PFS codes they bill, payment for an infusion drug administration calendar day is a unit of single payment and would not vary within each category. While the payment amounts do vary between categories to account for differences in therapy type, paying the maximum amount allowed by statute acknowledges the varying care needs of each individual patient within each category. For example, a qualified home infusion therapy supplier furnishing care for a patient receiving a category 2 infusion drug would receive a single payment amount for each infusion drug administration calendar day in the patient's home. However, this payment amount would not reflect the varying degrees of care among individual patients within each category, or from visit to visit for the same patient. And while the payment rates for each of the three payment categories is higher than the home health per-visit nursing rate, the home infusion therapy rates

reflect the increased complexity of the professional services provided per category, and as required by law.

Furthermore, furnishing care in the patient's home is fundamentally different from furnishing care in the physician's office. Healthcare professionals cannot achieve the economies of scale in the home that can be achieved in an office setting. As noted previously, the single unit of payment for each of the three categories is a bundled payment, meaning payment is made on the basis of expected costs for clinically-defined episodes of care, where some episodes of care for similar patients with similar care needs cost more than others. While the single unit of payment for the temporary transitional payments was set at 4 hours by law, the payment amount for home infusion therapy services beginning in CY 2021 cannot exceed 5 hours of infusion for a particular therapy. As such, the law provides more latitude for the payment of home infusion therapy services beginning in CY 2021. To ensure that payment for home infusion therapy adequately covers the different patient care needs and level of complexity of services provided, we are proposing that the bundled payment amount for home infusion therapy services furnished on and after January 1, 2021 should be set at the maximum allowed by statute, 5 hours, in order to account for these differences and still remain a unit of single payment.

Setting the payment amounts for each proposed payment category in accordance with the CPT infusion code amounts under the PFS accounts for variation in utilization of nursing services, patient acuity, and complexity of drug administration. CPT codes establish uniformity of the services that fall under each code in order to determine the amount of payment that a practitioner will receive for such services. Medicare PFS valuation of CPT codes uses a combination of the time and complexity used to furnish the service, as well as the amount and value of resources used. Relative value units (RVUs) are calculated for three components used to

determine the value of a CPT code. One component, the non-facility practice expense RVU, is based, in part, on the amount and complexity of services furnished by nursing and ancillary clinical staff involved in the procedure or service.[220] The CPT infusion codes under the PFS weight the non-facility practice expense RVUs more heavily than the other two components, which include physician work and malpractice expense.221 Therefore, the values of the CPT infusion code amounts, in accordance with the different payment categories, reflect variations in nursing utilization, patient acuity, and complexity of drug administration, as they are directly proportionate to the clinical labor involved in furnishing the infusion services in the patient's home.

TABLE 29: PAYMENT CATEGORIES FOR HOME INFUSION THERAPY SERVICES PAYMENT FOR CY 2021

CPT CODE	DESCRIPTION	UNITS
CATEGORY 1		
96365	Therapeutic, Prophylactic, and Diagnostic Injections and Infusions (Excludes Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration)- up to one hour	1
96366	Therapeutic, Prophylactic, and Diagnostic Injections and Infusions (Excludes Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration)- each additional hour	4
CATEGORY 2		
96369	Therapeutic, Prophylactic, and Diagnostic Injections and Infusions (Excludes Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration)- up to one hour	1
96370	Therapeutic, Prophylactic, and Diagnostic Injections and Infusions (Excludes Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration)- each additional hour	4
CATEGORY 3		
96413	Injection and Intravenous Infusion Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration- up to one hour	1
96415	Injection and Intravenous Infusion Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration- each additional hour	4

The payment methodology outlined previously meets the required payment adjustments, while remaining a single unit of payment. However, we recognize that often the first visit furnished by a home infusion therapy supplier to furnish services in the patient's home may be longer or more resource intensive than subsequent visits. In particular, patients with new

220 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3096340/
221 https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Relative-Value-Files-Items/RVU19A.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=descending

diagnoses may require more disease education, instruction on self-monitoring, and support from healthcare professionals. Patients who have not been hospitalized may be starting home infusion therapy without the benefit of having received any training or education prior to discharge. Additionally, considering that hospitals often discharge quickly once outside services are in place, patients who have started infusion therapy in the hospital, may arrive home with central vascular access devices and ambulatory pumps without sufficient education or instruction regarding maintenance or lifestyle changes. This could potentially lead to safety issues or an increase in doctor's office or emergency department visits. Therefore, the single payment amount discussed previously may not adequately compensate for the first patient visit furnished by the qualified home infusion therapy supplier in the patient's home. Section 1834(u)(1)(C) of the Act allows the Secretary discretion to adjust the single payment amount to reflect outlier situations and other factors as the Secretary determines appropriate, in a budget neutral manner. Payment for infusion therapy in the physician's office reflects whether a patient is new or existing, acknowledging that new patients may initially require more time and education. Therefore, we propose increasing the payment amounts for each of the three payment categories for the first visit by the relative payment for a new patient rate over an existing patient rate using the physician evaluation and management (E/M) payment amounts for a given year. Overall this adjustment would be budget-neutral, in accordance with the requirement at section 1834(u)(1)(C)(ii) of the Act, resulting in a small decrease to the payment amounts for any subsequent visits. This would be similar to the LUPA add-on payment under the home health benefit, which is paid for the first LUPA episode in a sequence of adjacent episodes or episodes that occur as the only episode. It is important to note that the first visit payment amount is only issued on the first home visit to initiate home infusion therapy services furnished by the qualified

home infusion therapy supplier. Any changes in the plan of care or drug regimen, including the addition of drugs or biologicals that may change the payment category, would not trigger a first visit payment amount. If a patient receiving home infusion therapy services is discharged, the home infusion therapy services claim must show a patient status code to indicate a discharge with a gap of more than 60 days in order to bill a first visit again if the patient is readmitted. This means that upon re-admission, there cannot be a G-code billed for this patient in the past 60 days, and the last G-code billed for this patient must show that the patient had been discharged. A qualified home infusion therapy supplier could bill the first visit payment amount on day 61 for a patient who had previously been discharged from service. We also recognize that many beneficiaries have been receiving services during the temporary transitional payment period, and as a result, many of these patients already have a working knowledge of their pump and may need less start-up time with the nurse during their initial week of visits during the permanent benefit. Therefore, suppliers would not be able to bill for the initial visit amount for those patients who have been receiving services under the temporary transitional payment, and have billed a G-code within the past 60 days. Table 30 shows the E/M visit codes and PFS payment amounts for CY 2019, for both new and existing patients, used to determine the increased payment amount for the first visit. Using the CY 2019 PFS rates, this results in a 60 percent increase in the first visit payment amount and a 3.76 percent decrease in subsequent visit amounts.

TABLE 30: AVERAGE DIFFERENCE BETWEEN PFS E/M CODES FOR NEW AND EXISTING PATIENTS222

New Patient E/M code	PFS Amount	Existing Patient E/M code	PFS Amount	Percent Difference
99201	$46.49	99211	$23.07	102%

222 This represents the average difference between the physician E/M payment amounts for new versus established patients: (the sum of the initial rates – the sum of the existing rates)/(the sum of the existing rates)=60%.

New Patient E/M code	PFS Amount	Existing Patient E/M code	PFS Amount	Percent Difference
99202	$77.48	99212	$25.95	199%
99203	$109.92	99213	$75.32	46%
99204	$166.86	99214	$110.28	51%
99205	$209.75	99215	$147.76	42%
Total	$610.50		$382.38	60%

In summary, we propose that the payment amounts per category, for an infusion drug administration calendar day under the permanent benefit, be in accordance with the six PFS infusion CPT codes and units for such codes, as described in section 1834(u)(7)(D) of the Act; however, we propose to set the amount equivalent to 5 hours of infusion in a physician's office, rather than 4 hours. We also propose increasing the payment amounts for each of the three payment categories for the first home infusion therapy visit by the qualified home infusion therapy supplier in the patient's home by the average difference between the PFS amounts for E/M existing patient visits and new patient visits for a given year, resulting in a small decrease to the payment amounts for the second and subsequent visits, using a budget neutrality factor. Table 31 shows the 5 hour payment amounts (using CY 2019 rates) reflecting the increased payment for the first visit and the decreased payment for all subsequent visits. We plan on monitoring home infusion therapy service lengths of visits, both initial and subsequent, in order to evaluate whether the data substantiates this increase or whether we should re-evaluate whether, or how much, to increase the initial visit payment amount. We are soliciting comments on the proposed CY 2021 payment amounts per category, including the proposed payment equivalent to 5 hours of infusion in a physician's office and increasing the payment amounts for each of the three categories for the first home infusion therapy visit by the average difference between the PFS amounts for E/M existing patient visits and new patient visits for a given year.

TABLE 31: 5-HOUR PAYMENT AMOUNTS REFLECTING PAYMENT RATES FOR FIRST AND SUBSEQUENT VISITS

CPT Code	Description	2019 PFS Amount	5-hour Payment – First Visit	5-hour Payment – Subsequent Visits
96365	Ther, Proph,Diag IV/IN infusion 1 hr	$72.80	$257.20 (category 1)	$154.70 (category 1)
96366	Ther, Proph,Diag IV/IN infusion add hr	$21.98		
96369	Sub Q Ther Inf 1 hr	$169.02	$371.94 (category 2)	$223.72 (category 2)
96370	Sub Q Ther Inf add hr	$15.86		
96413	Chemo Inf 1 hr	$143.08	$427.26 (category 3)	$256.99 (category 3)
96415	Chemo Inf add hr	$30.99		

E. Required Payment Adjustments for CY 2021 Home Infusion Therapy Services

1. Proposed Home Infusion Therapy Geographic Wage Index Adjustment

Section 1834(u)(1)(B)(i) of the Act requires that the single payment amount be adjusted to reflect a geographic wage index and other costs that may vary by region. In the 2019 HH PPS proposed rule (83 FR 32467) we stated that we were considering using the Geographic Practice Cost Indices (GPCIs) to account for regional variations in wages and adjust the payment for home infusion therapy professional services; however, after further analysis and consideration we believe the geographic adjustment factor (GAF) may be a more appropriate option to adjust home infusion therapy payments based on differences in geographic wages.

The GAF is a weighted composite of each PFS locality's work, practice expense (PE), and malpractice (MP) GPCIs and represents the combined impact of the three GPCI components. The GAF is calculated by multiplying the work, PE and MP GPCIs by the corresponding national cost share weight: work (50.886 percent), PE (44.839 percent), and MP (4.295

percent).[223] The work GPCI reflects the relative costs of physician labor by region. The PE GPCI measures the relative cost difference in the mix of goods and services comprising practice expenses among the PFS localities as compared to the national average of these costs. The MP GPCI measures the relative regional cost differences in the purchase of professional liability insurance (PLI). The GAF is updated at least every 3 years per statute and reflects a 1.5 work GPCI floor for services furnished in Alaska as well as a 1.0 PE GPCI floor for services furnished in frontier states (Montana, Nevada, North Dakota, South Dakota and Wyoming).

The GAF is not specific to any of the home infusion drug categories, so the GAF payment rate would equal the unadjusted rate multiplied by the GAF for each locality level, without a labor share adjustment. As such, based on locality, the GAF adjusted payment rate would be calculated using the following formula:

$$Rate_i^{GAF} = GAF * UnadjRate_i$$

We would apply the appropriate GAF value to the home infusion therapy single payment amount based on the site of service of the beneficiary. There are currently 112 total PFS localities, 34 of which are statewide areas (that is, only one locality for the entire state). There are 10 states with 2 localities, 2 states having 3 localities, 1 state having 4 localities, and 3 states having 5 or more localities. The combined District of Columbia, Maryland, and Virginia suburbs; Puerto Rico; and the Virgin Islands are the remaining three localities. Beginning in 2017, California's locality structure was modified to increase its number of localities from 9, under the previous locality structure, to 27 under the new Metropolitan Statistical Area based locality structure defined by the Office of Management and Budget (OMB).

223 *GAF* = (.50886 X Work GPCI) + (.44839 X PE GPCI) + (.04295 X MP GPCI)

The list of GAFs by locality for this proposed rule is available as a downloadable file at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Home-Infusion-Therapy/Overview.html.

We considered other alternatives to using the GAF (as discussed in section VIII.E) such as the hospital wage index (HWI), the GPCI, and using just the practice expense component of the GPCI; however, we are proposing to use the GAF to geographically wage adjust home infusion therapy for CY 2021 and subsequent years. We believe the GAF is the best option for geographic wage adjustment because it is the most operationally feasible. Utilizing the GAF would allow adjustments to be made while leveraging systems that are already in place. There are already mechanisms in place to geographically adjust using the GAF and applying this option would require less system changes. The adjustment would happen on the PFS and be based on the beneficiary zip code submitted on the 837P/CMS–1500 professional and supplier claims form.

Table 32 shows the 2019 rates for the temporary, transitional payment by drug category. Using the 2019 rates for the temporary, transitional payments, we estimate what the adjusted payments rates would be using the GAF. Table 33 shows the distribution of standardized adjusted payment rates for the GAF (sorted by standard deviation). The results indicate the distribution of payment rates center around the unadjusted payment rates when adjusting using the GAF.

TABLE 32: 2019 FEE SCHEDULE FOR TRANSITIONAL PAYMENT

Drug Category	Payment Rate
1 – Anti-infective, cardiovascular, pain, other	$138.75
2 – Immune globulin	$216.59
3 – Chemotherapy	$236.06

TABLE 33: GAF DISTRIBUTION OF STANDARDIZED ADJUSTED PAYMENT

RATES

Index	Mean	SD	Min	P10	P25	P50	P75	P90	Max
Drug Category 1									
GAF	138.69	8.49	126.77	129.82	132.45	136.33	144.50	151.02	179.28
Drug Category 2									
GAF	215.99	12.37	197.89	202.21	207.19	213.46	224.92	233.57	279.86
Drug Category 3									
GAF	235.93	15.20	215.68	220.86	225.34	229.35	250.09	259.05	305.01

The GAF is further discussed in the CY 2017 PFS final rule (81 FR 80170). Specific GAF values for each payment locality in past years are posted in Addendum D to this proposed rule and can be found at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Home-Health-Prospective-Payment-System-Regulations-and-Notices.html. The final CY 2020 GAF rates will be posted when they become available.

We are proposing that the application of the geographic wage adjustment be budget neutral so there would be no overall cost impact. However, this will result in some adjusted payments being higher than the average and others being lower. In order to make the application of the GAF budget neutral we are going to apply a budget-neutrality factor. If the rates were set for 2020 the budget neutrality factor would be 0.9985. The budget neutrality factor will be recalculated for 2021 in next year's rule using 2019 utilization data from the first year of the temporary transitional payment period. We welcome comments on our proposal to use the GAF to wage adjust the home infusion therapy services payment, and commenter's suggestions on whether a factor other than the GAF should be used.

2. Consumer Price Index

Subparagraphs (A) and (B) of section 1834(u)(3) of the Act specify annual adjustments to the single payment amount that are required to be made beginning January 1, 2022. In accordance with these sections we would increase the single payment amount by the percent

increase in the Consumer Price Index for all urban consumers (CPI-U) for the 12-month period ending with June of the preceding year, reduced by the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP). Accordingly, this may result in a percentage being less than 0.0 for a year, and may result in payment being less than such payment rates for the preceding year.

F. Other Optional Payment Adjustments/Prior Authorization for CY 2021 Home Infusion Therapy Services

1. Prior Authorization

Section 1834(u)(4) of the Act allows the Secretary discretion, as appropriate, to apply prior authorization for home infusion therapy services. Generally, prior authorization requires that a decision by a health insurer or plan be rendered to confirm health care service, treatment plan, prescription drug, or durable medical equipment is medically necessary.224 Prior authorization helps to ensure that a service, such as home infusion therapy, is being provided appropriately.

In the 2019 HH PPS proposed rule (83 FR 32469), we solicited comments as to whether and how prior authorization could potentially be used in home infusion. The majority of commenters were concerned that applying prior authorization would risk denying or delaying timely access to needed services, as an expeditious transition of care is clinically and economically important in home infusion. Another commenter stated that a CMS process would be welcome assuming the clinical information required is clearly defined, there is a defined CMS response time that does not prevent timely clinical care, that the process is appropriately limited to higher cost drugs, and once prior authorization has been made, retroactive denial for medical necessity would not be allowed.

224 https://www.healthcare.gov/glossary/preauthorization/

Ultimately, we do not consider prior authorization to be appropriate for the home infusion therapy benefit, at this time, as the benefit is contingent on the requirement that a home infusion drug or biological be administered through a Medicare Part B covered pump that is an item of DME. As discussed in section VI.E. of this proposed rule, payment for Medicare home infusion therapy is for services furnished in coordination with the furnishing of the infusion drugs and biologicals specified on the DME LCD for External Infusion Pumps (L33794), with the exception of insulin pump systems or any drugs or biologicals on a self-administered drug exclusion list. Therefore, we believe that prior authorization for home infusion therapy services is not necessary at this time, as services are contingent on the requirements under the DME benefit. We will monitor the provision of home infusion therapy services and revisit the need for prior authorization if issues arise.

2. Payments for High-Cost Outliers for Home Infusion Therapy Services

Section 1834(u)(1)(C) of the Act allows for discretionary adjustments which may include outlier situations and other factors as the Secretary determines appropriate. In the 2019 HH PPS proposed rule (83 FR 32467) we requested feedback on situations that may incur an outlier payment and potential designs for an outlier payment calculation. We received a comment stating that "it would be premature to consider outlier payments for home infusion therapy at the outset of the payment system. Given that the scope of covered home infusion therapy services is limited, and CMS is required to adjust the payment amount for patient acuity and complexity of drug administration, there may not be a need for outlier payments." We agree with this commenter that high cost outlier payments are not necessary at this time. We plan to monitor the need for such payments and if necessary address outlier situations in future rule making.

G. Billing Procedures for CY 2021 Home Infusion Therapy Services

In the CY 2019 HH PPS proposed rule we discussed billing procedures for home infusion therapy services for CY 2021 and subsequent years (83 FR 32467). We stated that we were considering processing claims for home infusion therapy services submitted on a Part B practitioner claim through the A/B MACs, rather than the DME MACs, given that "qualified home infusion therapy suppliers" are not limited to DME suppliers. We recognized that, although a qualified home infusion therapy supplier is not required to furnish DME equipment and supplies, in order for the same supplier to bill for both the home infusion therapy services and the DME equipment and supplies (including the drug), the provider or supplier would need to be enrolled as both a Part B qualified home infusion therapy supplier and as a DME supplier. In these instances, the same supplier would need to submit separate claims to both the A/B MACs and the DME MACs. We solicited comments on whether it is reasonable to require separate claims submissions to both the DME MACs and the A/B MACs for processing.

We received a few comments regarding this billing process, both in support of requiring separate claims submissions through the DME MACs and the A/B MACs. We continue to believe that, as a qualified home infusion therapy supplier is only required to enroll in Medicare as a Part B supplier, and is not required to enroll as a DME supplier, it is more practicable to process home infusion therapy service claims through the A/B MACs and the Multi-Carrier System (MCS) for Medicare Part B claims. DME suppliers, also enrolled as qualified home infusion therapy suppliers, would continue to submit DME claims through the DME MACs; however, they would also be required to submit home infusion therapy service claims to the A/B MACs for processing. Therefore, we plan to require that the qualified home infusion therapy supplier would submit all home infusion therapy service claims on the 837P/CMS-1500 professional and supplier claims form to the A/B MACs. DME suppliers, concurrently enrolled

as qualified home infusion therapy suppliers, would need to submit one claim for the DME, supplies, and drug on the 837P/CMS-1500 professional and supplier claims form to the DME MAC and a separate 837P/CMS-1500 professional and supplier claims form for the professional services to the A/B MAC. Because the home infusion therapy services are contingent upon a home infusion drug J-code being billed, home infusion therapy suppliers must ensure that the appropriate drug associated with the visit is billed with the visit or no more than 30 days prior to the visit. Additionally, we plan to add the home infusion G-codes to the PFS, incorporating the required annual and geographic wage adjustments. Home infusion therapy suppliers would include a modifier on the appropriate G-code to differentiate the first visit from all subsequent visits, as well as a modifier to indicate when a patient has been discharged from service. This would be necessary in order for the qualified home infusion therapy supplier to bill for the first visit payment amount for a patient who had previously received home infusion therapy services in order to demonstrate a gap of more than 60 days between a discharge and the start of subsequent home infusion therapy services. We will issue a Change Request (CR) providing more detailed instruction regarding billing and policy information for home infusion therapy services, which is expected upon release of the CY 2020 final rule.

VII. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In section V. of this proposed rule, we propose changes and updates to the HH QRP. We believe that the burden associated with the HH QRP proposals is the time and effort associated with data collection and reporting. As of February 1, 2019, there are approximately 11,385 HHAs reporting quality data to CMS under the HH QRP. For the purposes of calculating the costs associated with the collection of information requirements, we obtained mean hourly wages for these staff from the U.S. Bureau of Labor Statistics' May 2017 National Occupational Employment and Wage Estimates (https://www.bls.gov/oes/2017/may/oes_nat.htm). To account for overhead and fringe benefits (100 percent), we have doubled the hourly wage. These amounts are detailed in Table 34.

TABLE 34: U.S. BUREAU OF LABOR STATISTICS' MAY 2017 NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefit (100%) ($/hr)	Adjusted Hourly Wage ($/hr)
Registered Nurse (RN)	29-1141	$35.36	$35.36	$70.72
Physical therapists (PT)	29-1123	$42.34	$42.34	$84.68
Speech-Language Pathologists (SLP)	29-1127	$38.35	$38.35	$76.70
Occupational Therapists (OT)	29-1122	$40.69	$40.69	$81.38

As discussed in section V.D. of this proposed rule, we are proposing to remove the Improvement in Pain Interfering with Activity Measure (NQF #0177) from the HH QRP beginning with the CY 2022 HH QRP under our measure removal Factor 7: Collection or public reporting of a measure leads to negative unintended consequences other than patient harm. Additionally, we are proposing to remove OASIS item M1242. Removing M1242 will result in a decrease in burden of 0.3 minutes of clinical staff time to report data at start of care (SOC), 0.3 minutes of clinical staff time to report data at resumption of care (ROC) and 0.3 minutes of clinical staff time to report data at Discharge

As discussed in section V.E. of this proposed rule, we are proposing to adopt two new measures: (1) Transfer of Health Information to Provider–Post-Acute Care (PAC); and (2) Transfer of Health Information to Patient–Post-Acute Care (PAC), beginning with the CY 2022 HH QRP. We estimate the data elements for the proposed Transfer of Health Information quality measures will take 0.6 minutes of clinical staff time to report data at Discharge and 0.3 minutes of clinical staff time to report data at Transfer of Care (TOC).

In section V.G. of this proposed rule, we are proposing to collect standardized patient assessment data beginning with the CY 2022 HH QRP. We estimate the proposed SPADEs will take 10.05 minutes of clinical staff time to report data at SOC, 9.15 minutes of clinical staff time to report at ROC, and 11.25 minutes of clinical staff time to report data at Discharge.

We estimate that there would be a net increase in clinician burden per OASIS assessment of 9.75 minutes at SOC, 8.85 minutes at ROC, 0.3 minutes at TOC, and 11.55 minutes at Discharge as a result of all of the HH QRP proposals in this proposed rule.

The OASIS is completed by RNs or PTs, or very occasionally by occupational therapists (OT) or speech language pathologists (SLP/ST). Data from 2018 show that the SOC/ROC OASIS is completed by RNs (approximately 84.5 percent of the time), PTs (approximately 15.2 percent of the time), and other therapists, including OTs and SLP/STs (approximately 0.3 percent of the time). Based on this analysis, we estimated a weighted clinician average hourly wage of $72.90, inclusive of fringe benefits, using the hourly wage data in Table 34. Individual providers determine the staffing resources necessary.

Table 35 shows the total number of OASIS assessments submitted by HHAs in CY 2018 and estimated burden at each time point.

TABLE 35: CY 2018 OASIS SUBMISSIONS AND ESTIMATED BURDEN, BY TIME POINT

Time Point	CY 2018 Assessments Completed	Estimated Burden ($)
Start of Care	6,573,010	$77,865,519.71
Resumption of Care	1,113,156	$11,969,488.18
Follow-up	2,067,257	0
Transfer of Care	2,021,383	$736,794.10
Death at Home	42,550	0
Discharge from Agency	5,652,757	$79,326,552.17
TOTAL	**17,470,113**	$169,898,354.17

* Estimated Burden ($) at each Time-Point = (# CY 2018 Assessments Completed) x (clinician burden [min]/60) x ($72.90 [weighted clinician average hourly wage]).

Based on the data in Table 35, for the 11,385 active Medicare-certified HHAs in February 2019, we estimate the total average increase in cost associated with changes to the HH QRP at approximately $14,923.00 per HHA annually, or $169,898,354.17 for all HHAs annually. This corresponds to an estimated increase in clinician burden associated with proposed changes to the HH QRP of approximately 204.7 hours per HHA annually, or 2,330,567.3 hours for all HHAs

annually. This estimated increase in burden will be accounted for in the information collection under OMB control number 0938-1279.

VIII. Regulatory Impact Analysis

A. Statement of Need

1. Home Health Prospective Payment System (HH PPS)

Section 1895(b)(1) of the Act requires the Secretary to establish a HH PPS for all costs of home health services paid under Medicare. In addition, section 1895(b) of the Act requires: (1) the computation of a standard prospective payment amount include all costs for home health services covered and paid for on a reasonable cost basis and that such amounts be initially based on the most recent audited cost report data available to the Secretary; (2) the prospective payment amount under the HH PPS to be an appropriate unit of service based on the number, type, and duration of visits provided within that unit; and (3) the standardized prospective payment amount be adjusted to account for the effects of case-mix and wage levels among HHAs. Section 1895(b)(3)(B) of the Act addresses the annual update to the standard prospective payment amounts by the HH applicable percentage increase. Section 1895(b)(4) of the Act governs the payment computation. Sections 1895(b)(4)(A)(i) and (b)(4)(A)(ii) of the Act requires the standard prospective payment amount to be adjusted for case-mix and geographic differences in wage levels. Section 1895(b)(4)(B) of the Act requires the establishment of appropriate case-mix adjustment factors for significant variation in costs among different units of services. Lastly, section 1895(b)(4)(C) of the Act requires the establishment of wage adjustment factors that reflect the relative level of wages, and wage-related costs applicable to home health services furnished in a geographic area compared to the applicable national average level.

Section 1895(b)(3)(B)(iv) of the Act provides the Secretary with the authority to implement adjustments to the standard prospective payment amount (or amounts) for subsequent years to eliminate the effect of changes in aggregate payments during a previous year or years that were the result of changes in the coding or classification of different units of services that do not reflect real changes in

case-mix. Section 1895(b)(5) of the Act provides the Secretary with the option to make changes to the payment amount otherwise paid in the case of outliers because of unusual variations in the type or amount of medically necessary care. Section 1895(b)(3)(B)(v) of the Act requires HHAs to submit data for purposes of measuring health care quality, and links the quality data submission to the annual applicable percentage increase. Section 50208 of the BBA of 2018 (Pub. L. 115-123) requires the Secretary to implement a new methodology used to determine rural add-on payments for CYs 2019 through 2022.

Sections 1895(b)(2) and 1895(b)(3)(A) of the Act, as amended by section 51001(a)(1) and 51001(a)(2) of the BBA of 2018 respectively, require the Secretary to implement a 30-day unit of service, effective for CY 2020, and calculate a 30-day payment amount for CY 2020 in a budget neutral manner, respectively. In addition, section 1895(b)(4)(B) of the Act, as amended by section 51001(a)(3) of the BBA of 2018 requires the Secretary to eliminate the use of the number of therapy visits provided to determine payment, also effective for CY 2020.

2. HHVBP

The HHVBP Model applies a payment adjustment based on an HHA's performance on quality measures to test the effects on quality and expenditures.

3. HH QRP

Section 1895(b)(3)(B)(v) of the Act requires HHAs to submit data for purposes of measuring heath care quality, and links the quality data submission to the annual applicable percentage increase.

4. Home Infusion Therapy

Section 1834(u)(1) of the Act, as added by section 5012 of the 21st Century Cures Act, requires the Secretary to establish a home infusion therapy services payment system under Medicare. Under this payment system a single payment would be made to a qualified home infusion therapy supplier for items and services furnished by a qualified home infusion therapy supplier in coordination with the furnishing of home infusion drugs. Section 1834(u)(1)(A)(ii) of the Act states that a unit of single payment is for each infusion drug administration calendar day in the individual's home. The Secretary shall, as appropriate, establish single payment amounts for types of infusion therapy, including to take into account

variation in utilization of nursing services by therapy type. Section 1834(u)(1)(A)(iii) of the Act provides a limitation to the single payment amount, requiring that it shall not exceed the amount determined under the Physician Fee Schedule (under section 1848 of the Act) for infusion therapy services furnished in a calendar day if furnished in a physician office setting, except such single payment shall not reflect more than 5 hours of infusion for a particular therapy in a calendar day. Section 1834(u)(1)(B)(i) of the Act requires that the single payment amount be adjusted by a geographic wage index. Finally, section 1834(u)(1)(C) of the Act allows for discretionary adjustments which may include outlier payments and other factors as deemed appropriate by the Secretary, and are required to be made in a budget neutral manner. This payment system would become effective for home infusion therapy items and services furnished on or after January 1, 2021.

Section 50401 of the BBA of 2018 amended section 1834(u) of the Act, by adding a new paragraph (7) that establishes a home infusion therapy temporary transitional payment for eligible home infusion therapy suppliers for items and services associated with the furnishing of transitional home infusion drugs for CYs 2019 and 2020. Under this payment methodology (as described in section VI.B. of this proposed rule), the Secretary established three payment categories at amounts equal to the amounts determined under the Physician Fee Schedule established under section 1848 of the Act. This rule would continue this categorization for services furnished during CY 2020 for codes and units of such codes, determined without application of the geographic adjustment.

B. Overall Impact

We have examined the impacts of this 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 Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (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). Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action that is likely to result in a rule: (1) having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as "economically significant"); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. Given that we note the follow costs associated with the provisions of this proposed rule:

- A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimate that this rulemaking is "economically significant" as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking.

The net transfer impact related to the changes in payments under the HH PPS for CY 2020 is estimated to be $250 million (1.3 percent). The net transfer impact in CY 2020 related to the change in the unit of payment under the proposed PDGM is estimated to be $0 million as section 51001(a) of the BBA of 2018 requires such change to be implemented in a budget-neutral manner.

- HHVBP--The savings impacts related to the HHVBP Model as a whole are estimated at $378 million for CYs 2018 through 2022. We do not believe the proposal in this proposed rule would affect the prior estimate.

- HH QRP--The cost impact for HHA's related to proposed changes to the HH QRP are estimated at $169.9 million.

- Home Infusion Therapy--The CY 2020 cost impact related to the routine updates to the temporary transitional payments for home infusion therapy in CY 2020 is estimated to be less than $1 million in either an increase or a decrease in payments to home infusion therapy suppliers, depending on the final payment rates under the physician fee schedule for CY 2020. The cost impact in CY 2021 related to the implementation of the permanent home infusion therapy benefit is estimated to be a $3 million reduction in payments to home infusion therapy suppliers (using the CY 2019 physician fee schedule payment amounts as the 2020 physician fee schedule amounts were not available at the time of rulemaking).

C. Anticipated Effects

1. HH PPS

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, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $7.5 million to $38.5 million in any one year. For the purposes of the RFA, we estimate that almost all HHAs and home infusion therapy suppliers are small entities as that term is used in the RFA. Individuals and states are not included in the definition of a small entity. The economic impact assessment is based on estimated Medicare payments (revenues) and HHS's practice in interpreting the RFA is to consider effects economically ''significant'' only if greater than 5 percent of providers reach a threshold of 3 to 5 percent or more of total revenue or total costs. The majority of HHAs' visits are Medicare paid visits and therefore the majority of HHAs' revenue consists of Medicare payments. Based on our analysis, we conclude that the policies proposed in this rule would result in an estimated total impact of 3 to 5 percent or more on Medicare revenue for greater than 5 percent of HHAs and home

infusions therapy suppliers. Therefore, the Secretary has determined that this HH PPS proposed rule would have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This rule is not applicable to hospitals. Therefore, the Secretary has determined this final rule will not have a significant economic impact on the operations of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2019, that threshold is approximately $150 million. This rule is not anticipated to have an effect on State, local, or tribal governments, in the aggregate, or on the private sector of $150 million or more.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates 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. We have reviewed this proposed rule under these criteria of Executive Order 13132, and have determined that it will not impose substantial direct costs on state or local governments.

2. HHVBP

Under the HHVBP Model, the first payment adjustment was applied in CY 2018 based on PY 1 (2016) data and the final payment adjustment will apply in CY 2022 based on PY 5 (2020) data. In the CY 2016 HH PPS final rule, we estimated that the overall impact of the HHVBP Model from CY 2018 through CY 2022 was a reduction of approximately $380 million (80 FR 68716). In the CYs 2017, 2018, and 2019 HH PPS final rules, we estimated that the overall impact of the HHVBP Model from CY 2018 through CY 2022 was a reduction of approximately $378 million (81 FR 76795, 82 FR 51751, and 83 FR

56593, respectively). We do not believe the proposal in this proposed rule would affect the prior estimate.

3. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this final rule, we must estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that would review the rule, we assume that the total number of unique reviewers of this year's proposed rule would be the similar to the number of commenters on last 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 this 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 believe that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We welcome any comments on the approach in estimating the number of entities which would review this proposed rule. We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We seek comments on this assumption. Using the wage information from the BLS for medical and health service managers (Code 11-9111), we estimate that the cost of reviewing this rule is $109.36 per hour, including overhead and fringe benefits (https://www.bls.gov/oes/current/oes_nat.htm. Assuming an average reading speed of 250 words per minute, we estimate that it would take approximately 3.53 hours for the staff to review half of this proposed rule, which consists of approximately 105,837 words. For each HHA that reviews the rule, the estimated cost is $386.04 (3.53 hours x $109.36). Therefore, we estimate that the total cost of reviewing this proposed rule is $442,015.80 ($386.04 x 1,145 reviewers). For purposes of this estimate, the number of anticipated reviewers in this year's rule is equivalent to the number of commenters on the CY 2019 HH PPS proposed rule.

D. Detailed Economic Analysis

1. HH PPS

This rule proposes updates to Medicare payments under the HH PPS for the CY 2020. This rule also implements a change in the case-mix adjustment methodology for home health periods of care beginning on and after January 1, 2020 and implements the change in the unit of payment from 60-day episodes to 30-day periods. These changes are made in a budget-neutral manner. The impact analysis of this proposed rule presents the estimated expenditure effects of policy changes proposed in this rule. We use the latest data and best analysis available, but we do not make adjustments for future changes in such variables as number of visits or case-mix.

This analysis incorporates the latest estimates of growth in service use and payments under the Medicare HH benefit, based primarily on Medicare claims data from 2018. We note that certain events may combine to limit the scope or accuracy of our impact analysis, because such an analysis is future-oriented and, thus, susceptible to errors resulting from other changes in the impact time period assessed. Some examples of such possible events are newly-legislated general Medicare program funding changes made by the Congress, or changes specifically related to HHAs. In addition, changes to the Medicare program may continue to be made as a result of the Affordable Care Act, or new statutory provisions. Although these changes may not be specific to the HH PPS, the nature of the Medicare program is such that the changes may interact, and the complexity of the interaction of these changes could make it difficult to predict accurately the full scope of the impact upon HHAs.

Table 36 represents how HHA revenues are likely to be affected by the policy changes proposed in this rule for CY 2020. For this analysis, we used an analytic file with linked CY 2018 OASIS assessments and HH claims data for dates of service that ended on or before December 31, 2018. The first column of Table 36 classifies HHAs according to a number of characteristics including provider type, geographic region, and urban and rural locations. The second column shows the number of facilities in the impact analysis. The third column shows the payment effects of the CY 2020 wage index. The fourth column shows the payment effects of the CY 2020 rural add-on payment provision in statute. The fifth column shows the effects of the implementation of the PDGM case-mix methodology for CY 2020. The sixth column shows the payment effects of the CY 2020 home health payment update percentage as

required by section 53110 of the BBA of 2018. And the last column shows the combined effects of all the policies proposed in this rule.

Overall, it is projected that aggregate payments in CY 2020 would increase by 1.3 percent. As illustrated in Table 36, the combined effects of all of the changes vary by specific types of providers and by location. We note that some individual HHAs within the same group may experience different impacts on payments than others due to the distributional impact of the CY 2020 wage index, the extent to which HHAs are affected by changes in case-mix weights between the current 153-group case-mix model and the case-mix weights under the 432-group PDGM, the percentage of total HH PPS payments that were subject to the low-utilization payment adjustment (LUPA) or paid as outlier payments, and the degree of Medicare utilization.

TABLE 36: ESTIMATED HHA IMPACTS BY FACILITY TYPE AND AREA OF THE COUNTRY, CY 2020

	Number of Agencies	CY 2020 Wage Index	CY 2020 Rural Add-On	CY 2020 Case-Mix Weights (PDGM)	CY 2020 HH Payment Update Percentage	Total
All Agencies	**10,124**	**0%**	**-0.2%**	**0.0%**	**1.5%**	**1.3%**
Facility Type and Control						
Free-Standing/Other Vol/NP	1,009	-0.2%	-0.1%	2.7%	1.5%	3.9%
Free-Standing/Other Proprietary	8,092	0.0%	-0.1%	-1.1%	1.5%	0.2%
Free-Standing/Other Government	230	-0.2%	-0.4%	1.9%	1.5%	2.8%
Facility-Based Vol/NP	561	-0.1%	-0.2%	3.5%	1.5%	4.7%
Facility-Based Proprietary	62	0.2%	-0.3%	2.9%	1.5%	4.2%
Facility-Based Government	170	0.4%	-0.4%	4.0%	1.5%	5.4%
Subtotal: Freestanding	9,331	-0.1%	-0.1%	-0.3%	1.5%	1.0%
Subtotal: Facility-based	793	0.0%	-0.2%	3.5%	1.5%	4.8%
Subtotal: Vol/NP	1,570	-0.2%	-0.1%	2.9%	1.5%	4.1%
Subtotal: Proprietary	8,154	0.0%	-0.2%	-1.1%	1.5%	0.2%
Subtotal: Government	400	0.2%	-0.4%	3.1%	1.5%	4.4%
Facility Type and Control: Rural						
Free-Standing/Other Vol/NP	250	-0.3%	-0.8%	3.8%	1.5%	4.3%
Free-Standing/Other Proprietary	810	0.2%	-0.7%	3.7%	1.5%	4.7%
Free-Standing/Other Government	154	0.1%	-0.8%	0.0%	1.5%	0.8%
Facility-Based Vol/NP	249	0.6%	-0.8%	3.3%	1.5%	4.6%
Facility-Based Proprietary	32	0.3%	-0.8%	10.6%	1.5%	11.6%
Facility-Based Government	129	0.3%	-0.8%	4.5%	1.5%	5.5%
Facility Type and Control: Urban						
Free-Standing/Other Vol/NP	759	-0.2%	0.0%	2.6%	1.5%	3.8%
Free-Standing/Other Proprietary	7,282	-0.1%	-0.1%	-1.8%	1.5%	-0.4%
Free-Standing/Other Government	76	-0.4%	0.0%	3.5%	1.5%	4.6%

	Number of Agencies	CY 2020 Wage Index	CY 2020 Rural Add-On	CY 2020 Case-Mix Weights (PDGM)	CY 2020 HH Payment Update Percentage	Total
Facility-Based Vol/NP	312	-0.2%	-0.1%	3.5%	1.5%	4.8%
Facility-Based Proprietary	30	0.2%	-0.1%	-0.9%	1.5%	0.6%
Facility-Based Government	41	0.4%	-0.1%	3.6%	1.5%	5.4%
Facility Location: Urban or Rural						
Rural	1,624	0.2%	-0.7%	3.7%	1.5%	4.7%
Urban	8,500	-0.1%	-0.1%	-0.5%	1.5%	0.8%
Facility Location: Region of the Country (Census Region)						
New England	351	-0.7%	-0.1%	2.4%	1.5%	3.1%
Mid Atlantic	466	-0.2%	-0.1%	3.0%	1.5%	4.2%
East North Central	1,890	-0.1%	-0.1%	-0.8%	1.5%	0.4%
West North Central	680	0.5%	-0.3%	-4.2%	1.5%	-2.5%
South Atlantic	1,605	-0.2%	-0.1%	-5.3%	1.5%	-4.1%
East South Central	410	0.1%	-0.4%	0.6%	1.5%	1.8%
West South Central	2,567	0.2%	-0.2%	4.5%	1.5%	6.0%
Mountain	685	0.1%	-0.1%	-5.8%	1.5%	-4.3%
Pacific	1,426	0.0%	0.0%	3.8%	1.5%	5.3%
Outlying	44	-0.5%	-0.3%	10.5%	1.5%	11.3%
Facility Size (Number of 60-day Episodes)						
< 100 episodes	2,747	0.2%	-0.1%	2.1%	1.5%	3.6%
100 to 249	2,157	0.1%	-0.1%	0.9%	1.5%	2.4%
250 to 499	2,127	0.1%	-0.1%	0.6%	1.5%	2.0%
500 to 999	1,629	0.0%	-0.2%	-0.4%	1.5%	0.9%
1,000 or More	1,464	-0.1%	-0.2%	-0.2%	1.5%	1.1%

Source: CY 2018 Medicare claims data for episodes ending on or before December 31, 2018 for which we had a linked OASIS assessment.

[1] The CY 2020 home health payment update percentage reflects the home health payment update of 1.5 percent as described in section III.F.1 of this proposed rule.

Notes: The "PDGM" is the 30-day version of the model with no behavioral assumptions applied. This analysis omits 284,404 60-day episodes not grouped under the PDGM (either due to a missing SOC OASIS, because they could be assigned to a clinical grouping, or had missing therapy/nursing visits). After converting 60-day episodes to 30-day periods for the PDGM, a further 24 periods were excluded with missing NRS weights, and 2,607 periods with a missing urban/rural indicator. The standard 30-day payment amount used to achieve impact neutrality incorporates three behavioral assumptions: (1) that 1/3 of LUPAs 1-2 visits away from the LUPA threshold would receive extra visits and become case-mix adjusted; (2) that among available diagnoses the code leading to the highest payment clinical grouping classification would be designated as the principal diagnosis for clinical grouping; and (3) comorbidity level would be assigned by including comorbidities appearing on HHA claims and not just the OASIS.

REGION KEY:
New England=Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont
Middle Atlantic=Pennsylvania, New Jersey, New York;
South Atlantic=Delaware, District of Columbia, Florida, Georgia, Maryland, North Carolina, South Carolina, Virginia, West Virginia
East North Central=Illinois, Indiana, Michigan, Ohio, Wisconsin
East South Central=Alabama, Kentucky, Mississippi, Tennessee
West North Central=Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, South Dakota
West South Central=Arkansas, Louisiana, Oklahoma, Texas
Mountain=Arizona, Colorado, Idaho, Montana, Nevada, New Mexico, Utah, Wyoming
P**acific**=Alaska, California, Hawaii, Oregon, Washington
Other=Guam, Puerto Rico, Virgin Islands

2. HHVBP

As discussed in section IV. of this proposed rule, for the HHVBP Model, we are proposing to publicly report performance data for PY 5 (CY 2020) of the Model. This proposal would not affect our analysis of the distribution of payment adjustments for PY 5 as presented in the CY 2019 HH PPS final rule. Therefore, we are not providing a detailed analysis.

3. HH QRP

Failure to submit data required under section 1895(b)(3)(B)(v) of the Act with respect to a calendar year will result in the reduction of the annual home health market basket percentage increase otherwise applicable to a HHA for that calendar year by 2 percentage points. For the CY 2019 payment determination, 1,286 of the 11,444 active Medicare-certified HHAs, or approximately 11.2 percent, did not receive the full annual percentage increase. Information is not available to determine the precise number of HHAs that would not meet the requirements to receive the full annual percentage increase for the CY 2020 payment determination.

As discussed in section V.D. of this proposed rule, we are proposing to remove one measure beginning with the CY 2022 HH QRP. The measure we are proposing to remove is Improvement in Pain Interfering with Activity Measure (NQF #0177). As discussed in section V.E. of this proposed rule, we are proposing to add two measures beginning with the CY 2022 HH QRP. The two measures we are proposing to adopt are: (1) Transfer of Health Information to Provider–Post-Acute Care; and (2) Transfer of Health Information to Patient–Post-Acute Care. As discussed in section V.G. of this proposed rule, we are also proposing to collect standardized patient assessment data beginning with the CY 2022 HH QRP. Section VII. of this proposed rule provides a detailed description of the net increase in burden associated with these proposed changes. We have estimated this associated burden beginning with CY 2021 because HHAs will be required to submit data beginning with that calendar year. The cost impact related to OASIS item collection as a result of the changes to the HH QRP is estimated to be a net increase of approximately $169.9 million in annualized cost to HHAs, discounted at 7 percent relative to year 2016, over a perpetual time horizon beginning in CY 2021.

4. Home Infusion Therapy Services Payment

a. Home Infusion Therapy Services Temporary Transitional Payment

At the time of publication of this proposed rule, the CY 2020 PFS payment rates were not available, therefore we are unable to estimate whether the impact in CY 2020 would result in an increase or decrease in overall payments for home infusion therapy services receiving temporary transitional payments. However, we estimate the impact due to the updated payment amounts for furnishing home infusion therapy services, as determined under the physician fee schedule established under section 1848 of the Act, may result in up to a $1 million increase/decrease in payments for CY 2020.

b. Home Infusion Therapy Services Payment for CY 2021 and Subsequent Years

The following analysis applies to payment for home infusion therapy as set forth in section 1834(u)(1) of the Act, as added by section 5012 of the 21st Century Cures Act (Pub. L. 114-255), and accordingly, describes the preliminary impact for CY 2021 only. We should also note that as payment amounts are contingent on the Physician Fee Schedule (PFS) rates, this impact analysis will be affected by whether rates increase or decrease in CY 2020. At the time of publication these rates were not available, therefore we used the CY 2019 PFS payment rates for the purpose of this analysis. We used CY 2018 claims data to identify beneficiaries with DME claims containing 1 of the 37 HCPCS codes identified on the DME LCD for External Infusion Pumps (L33794), excluding drugs that are statutorily excluded from coverage under the permanent home infusion therapy benefit. These include drugs and biologicals listed on self-administered drug exclusion lists and drugs administered by routes other than intravenous or subcutaneous infusion. Because we do not have complete data for CY 2019 (the first year of the temporary transitional payments), we used the visit assumptions identified in the CY 2019 HH PPS final rule. We calculated the total weeks of care, which is the sum of weeks of care across all beneficiaries found in each category (as determined from the 2018 claims). Weeks of care for categories 1 and 3 are defined as the week of the last infusion drug or pump claim minus the week of the first infusion drug or pump claim plus one. For category 2, we used the median number of weeks of care and assumed 1 visit per month, or 12 visits per year. And finally, we assumed 2 visits for the initial week of

care, with 1 visit per week for all subsequent weeks in order to estimate the total visits of care per category. For this analysis, we did not factor in an increase in beneficiaries receiving home infusion therapy services due to switching from physician's offices or outpatient centers. Because home infusion therapy services under Medicare are contingent on utilization of the DME benefit, we anticipate utilization will remain fairly stable and that there would be no significant changes in the settings of care where current infusion therapy is provided. We will continue to monitor utilization to determine if referral patterns change significantly once the permanent benefit is implemented in CY 2021. Table 37 reflects the estimated wage-adjusted beneficiary impact, representative of a 4-hour payment rate, compared to a 5-hour payment rate, excluding statutorily excluded drugs and biologicals. Column 3 represents the percent change from the estimated CY 2019 payment under the temporary transitional payment to the estimated CY 2021 payment after applying the GAF wage adjustment. Column 4 represents the percent change from the estimated CY 2021 payment after applying the GAF wage adjustment index and the 5 hour payment rate to the estimated payment after removing the statutorily excluded drugs. Column 5 represents the percent change from the estimated CY 2021 payment after applying the GAF wage adjustment to the estimated CY 2021 payment after applying the 5-hour payment rate (prior to removing statutorily excluded drugs and biologicals). Overall, we estimate a 4.3 percent decrease ($3 million) in payments to home infusion therapy suppliers in CY 2021.

TABLE 37: ESTIMATED IMPACTS FOR HOME INFUSION THERAPY SERVICES, CY 2021

	Number of Beneficiaries	CY 2021 Wage Adjustment (GAF)	CY 2021 Statutorily Excluded Drugs	CY 2021 Payment Proposal	Total
All Beneficiaries	18,290	0.0%	-16.4%	12.1%	-4.3%
Beneficiary Location: Urban or Rural					
Urban	15,144	0.8%	-16.7%	12.1%	-3.8%
Rural	3,146	-3.9%	-14.6%	11.9%	-6.6%
Beneficiary Location: Region of the Country (Census Division)					
New England	747	4.2%	-22.8%	12.4%	-6.2%
Mid-Atlantic	3,369	4.5%	-6.9%	13.4%	10.9%
East North Central	2,405	-2.5%	-12.9%	12.4%	-2.9%
West North Central	1,336	-4.5%	-18.9%	11.2%	-12.2%
South Atlantic	4,703	-0.8%	-19.7%	11.6%	-8.8%
East South Central	1,227	-7.1%	-22.5%	10.5%	-19.0%

	Number of Beneficiaries	CY 2021 Wage Adjustment (GAF)	CY 2021 Statutorily Excluded Drugs	CY 2021 Payment Proposal	Total
West South Central	1,809	-4.1%	-15.4%	11.6%	-7.9%
Mountain	959	-1.4%	-28.8%	10.7%	-19.5%
Pacific	1,718	6.4%	-19.9%	12.6%	-0.9%
Other	17	0.1%	-0.1%	13.2%	13.1%
Payment Category					
BBA Category 1	6,055	0.0%	-0.1%	15.9%	15.8%
BBA Category 2*	7,322	-0.3%	-48.6%	7.3%	-41.6%
BBA Category 3	4,913	0.2%	-0.1%	13.1%	13.2%

Source: CY 2018 Medicare DME claims data as of March, 2018 containing HCPCS codes equal to one of the 37 codes listed in the BBA of 2018.

*Decrease due to exclusion of Hizentra.

REGION KEY:
New England=Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont
Middle Atlantic=Pennsylvania, New Jersey, New York;
South Atlantic=Delaware, District of Columbia, Florida, Georgia, Maryland, North Carolina, South Carolina, Virginia, West Virginia
East North Central=Illinois, Indiana, Michigan, Ohio, Wisconsin
East South Central=Alabama, Kentucky, Mississippi, Tennessee
West North Central=Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, South Dakota
West South Central=Arkansas, Louisiana, Oklahoma, Texas
Mountain=Arizona, Colorado, Idaho, Montana, Nevada, New Mexico, Utah, Wyoming
P**acific**=Alaska, California, Hawaii, Oregon, Washington
Other=Guam, Puerto Rico, Virgin Islands

E. Alternatives Considered

1. HH PPS

For CY 2020, we did not consider alternatives to changing the unit of payment from 60 days to 30 days, eliminating the use of therapy thresholds for the case-mix adjustment, and requiring the revised payments to be budget neutral as the BBA of 2018 requires these changes to be implemented on January 1, 2020. Section 51001 of the BBA of 2018 requires the change in the unit of payment from 60 days to 30 days to be made in a budget neutral manner and mandates the elimination of the use of therapy thresholds for case-mix adjustment purposes. The BBA of 2018 also requires that we make assumptions about behavior changes that could occur as a result of the implementation of the 30-day unit of payment and as a result of the case-mix adjustment factors that are implemented in CY 2020 in calculating a 30-day payment amount for CY 2020 in a budget neutral manner.

We did consider alternatives to complete RAP elimination by CY 2021. Specifically, considered a RAP phase-out over 2 years instead of the proposed 1 year (that is, complete elimination of RAPs by CY 2022) because we believed that additional time would be needed for HHAs to appropriately align their systems with the new policy. However, we chose to propose this change in CY 2020 due to imminent program integrity concerns that have shown increasing amounts of fraudulent activity due to the current RAP policy. We also considered different time frames for the submission of the NOA, including a 7 day timeframe in which to submit a timely-filed NOA. However, to be consistent with similar requirements in other settings (for example, hospice where the NOE must be submitted within 5 calendar days), we believe the 5 day timely-filing requirement would ensure that the Medicare claims processing system is alerted to mitigate any overpayments for services that should be covered under the home health benefit.

2. HHVBP

With regard to our proposal to publicly report on the CMS Website the CY 2020 (PY 5) Total Performance Score (TPS) and the percentile ranking of the TPS for each competing HHA that qualifies for a payment adjustment in CY 2020, we also considered not making this Model performance data

public, and whether there was any potential cost to stakeholders and beneficiaries if the data were to be misinterpreted. However, we believe that providing definitions for the HHVBP TPS and the TPS Percentile Ranking methodology would address any such concerns by ensuring the public understands the relevance of these data points and how they were calculated. We also considered the financial costs associated with our proposal to publicly report HHVBP data, but do not anticipate such costs to CMS, stakeholders or beneficiaries, as CMS already calculates and reports the TPS and TPS Percentile Ranking in the Annual Reports to HHAs. As discussed in section IV. of this proposed rule, we believe the public reporting of such data would further enhance quality reporting under the Model by encouraging participating HHAs to provide better quality of care through focusing on quality improvement efforts that could potentially improve their TPS. In addition, we believe that publicly reporting performance data that indicates overall performance may assist beneficiaries, physicians, discharge planners, and other referral sources in choosing higher-performing HHAs within the nine Model states and allow for more meaningful and objective comparisons among HHAs on their level of quality relative to their peers.

3. HH QRP

We believe that removing the Pain Interfering with Activity Measure (NQF #0177) from the HH QRP beginning with the CY 2022 HH QRP would reduce negative unintended consequences. We are proposing the removal of the measure under Meaningful Measures Initiative measure removal Factor 7: Collection or public reporting of a measure leads to negative unintended consequences other than patient harm. We considered alternatives to this measure and no appropriate alternative measure is ready at this time. Out of an abundance of caution to potential harm from over-prescription of opioid medications inadvertently driven by this measure, we have determined that removing the current pain measure is the most appropriate proposal.

The proposed adoption of two transfer of health information process measures is vital to satisfying 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 of accurately communicating the existence of and providing for the transfer of health information and care preferences of an individual

when the individual transitions from a PAC provider to another applicable setting. We believe adopting these measures best addresses the requirements of the IMPACT Act for this domain. We considered not adopting these proposals and doing additional analyses for a future implementation. This approach was not viewed as a viable alternative because of the extensive effort invested in creating the best measures possible and failure to adopt measures in the domain of transfer of health information puts CMS at risk of not meeting the legislative mandate of the IMPACT Act.

Collecting and reporting standardized patient assessment data under the HH QRP is required under section 1899B(b)(1) of the Act. We have carefully considered assessment items for each of the categories of assessment data and believe these proposals best address the requirements of the Act for the HH QRP. The proposed SPADEs are items that received additional national testing after they were proposed in the CY 2018 HH PPS proposed rule (82 FR 35354 through 35371) and more extensively vetted. These items have been carefully considered and the alternative of not proposing to adopt standardized patient assessment data will result in CMS not meeting our legislative mandate under the IMPACT Act.

4. Home Infusion Therapy

a. Home Infusion Therapy Services Temporary Transitional Payment

We did not consider alternatives to updating the home infusion therapy services temporary transitional payment rates for CY 2020 because section 1834(u)(7)(D) of the Act requires the Secretary to pay eligible home infusion suppliers for home infusion therapy services at amounts equal to the amounts determined under the physician fee schedule for services furnished during the year for codes and units of such codes with respect to drugs included in payment categories as outlined in section 1834(u)(7)(C) of the Act, determined without application of the geographic wage adjustment.

b. Home Infusion Therapy Services Payment for CY 2021 and Subsequent Years

We did not consider alternatives to proposing the home infusion therapy services payment system for CY 2021 in the CY 2020 HH PPS proposed rule, given that qualified home infusion therapy suppliers

would need ample time to understand and implement the payment policies and billing procedures related to the new payment system.

For the CY 2020 HH PPS proposed rule, we did consider three alternatives to the payment proposals articulated in section VI.D. of this proposed rule. We considered proposing a payment methodology that maintains the three payment categories and PFS codes; but that pays per amount and per unit for the current PFS infusion codes, up to 5 hours, meaning we would not set the payment amount to a base amount of 5 hours of infusion. We would utilize two existing home infusion codes for billing, which would then correspond with the PFS code amounts per hour. Suppliers would bill code 99601 (Home infusion/specialty drug administration, per visit (up to 2 hours)), which would correspond to the first 2 hours of the visit, after which suppliers would bill code 99602 (Home infusion/specialty drug administration, per visit (up to 2 hours); each additional hour), up to 3 hours. We would set the minimum payment amount equal to 2 hours of infusion in a physician's office; however, in analyzing CY 2018 physician office (carrier) claims we found that the time required for most infusion services is about an hour. Only 25 to 30 percent of the time, physicians billed for 2 hours of care and the service almost never extended to exceed 2 hours. Nonetheless, we did not propose this option in order to ensure that suppliers are paid appropriately for services provided outside of an infusion drug administration calendar day, and that patients are assured the full scope of services under the home infusion therapy services benefit, which includes remote monitoring.

We also considered proposing to carry forward the payment methodology as outlined in section 50401 of the BBA of 2018, using the current payment categories and PFS infusion code amounts and units for such codes, and setting payment equal to 4 hours of infusion in the physician's office. This methodology would be consistent with the current payment methodology for the temporary transitional payment, and would not require significant changes in billing procedures. Additionally, the three payment categories would reflect therapy type and complexity of drug administration, as required under section 1834(u)(1)(B) of the Act. This payment methodology is similar to the proposed payment rates; however, setting payment equal to 5 hours of infusion in the physician's office is more in alignment with the

language at section 1834(u)(1)(A)(iii) of the Act, which sets the maximum payment amount at 5 hours of infusion for a particular therapy in a calendar day for CY 2021, rather than 4 hours.

And finally, we considered a third alternative which utilizes the 5-hour payment amount, but without the increased payment for the first visit. This option does not recognize the additional time and resources spent during the very first home infusion therapy visit. Increasing the payment rate for the first visit more adequately compensates for the potential increase in visit length as compared to subsequent visits.

Additionally, we considered an alternative to the proposed required geographic wage adjustment articulated in section V1.E. of this proposed rule. Specifically, we considered proposing the pre-floor, pre-reclassified hospital wage index (HWI) that we currently use to wage-adjust payments for both home health and hospice. With the HWI geographic areas are defined using the Core Based Statistical Areas (CBSA) established by the Office of Management and Budget (OMB). The wage index value that is given to a CBSA is the ratio of the area's average hourly wage to the national average hourly wage. The payment for a given region would be determined by applying the wage index value to the labor portion of the single payment amount. Although the HWI is used for other home based services, it presents operational challenges that would make it difficult to use for geographic wage adjustment for home infusion therapy services. These challenges include mapping zip codes to the correct CBSA. In order to utilizing the HWI there would need to be significant system changes to accommodate this option. We do not believe that the benefits of using the HWI outweigh the operational complexity of implementing this option. Also, data analysis showed that payment rates fluctuate more and payments tend to be lower in rural areas when using the HWI. The most negatively affected states using HWI are North Dakota, West Virginia, Alabama, Arkansas, and Louisiana.

In the 2019 proposed home health rule we considered using the Geographic Price Cost Index (GPCI) as the method of wage adjustment (83 FR 32467). The GPCI measures the relative differences in costs of work, practice expense and malpractice in 112 localities compared to the national average. After further analysis we determined the GPCI was not a viable option. GPCI payments are calculated by

adjusting the work, practice expense and malpractice relative value units included in the PFS by the corresponding GPCI. The relative value units are then converted into a dollar amount using a conversion factor. The payment for home infusion therapy will be a single payment amount, therefore, a single index is needed to geographically adjust the payment.

Finally, we considered using only the practice expense (PE) GPCI to geographically adjust the home infusion single payment amount. The PE GPCI is designed to measure the relative cost difference in the mix of goods and services comprising practice expenses (not including malpractice expenses) among the PFS localities compared to the national average of these costs. The PE GPCI comprises four component indices (employee wages; purchased services; office rent; and equipment, supplies, and other miscellaneous expenses. The PE GPCI comprises costs that are similar to home infusion costs. However, we believe that this is not the best method for geographical wage adjustment for several reasons. First, data analysis showed that the PE GPCI is more variable than the GAF. Also, using only the PE GPCI excludes services furnished in Alaska from the 1.0 PE floor and they would also not benefit from the 1.5 work GPCI floor. Finally, the PE GPCI has not been used on its own previously for geographic wage adjustment.

We solicit comments on the alternatives considered for this proposed rule.

F. Accounting Statement and Tables

As required by OMB Circular A-4 (available at https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf), in Table 38, we have prepared an accounting statement showing the classification of the transfers and costs associated with the CY 2020 HH PPS provisions of this rule. Table 39 shows the burden to HHA's for submission of OASIS. Table 40 provides our best estimate of the increase in Medicare payments to home infusion therapy suppliers for home infusion therapy beginning in CY 2021.

TABLE 38: ACCOUNTING STATEMENT: HH PPS CLASSIFICATION OF ESTIMATED TRANSFERS, FROM CY 2019 TO 2020

Category	Transfers

Annualized Monetized Transfers	$250 million
From Whom to Whom?	Federal Government to HHAs

TABLE 39: ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS OF OASIS ITEM COLLECTION, FROM CY 2019 TO CY 2020

Category	Costs
Annualized Monetized Net Burden for HHAs' Submission of the OASIS	+$169.9 million

TABLE 40: ACCOUNTING STATEMENT: PAYMENT FOR HOME INFUSTION THERAPY CLASSIFICATION OF ESTIMATED TRANSFERS, FROM CY 2020 TO 2021

Category	Transfers
Annualized Monetized Transfers	-$3 million
From Whom to Whom?	Federal Government to Home Infusion Therapy Suppliers

G. Regulatory Reform Analysis under E.O. 13771

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 proposed rule, if finalized, is considered an EO 13771 regulatory action. We estimate the rule generates $169.9 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.

H. Conclusion

1. HH PPS for CY 2020

In conclusion, we estimate that the net impact of the HH PPS policies in this rule is an increase of 1.3 percent, or $250 million, in Medicare payments to HHAs for CY 2020. The $250 million increase reflects the effects of the CY 2020 home health payment update percentage of 1.5 percent as required by section 53110 of the BBA of 2018 ($290 million increase), and a 0.2 percent decrease in CY 2020 payments due to the rural add-on percentages mandated by the BBA of 2018 ($40 million decrease).

2. HHVBP

In conclusion, as noted previously for the HHVBP Model, we are proposing to publicly report performance data for PY 5 (CY 2020) of the Model. This proposal would not affect our analysis of the distribution of payment adjustments for PY 5 as presented in the CY 2019 HH PPS final rule.

We estimate there would be no net impact (to include either a net increase or reduction in payments) for this proposed rule in Medicare payments to HHAs competing in the HHVBP Model. However, the overall economic impact of the HHVBP Model is an estimated $378 million in total savings from a reduction in unnecessary hospitalizations and SNF usage as a result of greater quality improvements in the home health industry over the life of the HHVBP Model.

3. HH QRP

In conclusion, we estimate that the changes to OASIS item collection as a result of the proposed changes to the HH QRP effective on January 1, 2021 would result in a net additional annualized cost of $169.9 million, discounted at 7 percent relative to year 2016, over a perpetual time horizon beginning in CY 2021.

4. Home Infusion Therapy

a. Home Infusion Therapy Services Temporary Transitional Payment for CY 2020

In conclusion, we estimate that the net impact of the temporary transitional payment to eligible home infusion suppliers for items and services associated with the furnishing of transitional home infusion drugs may result in up to a $1 million dollar increase/decrease in payments for CY 2020 as determined under the physician fee schedule established under section 1848 of the Act.

b. Home Infusion Therapy Services Payment for CY 2021

In conclusion, we estimate that the net impact of the payment for home infusion therapy services for CY 2021 is approximately $3 million in reduced payments to home infusion therapy suppliers.

This analysis, together with the remainder of this preamble, provides an initial Regulatory Flexibility Analysis.

In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by the OMB.

List of Subjects

42 CFR Part 409

Health facilities, Medicare.

42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 484

Health facilities, Health professions, Medicare, and Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as follows:

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.

2. Section 409.43 is amended by revising paragraph (a) to read as follows:

§409.43 Plan of care requirements.

(a) *Contents.* An individualized plan of care must be established and periodically reviewed by the certifying physician.

(1) The HHA must be acting upon a physician plan of care that meets the requirements of this section for HHA services to be covered.

(2) For HHA services to be covered, the individualized plan of care must specify the services necessary to meet the patient-specific needs identified in the comprehensive assessment.

(3) The plan of care must include the identification of the responsible discipline(s) and the frequency and duration of all visits as well as those items listed in §484.60(a) of this chapter that establish the need for such services. All care provided must be in accordance with the plan of care.

* * * * *

3. Section 409.44 is amended by revising paragraph (c)(2)(iii)(C) to read as follows:

§409.44 Skilled services requirements.

* * * * *

(c) * * *

(2) * * *

(iii) * * *

(C) The unique clinical condition of a patient may require the specialized skills of a qualified therapist or therapist assistant to perform a safe and effective maintenance program required in connection with the patient's specific illness or injury. Where the clinical condition of the patient is such that the complexity of the therapy services required--

(*1*) Involve the use of complex and sophisticated therapy procedures to be delivered by the therapist or the physical therapist assistant in order to maintain function or to prevent or slow further deterioration of function; or

(*2*) To maintain function or to prevent or slow further deterioration of function must be delivered by the therapist or the physical therapist assistant in order to ensure the patient's safety and to provide an effective maintenance program, then those reasonable and necessary services must be covered.

* * * * *

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

4. The authority citation for part 414 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr(b)(l).

5. Add subpart P to read as follows:

Subpart P--Home Infusion Therapy Services Payment

Conditions for Payment

Sec.

Subpart P--Home Infusion Therapy Services Payment

Conditions for Payment

§414.1500 Basis, purpose, and scope.

This subpart implements section 1861(iii) of the Act with respect to the requirements that must be met for Medicare payment to be made for home infusion services furnished to eligible beneficiaries.

§414.1505 Requirement for payment.

In order for home infusion therapy services to qualify for payment under the Medicare program the services must be furnished to an eligible beneficiary by, or under arrangements with, a qualified home infusion therapy supplier that meets following:

(a) The health and safety standards for qualified home infusion therapy suppliers at § 486.520(a) through (c) of this chapter.

(b) All requirements set forth in §§ 414.1510 through 414.1550.

§414.1510 Beneficiary qualifications for coverage of services.

To qualify for Medicare coverage of home infusion therapy services, a beneficiary must meet each of the following requirements:

(a) *Under the care of an applicable provider.* The beneficiary must be under the care of an applicable provider, as defined in section 1861(iii)(3)(A) of the Act as a physician, nurse practitioner, or physician assistant.

(b) *Under a physician plan of care.* The beneficiary must be under a plan of care that meets the requirements for plans of care specified in § 414.1515.

§414.1515 Plan of care requirements.

(a) *Contents.* The plan of care must contain those items listed in § 486.520(b) of this chapter that specify the standards relating to a plan of care that a qualified home infusion therapy supplier must meet in order to participate in the Medicare program.

(b) *Physician's orders.* The physician's orders for services in the plan of care must specify at what frequency the services will be furnished, as well as the discipline that will furnish the ordered professional services. Orders for care may indicate a specific range in frequency of visits to ensure that the most appropriate level of services is furnished.

(c) *Plan of care signature requirements.* The plan of care must be signed and dated by the ordering physician prior to submitting a claim for payment. The ordering physician must sign and date the plan of care upon any changes to the plan of care.

Payment System

§414.1550 Basis of payment.

(a) *General rule.* For home infusion therapy services furnished on or after January 1, 2021, Medicare payment is made on the basis of 80 percent of the lesser of the following:

(1) The actual charge for the item.

(2) The fee schedule amount for the item, as determined in accordance with the provisions of this section.

(b) *Unit of single payment*. A unit of single payment is made for items and services furnished by a qualified home infusion therapy supplier per payment category for each infusion

drug administration calendar day, as defined at §486.505 of this chapter.

(c) *Initial establishment of the payment amounts*. In calculating the initial single payment amounts for CY 2021, CMS determined such amounts using the equivalent to 5 hours of infusion services in a physician's office as determined by codes and units of such codes under the annual fee schedule issued under section 1848 of the Act as follows:

(1) *Category 1*. Includes certain intravenous infusion drugs for therapy, prophylaxis, or diagnosis, including antifungals and antivirals; inotropic and pulmonary hypertension drugs; pain management drugs; chelation drugs; and other intravenous drugs as added to the durable medical equipment local coverage determination (DME LCD) for external infusion pumps. Payment equals 1 unit of 96365 plus 4 units of 96366.

(2) *Category 2*. Includes certain subcutaneous infusion drugs for therapy or prophylaxis, including certain subcutaneous immunotherapy infusions. Payment equals 1 unit of 96369 plus 4 units of 96370.

(3) *Category 3*. (i) Includes intravenous chemotherapy infusions, including certain chemotherapy drugs and biologicals.

(ii) Payment equals 1 unit of 96413 plus 4 units of 96415.

(4) *Initial visit*. (i) For each of the three categories listed in paragraphs (c)(1) through (3) of this section, the payment amounts are set higher for the first visit by the qualified home infusion therapy supplier to initiate the furnishing of home infusion therapy services in the patient's home and lower for subsequent visits in the patient's home. The difference in payment amounts is a percentage based on the relative payment for a new patient rate over an existing patient rate using the annual physician fee schedule evaluation and management payment amounts for a given year and calculated in a budget neutral manner.

(ii) The first visit payment amount is subject to the following requirements if a patient has previously received home infusion therapy services:

(A) The previous home infusion therapy services claim must include a patient status code to indicate a discharge.

(B) If a patient has a previous claim for HIT services, the first visit home infusion therapy services claim subsequent to the previous claim must show a gap of more than 60 days between the last home infusion therapy services claim and must indicate a discharge in the previous period before a HIT supplier may submit a home infusion therapy services claim for the first visit payment amount.

(d) *Required payment adjustments.* The single payment amount represents payment in full for all costs associated with the furnishing of home infusion therapy services and is subject to the following adjustments:

(1) An adjustment for a geographic wage index and other costs that may vary by region, using an appropriate wage index based on the site of service of the beneficiary.

(2) Beginning in 2022, an annual increase in the single payment amounts from the prior year by the percentage increase in the Consumer Price Index (CPI) for all urban consumers (United States city average) for the 12-month period ending with June of the preceding year.

(3)(i) An annual reduction in the percentage increase described in paragraph (c)(2) of this section by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

(ii) The application of the paragraph (c)(3)(i) of this section may result in both of the following:

(A) A percentage being less than zero for a year.

(B) Payment being less than the payment rates for the preceding year.

(e) *Medical review*. All payments under this system may be subject to a medical review adjustment reflecting the following:

(1) Beneficiary eligibility.

(2) Plan of care requirements.

(3) Medical necessity determinations.

PART 484—HOME HEALTH SERVICES

6. The authority citation for part 484 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh unless otherwise indicated.

7. Section 484.202 is amended by adding the definitions of "HHCAHPS" and "HH QRP" in alphabetical order to read as follows:

§484.202 Definitions.

* * * * *

HHCAHPS stands for Home Health Care Consumer Assessment of Healthcare Providers and Systems.

HH QRP stands for Home Health Quality Reporting Program.

* * * * *

8. Section 484.205 is amended by--

a. Revising paragraph (g)(2)(i);

b. Removing paragraph (g)(2)(ii);

c. Redesignating paragraph (g)(2)(iii) as paragraph (g)(2)(ii);

d. Revising newly resdesignated paragraph (g)(2)(ii);

e. Adding paragraph (g)(3);

f. Revising the heading for paragraph (h); and

g. Adding paragraph (i).

The revisions and additions read as follows:

§484.205 Basis of payment.

* * * * *

(g) * * *

(2) * * *

(i) *HHAs certified for participation in Medicare on or before December 31, 2018.* (A) The initial payment for all 30-day periods is paid to an HHA at 20 percent of the case-mix and wage-adjusted 30-day payment rate.

(B) The residual final payment for all 30-day periods is paid at 80 percent of the case-mix and wage-adjusted 30-day payment rate.

(ii) *HHAs certified for participation in Medicare on or after January 1, 2019.* An HHA that is certified for participation in Medicare effective on or after January 1, 2019 receives a single payment for a 30-day period of care after the final claim is submitted.

(3) *Payments for periods beginning on or after January 1, 2021*. HHAs receive a single payment for a 30-day period of care after the final claim is submitted.

(h) *Requests for anticipated payment (RAP) prior to January 1, 2021.* * * *

(i) *Submission of Notice of Admission (NOA)*--(1) *For periods of care on and after January 1, 2021.* For periods of care beginning on and after January 1, 2021, all HHAs must submit a Notice of Admission (NOA) when either of the following conditions are met:

(i)(A) The plan of care has been signed by the certifying physician.

(B) If the physician-signed plan of care is not available at the time of submission of the NOA, then the submission must be based on either of the following:

(*1*) A physician's verbal order that—

(*i*) Is recorded in the plan of care;

(*ii*) Includes a description of the patient's condition and the services to be provided by the home health agency;

(*iii*) Includes an attestation (relating to the physician's orders and the date received) signed and dated by the registered nurse or qualified therapist (as defined in § 484.115) responsible for furnishing or supervising the ordered service in the plan of care; and

(*iv*) Is copied into the plan of care and the plan of care is immediately submitted to the physician.

(*2*) A referral prescribing detailed orders for the services to be rendered that is signed and dated by a physician.

(ii) [Reserved]

(2) *Consequences of failure to submit a timely Notice of Admission*. When a home health agency does not file the required NOA for its Medicare patients within 5 calendar days after the start of care--

(i) Medicare does not pay for those days of home health services from the start date to the date of filing of the notice of admission;

(ii) The wage-adjusted 30-day period payment amount is reduced by $1/30^{th}$ for each day from the home health start of care date until the date the HHA submits the NOA;

(iii) No LUPA payments are made that fall within the late NOA period;

(iv) The payment reduction cannot exceed the total payment of the claim.

(v)(A) The non-covered days are a provider liability; and

(B) The provider must not bill the beneficiary for the noncovered days.

(3) *Exception to the consequences for filing the NOA late.* (i) CMS may waive the consequences of failure to submit a timely-filed NOA specified in paragraph (i)(2) of this section.

(ii) CMS determines if a circumstance encountered by a home health agency is exceptional and qualifies for waiver of the consequence specified in paragraph (i)(2) of this section.

(iii) A home health agency must fully document and furnish any requested documentation to CMS for a determination of exception. An exceptional circumstance may be due to, but is not limited to the following:

(A) Fires, floods, earthquakes, or similar unusual events that inflict extensive damage to the home health agency's ability to operate.

(B) A CMS or Medicare contractor systems issue that is beyond the control of the home health agency.

(C) A newly Medicare-certified home health agency that is notified of that certification after the Medicare certification date, or which is awaiting its user ID from its Medicare contractor.

(D) Other situations determined by CMS to be beyond the control of the home health agency.

§484.225 [Amended]

9. Section 484.225 is amended by--

a. Removing paragraph (b).

b. Redesignating paragraphs (c) and (d) as paragraphs (b) and (c).

c. In newly redesignated paragraph (c), removing the phrase "paragraphs (a) through (c) of this section" and adding in its place the phrase “paragraphs (a) and (b) of this section".

10. Add §484.245 to read as follows:

§484.245 Requirements under the Home Health Quality Reporting Program (HH QRP).

(a) *Participation*. Beginning January 1, 2007, an HHA must report Home Health Quality Reporting Program (HH QRP) data in accordance with the requirements of this section.

(b) *Data submission*. (1) Except as provided in paragraph (d) of this section, and for a program year, a HHA must submit all of the following to CMS:

(i) Data on measures specified under sections 1899B(c)(1) and 1899B(d)(1) of the Act.

(ii) Standardized patient assessment data required under section 1899B(b)(1) of the Act.

(iii) Quality data required under section 1895(b)(3)(B)(v)(II) of the Act, including HHCAHPS survey data. For purposes of HHCAHPS survey data submission, the following additional requirements apply:

(A) *Patient count*. An HHA that has less than 60 eligible unique HHCAHPS patients must annually submit their total HHCAHPS patient count to CMS to be exempt from the HHCAHPS reporting requirements for a calendar year.

(B) *Survey requirements*. An HHA must contract with an approved, independent HHCAHPS survey vendor to administer the HHCAHPS on its behalf.

(C) *CMS approval*. CMS approves an HHCAHPS survey vendor if the applicant has been in business for a minimum of 3 years and has conducted surveys of individuals and samples for at least 2 years.

(*1*) For HHCAHPS, a "survey of individuals" is defined as the collection of data from at least 600 individuals selected by statistical sampling methods and the data collected are used for statistical purposes.

(*2*) All applicants that meet these requirements will be approved by CMS.

(D) *Disapproval by CMS*. No organization, firm, or business that owns, operates, or provides staffing for a HHA is permitted to administer its own HHCAHPS survey or administer the survey on behalf of any other HHA in the capacity as an HHCAHPS survey vendor. Such organizations will not be approved by CMS as HHCAHPS survey vendors.

(E) *Compliance with oversight activities*. Approved HHCAHPS survey vendors must fully comply with all HHCAHPS oversight activities, including allowing CMS and its HHCAHPS program team to perform site visits at the vendors' company locations.

(2) The data submitted under paragraphs (b)(1)(i) through (iii) of this section must be submitted in the form and manner, and at a time, specified by CMS.

(c) *Exceptions and extension requirements.* (1) A HHA may request and CMS may grant exceptions or extensions to the reporting requirements under paragraph (b) of this section for one or more quarters, when there are certain extraordinary circumstances beyond the control of the HHA.

(2) A HHA may request an exception or extension within 90 days of the date that the extraordinary circumstances occurred by sending an email to CMS Home Health Annual Payment Update (HHAPU) reconsiderations at *HHAPUReconsiderations@cms.hhs.gov* that contains all of the following information:

(i) HHA CMS Certification Number (CCN).

(ii) HHAs Business Name.

(iii) HHA Business Address.

(iv) CEO or CEO-designated personnel contact information including name, title, telephone number, email address, and mailing address (the address must be a physical address, not a post office box).

(v) HHA's reason for requesting the exception or extension.

(vi) Evidence of the impact of extraordinary circumstances, including, but not limited to, photographs, newspaper, and other media articles.

(vii) Date when the HHA believes it will be able to again submit data under paragraph (b) of this section and a justification for the proposed date.

(3) Except as provided in paragraph (c)(4) of this section, CMS does not consider an exception or extension request unless the HHA requesting such exception or extension has complied fully with the requirements in this paragraph (c).

(4) CMS may grant exceptions or extensions to HHAs without a request if it determines that one or more of the following has occurred:

(i) An extraordinary circumstance, such as an act of nature, affects an entire region or locale.

(ii) A systemic problem with one of CMS's data collection systems directly affects the ability of a HHA to submit data under paragraph (b) of this section.

(d) *Reconsiderations.* (1)(i) HHAs that do not meet the quality reporting requirements under this section for a program year will receive a letter of noncompliance via the United States Postal Service and notification in the Certification and Survey Provider Enhanced Report (CASPER) system.

(ii) An HHA may request reconsideration no later than 30 calendar days after the date identified on the letter of non-compliance.

(2) Reconsideration requests may be submitted to CMS by sending an email to CMS HHAPU reconsiderations at *HHAPureConsiderations@cms.hhs.gov* containing all of the following information:

(i) HHA CCN.

(ii) HHA Business Name.

(iii) HHA Business Address.

(iv) CEO or CEO-designated personnel contact information including name, title, telephone number, email address, and mailing address (the address must be a physical address, not a post office box).

(v) CMS identified reason(s) for non-compliance from the non-compliance letter.

(vi) Reason(s) for requesting reconsideration, including all supporting documentation.

(3) CMS will not consider a reconsideration request unless the HHA has complied fully with the submission requirements in paragraph (d)(2) of this section.

(4) CMS will make a decision on the request for reconsideration and provide notice of the decision to the HHA through CASPER and via letter sent via the United States Postal Service.

(e) *Appeals*. An HHA that is dissatisfied with CMS' decision on a request for reconsideration submitted under paragraph (d) of this section may file an appeal with the Provider Reimbursement Review Board (PRRB) under 42 CFR part 405, subpart R.

11. Section 484.250 is revised to read as follows:

§484.250 OASIS data.

An HHA must submit to CMS the OASIS data described at § 484.55(b) and (d) as is necessary for CMS to administer the payment rate methodologies described in §§ 484.215, 484.220, 484.230, 484.235, and 484.240.

12. Section 484.315 is amended by revising the section heading and adding paragraph (d) to read as follows:

§484.315 Data reporting for measures and evaluation and the public reporting of model data under the Home Health Value-Based Purchasing (HHVBP) Model.

* * * * *

(d) For performance year 5, CMS publicly reports the following for each competing home health agency on the CMS Web site:

(1) The Total Performance Score.

(2) The percentile ranking of the Total Performance Score.

Dated: June 14, 2019.

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Seema Verma,

Administrator,

Centers for Medicare and Medicaid Services.

Dated: June 20, 2019.

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Alex M. Azar II,

Secretary,

Department of Health and Human Services.

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